Australian Government

Department of Health

PBS

Schedule of Pharmaceutical Benefits

Summary of Changes

Effective 1 March 2018

Fees, Patient Contributions and Safety Net Thresholds

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

Dispensing Fees:	Ready-prepared	$7.15
	Dangerous drug fee	$3.01
	Extemporaneously-prepared	$9.19
	Allowable additional patient charge*	$4.45
Additional Fees (for safety net prices):	Ready-prepared	$1.21
	Extemporaneously-prepared	$1.57
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 March 2018. The Schedule is updated on the first day of each month and is available on the internet at www.pbs.gov.au.

Prescriber Bag

Additions

Addition – Item

11265X **BENZATROPINE**, benzatropine mesilate 2 mg/2 mL injection, 5 x 2 mL vials *(Benzatropine Injection)*

Alterations

Alteration – Item Description

From
3451P **ADRENALINE**, adrenaline 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules *(Link Medical Products Pty Ltd)*
To
3451P **ADRENALINE** (**EPINEPHRINE**), adrenaline (epinephrine) 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules *(Link Medical Products Pty Ltd)*

From
10209H **LIGNOCAINE**, lignocaine hydrochloride anhydrous 1% (50 mg/5 mL) injection, 5 x 5 mL ampoules *(Pfizer Australia Pty Ltd)*
To
10209H **LIDOCAINE** (LIGNOCAINE), lidocaine (lignocaine) hydrochloride monohydrate 1% (50 mg/5 mL) injection, 5 x 5 mL ampoules *(Pfizer Australia Pty Ltd)*

From
10862Q **MORPHINE**, morphine hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules *(Morphine Juno)*
To
10862Q **MORPHINE**, morphine hydrochloride trihydrate 10 mg/mL injection, 5 x 1 mL ampoules *(Morphine Juno)*

From
3479D **MORPHINE**, morphine sulfate 15 mg/mL injection, 5 x 1 mL ampoules *(Hospira Pty Limited)*
To
3479D **MORPHINE**, morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules *(Hospira Pty Limited)*

From
10868B **MORPHINE**, morphine hydrochloride 20 mg/mL injection, 5 x 1 mL ampoules *(Morphine Juno)*
To
10868B **MORPHINE**, morphine hydrochloride trihydrate 20 mg/mL injection, 5 x 1 mL ampoules *(Morphine Juno)*

From
3480E **MORPHINE**, morphine sulfate 30 mg/mL injection, 5 x 1 mL ampoules *(Hospira Pty Limited)*
To
3480E **MORPHINE**, morphine sulfate pentahydrate 30 mg/mL injection, 5 x 1 mL ampoules *(Hospira Pty Limited)*

Alteration – Manufacturer Code

		From	To
3476Y	*Maxolon* – **METOCLOPRAMIDE**, metoclopramide hydrochloride 10 mg/2 mL injection, 10 x 2 mL ampoules	IA	IL

General Pharmaceutical Benefits

Additions

Addition – Item

11249C **BENZATROPINE**, benzatropine mesilate 2 mg/2 mL injection, 5 x 2 mL vials *(Benzatropine Injection)*

11255J **BENZATROPINE**, benzatropine mesilate 2 mg/2 mL injection, 5 x 2 mL vials *(Benzatropine Injection)*

11263T **ERLOTINIB**, erlotinib 25 mg tablet, 30 *(Tarceva)*

11260P **ERLOTINIB**, erlotinib 100 mg tablet, 30 *(Tarceva)*

11259N **ERLOTINIB**, erlotinib 150 mg tablet, 30 *(Tarceva)*

11258M **EVEROLIMUS**, everolimus 2.5 mg tablet, 30 *(Afinitor)*

11254H **EVEROLIMUS**, everolimus 5 mg tablet, 30 *(Afinitor)*

11257L **EVEROLIMUS**, everolimus 5 mg tablet, 30 *(Afinitor)*

11262R **EVEROLIMUS**, everolimus 10 mg tablet, 30 *(Afinitor)*

11267B **EVEROLIMUS**, everolimus 10 mg tablet, 30 *(Afinitor)*

11264W **GEFITINIB**, gefitinib 250 mg tablet, 30 *(Iressa)*

11251E **LAPATINIB**, lapatinib 250 mg tablet, 70 *(Tykerb)*

11252F **PAZOPANIB**, pazopanib 200 mg tablet, 90 *(Votrient)*

11261Q **PAZOPANIB**, pazopanib 400 mg tablet, 60 *(Votrient)*

11266Y **SUNITINIB**, sunitinib 12.5 mg capsule, 28 *(Sutent)*

11253G **SUNITINIB**, sunitinib 25 mg capsule, 28 *(Sutent)*

11256K **SUNITINIB**, sunitinib 37.5 mg capsule, 28 *(Sutent)*

11250D **SUNITINIB**, sunitinib 50 mg capsule, 28 *(Sutent)*

Addition – Restriction

2832C **TETRACOSACTIDE (TETRACOSACTRIN)**, tetracosactide (tetracosactrin) 1 mg/mL modified release injection, 1 mL ampoule *(Synacthen Depot 1 mg/1 mL)*

Deletions

Deletion – Item

8973G **RISEDRONATE (&) CALCIUM CARBONATE**, RISEDRONATE SODIUM and CALCIUM CARBONATE Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium), 1 *(Actonel EC Combi)*

Deletion – Brand

5052X *Zinnat, AS* – **CEFUROXIME**, cefuroxime 250 mg tablet, 14

8292K *Zinnat, AS* – **CEFUROXIME**, cefuroxime 250 mg tablet, 14

10551H *Chem mart Rizatriptan, CH* – **RIZATRIPTAN**, rizatriptan 10 mg orally disintegrating tablet, 2

10551H *Terry White Chemists Rizatriptan, TW* – **RIZATRIPTAN**, rizatriptan 10 mg orally disintegrating tablet, 2

2590H *Rosuvastatin GH, GQ* – **ROSUVASTATIN**, rosuvastatin 5 mg tablet, 30

2606E *Rosuvastatin GH, GQ* – **ROSUVASTATIN**, rosuvastatin 5 mg tablet, 30

3402C *Rosuvastatin GH, GQ* – **ROSUVASTATIN**, rosuvastatin 5 mg tablet, 30

9042X *Rosuvastatin GH, GQ* – **ROSUVASTATIN**, rosuvastatin 5 mg tablet, 30

2584B *Rosuvastatin GH, GQ* – **ROSUVASTATIN**, rosuvastatin 10 mg tablet, 30

2628H *Rosuvastatin GH, GQ* – **ROSUVASTATIN**, rosuvastatin 10 mg tablet, 30

3403D *Rosuvastatin GH, GQ* – **ROSUVASTATIN**, rosuvastatin 10 mg tablet, 30

9043Y *Rosuvastatin GH, GQ* – **ROSUVASTATIN**, rosuvastatin 10 mg tablet, 30

2574L *Rosuvastatin GH, GQ* – **ROSUVASTATIN**, rosuvastatin 20 mg tablet, 30

2609H *Rosuvastatin GH, GQ* – **ROSUVASTATIN**, rosuvastatin 20 mg tablet, 30

3404E *Rosuvastatin GH, GQ* – **ROSUVASTATIN**, rosuvastatin 20 mg tablet, 30

9044B *Rosuvastatin GH, GQ* – **ROSUVASTATIN**, rosuvastatin 20 mg tablet, 30

2594M *Rosuvastatin GH, GQ* – **ROSUVASTATIN**, rosuvastatin 40 mg tablet, 30

2636R *Rosuvastatin GH, GQ* – **ROSUVASTATIN**, rosuvastatin 40 mg tablet, 30

3405F *Rosuvastatin GH, GQ* – **ROSUVASTATIN**, rosuvastatin 40 mg tablet, 30

9045C *Rosuvastatin GH, GQ* – **ROSUVASTATIN**, rosuvastatin 40 mg tablet, 30

Deletion – Equivalence Indicator

5052X *Pharmacor Cefuroxime, CR* – **CEFUROXIME**, cefuroxime 250 mg tablet, 14

8292K *Pharmacor Cefuroxime, CR* – **CEFUROXIME**, cefuroxime 250 mg tablet, 14

Deletion – Note

10234P **DESVENLAFAXINE**, desvenlafaxine 50 mg modified release tablet, 28 *(APO-Desvenlafaxine MR, Desvenlafaxine GH XR)*

10241B **DESVENLAFAXINE**, desvenlafaxine 50 mg modified release tablet, 28 *(DESVEN, Desfax, Desvenlafaxine Actavis, Desvenlafaxine Sandoz)*

9366Y **DESVENLAFAXINE**, desvenlafaxine 50 mg modified release tablet, 28 *(Pristiq)*

10231L **DESVENLAFAXINE**, desvenlafaxine 100 mg modified release tablet, 28 *(DESVEN, Desfax, Desvenlafaxine Actavis, Desvenlafaxine Sandoz)*

10245F **DESVENLAFAXINE**, desvenlafaxine 100 mg modified release tablet, 28 *(APO-Desvenlafaxine MR, Desvenlafaxine GH XR)*

9367B **DESVENLAFAXINE**, desvenlafaxine 100 mg modified release tablet, 28 *(Pristiq)*

10131F **EVEROLIMUS**, everolimus 5 mg tablet, 30 *(Afinitor)*

10135K **EVEROLIMUS**, everolimus 10 mg tablet, 30 *(Afinitor)*

10915L **IMATINIB**, imatinib 100 mg capsule, 60 *(CIPLA IMATINIB ADULT, Glivanib, IMATINIB-DRLA, IMATINIB AN, Imatinib-APOTEX, Imatinib GH)*

10918P **IMATINIB**, imatinib 100 mg capsule, 60 *(CIPLA IMATINIB ADULT, Glivanib, IMATINIB-DRLA, IMATINIB AN, Imatinib-APOTEX, Imatinib GH)*

10920R **IMATINIB**, imatinib 100 mg capsule, 60 *(CIPLA IMATINIB ADULT, Glivanib, IMATINIB-DRLA, IMATINIB AN, Imatinib-APOTEX, Imatinib GH)*

10924Y **IMATINIB**, imatinib 100 mg capsule, 60 *(CIPLA IMATINIB ADULT, Glivanib, IMATINIB-DRLA, IMATINIB AN, Imatinib-APOTEX, Imatinib GH)*

10940T **IMATINIB**, imatinib 100 mg capsule, 60 *(CIPLA IMATINIB ADULT, Glivanib, IMATINIB-DRLA, IMATINIB AN, Imatinib-APOTEX, Imatinib GH)*

10941W **IMATINIB**, imatinib 100 mg capsule, 60 *(CIPLA IMATINIB ADULT, Glivanib, IMATINIB-DRLA, IMATINIB AN, Imatinib-APOTEX, Imatinib GH)*

10942X **IMATINIB**, imatinib 100 mg capsule, 60 *(CIPLA IMATINIB ADULT, Glivanib, IMATINIB-DRLA, IMATINIB AN, Imatinib-APOTEX, Imatinib GH)*

10916M **IMATINIB**, imatinib 400 mg capsule, 30 *(CIPLA IMATINIB ADULT, Glivanib, IMATINIB-DRLA, IMATINIB AN, Imatinib-APOTEX, Imatinib GH)*

10917N **IMATINIB**, imatinib 400 mg capsule, 30 *(CIPLA IMATINIB ADULT, Glivanib, IMATINIB-DRLA, IMATINIB AN, Imatinib-APOTEX, Imatinib GH)*

10921T **IMATINIB**, imatinib 400 mg capsule, 30 *(CIPLA IMATINIB ADULT, Glivanib, IMATINIB-DRLA, IMATINIB AN, Imatinib-APOTEX, Imatinib GH)*

10925B **IMATINIB**, imatinib 400 mg capsule, 30 *(CIPLA IMATINIB ADULT, Glivanib, IMATINIB-DRLA, IMATINIB AN, Imatinib-APOTEX, Imatinib GH)*

10933K **IMATINIB**, imatinib 400 mg capsule, 30 *(CIPLA IMATINIB ADULT, Glivanib, IMATINIB-DRLA, IMATINIB AN, Imatinib-APOTEX, Imatinib GH)*

10935M **IMATINIB**, imatinib 400 mg capsule, 30 *(CIPLA IMATINIB ADULT, Glivanib, IMATINIB-DRLA, IMATINIB AN, Imatinib-APOTEX, Imatinib GH)*

10939R **IMATINIB**, imatinib 400 mg capsule, 30 *(CIPLA IMATINIB ADULT, Glivanib, IMATINIB-DRLA, IMATINIB AN, Imatinib-APOTEX, Imatinib GH)*

9113P **IMATINIB**, imatinib 100 mg tablet, 60 *(Glivec, IMATINIB RBX, Imatinib-Teva)*

9115R **IMATINIB**, imatinib 100 mg tablet, 60 *(Glivec, IMATINIB RBX, Imatinib-Teva)*

9123E **IMATINIB**, imatinib 100 mg tablet, 60 *(Glivec, IMATINIB RBX, Imatinib-Teva)*

9172R **IMATINIB**, imatinib 100 mg tablet, 60 *(Glivec, IMATINIB RBX, Imatinib-Teva)*

9174W **IMATINIB**, imatinib 100 mg tablet, 60 *(Glivec, IMATINIB RBX, Imatinib-Teva)*

9176Y **IMATINIB**, imatinib 100 mg tablet, 60 *(Glivec, IMATINIB RBX, Imatinib-Teva)*

9178C **IMATINIB**, imatinib 100 mg tablet, 60 *(Glivec, IMATINIB RBX)*

9114Q **IMATINIB**, imatinib 400 mg tablet, 30 *(Glivec, IMATINIB RBX, Imatinib-Teva)*

9116T **IMATINIB**, imatinib 400 mg tablet, 30 *(Glivec, IMATINIB RBX, Imatinib-Teva)*

9124F **IMATINIB**, imatinib 400 mg tablet, 30 *(Glivec, IMATINIB RBX, Imatinib-Teva)*

9173T **IMATINIB**, imatinib 400 mg tablet, 30 *(Glivec, IMATINIB RBX, Imatinib-Teva)*

9175X **IMATINIB**, imatinib 400 mg tablet, 30 *(Glivec, IMATINIB RBX, Imatinib-Teva)*

9177B **IMATINIB**, imatinib 400 mg tablet, 30 *(Glivec, IMATINIB RBX, Imatinib-Teva)*

9179D **IMATINIB**, imatinib 400 mg tablet, 30 *(Glivec, IMATINIB RBX)*

9148L **LAPATINIB**, lapatinib 250 mg tablet, 70 *(Tykerb)*

8887R **MELOXICAM**, meloxicam 7.5 mg capsule, 30 *(APO-Meloxicam, Chem mart Meloxicam, Meloxicam Sandoz, Mobic, Movalis 7.5, Moxicam, Terry White Chemists Meloxicam)*

8888T **MELOXICAM**, meloxicam 15 mg capsule, 30 *(APO-Meloxicam, Chem mart Meloxicam, Meloxicam Sandoz, Mobic, Movalis 15, Moxicam, Terry White Chemists Meloxicam)*

8561N **MELOXICAM**, meloxicam 7.5 mg tablet, 30 *(APO-Meloxicam, Chem mart Meloxicam 7.5 mg, Meloxiauro 7.5, Meloxibell, Meloxicam AN, Meloxicam Ranbaxy, Meloxicam Sandoz, Meloxicam-GA, Mobic, Movalis 7.5, Moxicam 7.5, Pharmacor Meloxicam 7.5, Terry White Chemists Meloxicam 7.5 mg)*

8562P **MELOXICAM**, meloxicam 15 mg tablet, 30 *(APO-Meloxicam, Chem mart Meloxicam 15 mg, Meloxiauro 15, Meloxibell, Meloxicam AN, Meloxicam Ranbaxy, Meloxicam Sandoz, Meloxicam-GA, Mobic, Movalis 15, Moxicam 15, Pharmacor Meloxicam 15, Terry White Chemists Meloxicam 15 mg)*

2232L **PAZOPANIB**, pazopanib 200 mg tablet, 30 *(Votrient)*

2201W **PAZOPANIB**, pazopanib 400 mg tablet, 30 *(Votrient)*

9488J **SUNITINIB**, sunitinib 12.5 mg capsule, 28 *(Sutent)*

9489K **SUNITINIB**, sunitinib 25 mg capsule, 28 *(Sutent)*

10503T **SUNITINIB**, sunitinib 37.5 mg capsule, 28 *(Sutent)*

9490L **SUNITINIB**, sunitinib 50 mg capsule, 28 *(Sutent)*

Deletion – Restriction

10943Y **DEXAMETHASONE**, dexamethasone 700 microgram implant, 1 *(Ozurdex)*

10022L **ERLOTINIB**, erlotinib 25 mg tablet, 30 *(Tarceva)*

10020J **ERLOTINIB**, erlotinib 100 mg tablet, 30 *(Tarceva)*

10014C **ERLOTINIB**, erlotinib 150 mg tablet, 30 *(Tarceva)*

2818H **EVEROLIMUS**, everolimus 2.5 mg tablet, 30 *(Afinitor)*

10131F **EVEROLIMUS**, everolimus 5 mg tablet, 30 *(Afinitor)*

2819J **EVEROLIMUS**, everolimus 5 mg tablet, 30 *(Afinitor)*

10135K **EVEROLIMUS**, everolimus 10 mg tablet, 30 *(Afinitor)*

2985D **EVEROLIMUS**, everolimus 10 mg tablet, 30 *(Afinitor)*

8769M **GEFITINIB**, gefitinib 250 mg tablet, 30 *(Iressa)*

9148L **LAPATINIB**, lapatinib 250 mg tablet, 70 *(Tykerb)*

9488J **SUNITINIB**, sunitinib 12.5 mg capsule, 28 *(Sutent)*

9489K **SUNITINIB**, sunitinib 25 mg capsule, 28 *(Sutent)*

10503T **SUNITINIB**, sunitinib 37.5 mg capsule, 28 *(Sutent)*

9490L **SUNITINIB**, sunitinib 50 mg capsule, 28 *(Sutent)*

Alterations

Alteration – Item Description

From
10565C **ACLIDINIUM + FORMOTEROL (EFORMOTEROL)**, aclidinium 340 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 12 microgram/actuation inhalation: powder for, 60 actuations *(Brimica Genuair)*
To
10565C **ACLIDINIUM + FORMOTEROL (EFORMOTEROL)**, aclidinium 340 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations *(Brimica Genuair)*

From
8697R **ADRENALINE**, adrenaline 150 microgram/0.3 mL injection, 1 dose *(EpiPen Jr.)*
To
8697R **ADRENALINE (EPINEPHRINE)**, adrenaline (epinephrine) 150 microgram/0.3 mL injection, 1 dose *(EpiPen Jr.)*

From
8698T **ADRENALINE**, adrenaline 300 microgram/0.3 mL injection, 1 dose *(EpiPen)*
To
8698T **ADRENALINE (EPINEPHRINE)**, adrenaline (epinephrine) 300 microgram/0.3 mL injection, 1 dose *(EpiPen)*

From
1016L **ADRENALINE**, adrenaline 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules *(Link Medical Products Pty Ltd)*
To
1016L **ADRENALINE (EPINEPHRINE)**, adrenaline (epinephrine) 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules *(Link Medical Products Pty Ltd)*

From
5004J **ADRENALINE**, adrenaline 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules *(Link Medical Products Pty Ltd)*
To
5004J **ADRENALINE (EPINEPHRINE)**, adrenaline (epinephrine) 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules *(Link Medical Products Pty Ltd)*

From
2964B **CEPHALOTHIN**, cephalothin 1 g injection, 10 vials *(Hospira Pty Limited)*
To
2964B **CEFALOTIN**, cefalotin 1 g injection, 10 vials *(Hospira Pty Limited)*

From
3376Q **CEPHALOTHIN**, cephalothin 1 g injection, 10 vials *(Hospira Pty Limited)*
To
3376Q **CEFALOTIN**, cefalotin 1 g injection, 10 vials *(Hospira Pty Limited)*

From
1779P **DANTROLENE**, dantrolene sodium 25 mg capsule, 100 *(Dantrium)*
To
1779P **DANTROLENE**, dantrolene sodium hemiheptahydrate 25 mg capsule, 100 *(Dantrium)*

From
1780Q **DANTROLENE**, dantrolene sodium 50 mg capsule, 100 *(Dantrium)*
To
1780Q **DANTROLENE**, dantrolene sodium hemiheptahydrate 50 mg capsule, 100 *(Dantrium)*

From
1357K **DOTHIEPIN**, dothiepin hydrochloride 25 mg capsule, 50 *(Dothep 25)*
To
1357K **DOSULEPIN (DOTHIEPIN)**, dosulepin (dothiepin) hydrochloride 25 mg capsule, 50 *(Dothep 25)*

From
1358L **DOTHIEPIN**, dothiepin hydrochloride 75 mg tablet, 30 *(Dothep 75)*
To
1358L **DOSULEPIN (DOTHIEPIN)**, dosulepin (dothiepin) hydrochloride 75 mg tablet, 30 *(Dothep 75)*

From
8985X **FERROUS FUMARATE**, ferrous fumarate 200 mg (equivalent to 65.7 mg of elemental iron) tablet, 60 *(Ferro-tab)*
To
8985X **FERROUS FUMARATE**, ferrous fumarate 200 mg (iron 65.7 mg) tablet, 60 *(Ferro-tab)*

From
9011G **FERROUS FUMARATE + FOLIC ACID**, ferrous fumarate 310 mg (equivalent to 100 mg elemental iron) + folic acid 350 microgram tablet, 60 *(Ferro-f-tab)*
To
9011G **FERROUS FUMARATE + FOLIC ACID**, ferrous fumarate 310 mg (iron 100 mg) + folic acid 350 microgram tablet, 60 *(Ferro-f-tab)*

From

8970D **LEVODOPA + CARBIDOPA ANHYDROUS**, levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL *(Duodopa)*

To

8970D **LEVODOPA + CARBIDOPA**, levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL *(Duodopa)*

From

1242J **LEVODOPA + CARBIDOPA ANHYDROUS**, levodopa 100 mg + carbidopa anhydrous 25 mg tablet, 100 *(Kinson, Sinemet 100/25)*

To

1242J **LEVODOPA + CARBIDOPA**, levodopa 100 mg + carbidopa 25 mg tablet, 100 *(Kinson, Sinemet 100/25)*

From

1255C **LEVODOPA + CARBIDOPA ANHYDROUS**, levodopa 200 mg + carbidopa anhydrous 50 mg modified release tablet, 100 *(Sinemet CR)*

To

1255C **LEVODOPA + CARBIDOPA**, levodopa 200 mg + carbidopa 50 mg modified release tablet, 100 *(Sinemet CR)*

From

1245M **LEVODOPA + CARBIDOPA ANHYDROUS**, levodopa 250 mg + carbidopa anhydrous 25 mg tablet, 100 *(Sinemet)*

To

1245M **LEVODOPA + CARBIDOPA**, levodopa 250 mg + carbidopa 25 mg tablet, 100 *(Sinemet)*

From

8797B **LEVODOPA + CARBIDOPA ANHYDROUS + ENTACAPONE**, levodopa 50 mg + carbidopa anhydrous 12.5 mg + entacapone 200 mg tablet, 100 *(Stalevo 50/12.5/200mg)*

To

8797B **LEVODOPA + CARBIDOPA + ENTACAPONE**, levodopa 50 mg + carbidopa 12.5 mg + entacapone 200 mg tablet, 100 *(Stalevo 50/12.5/200mg)*

From

9344T **LEVODOPA + CARBIDOPA ANHYDROUS + ENTACAPONE**, levodopa 75 mg + carbidopa anhydrous 18.75 mg + entacapone 200 mg tablet, 100 *(Stalevo 75/18.75/200mg)*

To

9344T **LEVODOPA + CARBIDOPA + ENTACAPONE**, levodopa 75 mg + carbidopa 18.75 mg + entacapone 200 mg tablet, 100 *(Stalevo 75/18.75/200mg)*

From

8798C **LEVODOPA + CARBIDOPA ANHYDROUS + ENTACAPONE**, levodopa 100 mg + carbidopa anhydrous 25 mg + entacapone 200 mg tablet, 100 *(Stalevo 100/25/200mg)*

To

8798C **LEVODOPA + CARBIDOPA + ENTACAPONE**, levodopa 100 mg + carbidopa 25 mg + entacapone 200 mg tablet, 100 *(Stalevo 100/25/200mg)*

From

9345W **LEVODOPA + CARBIDOPA ANHYDROUS + ENTACAPONE**, levodopa 125 mg + carbidopa anhydrous 31.25 mg + entacapone 200 mg tablet, 100 *(Stalevo 125/31.25/200mg)*

To

9345W **LEVODOPA + CARBIDOPA + ENTACAPONE**, levodopa 125 mg + carbidopa 31.25 mg + entacapone 200 mg tablet, 100 *(Stalevo 125/31.25/200mg)*

From

8799D **LEVODOPA + CARBIDOPA ANHYDROUS + ENTACAPONE**, levodopa 150 mg + carbidopa anhydrous 37.5 mg + entacapone 200 mg tablet, 100 *(Stalevo 150/37.5/200mg)*

To

8799D **LEVODOPA + CARBIDOPA + ENTACAPONE**, levodopa 150 mg + carbidopa 37.5 mg + entacapone 200 mg tablet, 100 *(Stalevo 150/37.5/200mg)*

From

9292C **LEVODOPA + CARBIDOPA ANHYDROUS + ENTACAPONE**, levodopa 200 mg + carbidopa anhydrous 50 mg + entacapone 200 mg tablet, 100 *(Stalevo 200/50/200mg)*

To

9292C **LEVODOPA + CARBIDOPA + ENTACAPONE**, levodopa 200 mg + carbidopa 50 mg + entacapone 200 mg tablet, 100 *(Stalevo 200/50/200mg)*

From

2174K **THYROXINE**, thyroxine sodium 50 microgram tablet, 200 *(Eutroxsig, Oroxine)*

To

2174K **LEVOTHYROXINE**, levothyroxine sodium 50 microgram tablet, 200 *(Eutroxsig, Oroxine)*

From

9287T **THYROXINE**, thyroxine sodium 75 microgram tablet, 200 *(Eutroxsig, Oroxine)*

To

9287T **LEVOTHYROXINE**, levothyroxine sodium 75 microgram tablet, 200 *(Eutroxsig, Oroxine)*

From
2175L **THYROXINE**, thyroxine sodium 100 microgram tablet, 200 *(Eutroxsig, Oroxine)*
To
2175L **LEVOTHYROXINE**, levothyroxine sodium 100 microgram tablet, 200 *(Eutroxsig, Oroxine)*

From
2173J **THYROXINE**, thyroxine sodium 200 microgram tablet, 200 *(Eutroxsig, Oroxine)*
To
2173J **LEVOTHYROXINE**, levothyroxine sodium 200 microgram tablet, 200 *(Eutroxsig, Oroxine)*

From
2876J **LIGNOCAINE**, lignocaine hydrochloride anhydrous 500 mg/5 mL injection, 10 x 5 mL ampoules *(Xylocard 500)*
To
2876J **LIDOCAINE (LIGNOCAINE)**, lidocaine (lignocaine) hydrochloride 10% (500 mg/5 mL) injection, 10 x 5 mL ampoules *(Xylocard 500)*

From
5146W **MAGNESIUM ASPARTATE DIHYDRATE**, magnesium aspartate dihydrate 500 mg (equivalent to 37.4 mg of magnesium) tablet, 50 *(Mag-Sup, MagMin (PBS))*
To
5146W **MAGNESIUM ASPARTATE DIHYDRATE**, magnesium aspartate dihydrate 500 mg (magnesium 37.4 mg) tablet, 50 *(Mag-Sup, MagMin (PBS))*

From
8349K **MORPHINE**, morphine Capsule 10 mg (containing sustained release pellets), 28 *(Kapanol)*
To
8349K **MORPHINE, morphine sulfate pentahydrate 10 mg modified release capsule, 28 *(Kapanol)***

From
2839K **MORPHINE**, morphine Capsule 20 mg (containing sustained release pellets), 28 *(Kapanol)*
To
2839K **MORPHINE**, morphine sulfate pentahydrate 20 mg modified release capsule, 28 *(Kapanol)*

From
8491X **MORPHINE**, morphine sulfate 30 mg modified release capsule, 14 *(MS Mono)*
To
8491X **MORPHINE**, morphine sulfate pentahydrate 30 mg modified release capsule, 14 *(MS Mono)*

From
2840L **MORPHINE**, morphine Capsule 50 mg (containing sustained release pellets), 28 *(Kapanol)*
To
2840L **MORPHINE**, morphine sulfate pentahydrate 50 mg modified release capsule, 28 *(Kapanol)*

From
8492Y **MORPHINE**, morphine sulfate 60 mg modified release capsule, 14 *(MS Mono)*
To
8492Y **MORPHINE**, morphine sulfate pentahydrate 60 mg modified release capsule, 14 *(MS Mono)*

From
8493B **MORPHINE**, morphine sulfate 90 mg modified release capsule, 14 *(MS Mono)*
To
8493B **MORPHINE**, morphine sulfate pentahydrate 90 mg modified release capsule, 14 *(MS Mono)*

From
2841M **MORPHINE**, morphine Capsule 100 mg (containing sustained release pellets), 28 *(Kapanol)*
To
2841M **MORPHINE**, morphine sulfate pentahydrate 100 mg modified release capsule, 28 *(Kapanol)*

From
8494C **MORPHINE**, morphine sulfate 120 mg modified release capsule, 14 *(MS Mono)*
To
8494C **MORPHINE**, morphine sulfate pentahydrate 120 mg modified release capsule, 14 *(MS Mono)*

From
10863R **MORPHINE**, morphine hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules *(Morphine Juno)*
To
10863R **MORPHINE**, morphine hydrochloride trihydrate 10 mg/mL injection, 5 x 1 mL ampoules *(Morphine Juno)*

From
10864T **MORPHINE**, morphine hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules *(Morphine Juno)*
To
10864T **MORPHINE**, morphine hydrochloride trihydrate 10 mg/mL injection, 5 x 1 mL ampoules *(Morphine Juno)*

From
1644M **MORPHINE**, morphine sulfate 10 mg/mL injection, 5 x 1 mL ampoules *(Hospira Pty Limited)*
To
1644M **MORPHINE**, morphine sulfate pentahydrate 10 mg/mL injection, 5 x 1 mL ampoules *(Hospira Pty Limited)*

From
5168B **MORPHINE**, morphine sulfate 10 mg/mL injection, 5 x 1 mL ampoules *(Hospira Pty Limited)*
To
5168B **MORPHINE**, morphine sulfate pentahydrate 10 mg/mL injection, 5 x 1 mL ampoules *(Hospira Pty Limited)*

From
1645N **MORPHINE**, morphine sulfate 15 mg/mL injection, 5 x 1 mL ampoules *(Hospira Pty Limited)*
To
1645N **MORPHINE**, morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules *(Hospira Pty Limited)*

From
5169C **MORPHINE**, morphine sulfate 15 mg/mL injection, 5 x 1 mL ampoules *(Hospira Pty Limited)*
To
5169C **MORPHINE**, morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules *(Hospira Pty Limited)*

From
10858L **MORPHINE**, morphine hydrochloride 20 mg/mL injection, 5 x 1 mL ampoules *(Morphine Juno)*
To
10858L **MORPHINE**, morphine hydrochloride trihydrate 20 mg/mL injection, 5 x 1 mL ampoules *(Morphine Juno)*

From
10874H **MORPHINE**, morphine hydrochloride 20 mg/mL injection, 5 x 1 mL ampoules *(Morphine Juno)*
To
10874H **MORPHINE**, morphine hydrochloride trihydrate 20 mg/mL injection, 5 x 1 mL ampoules *(Morphine Juno)*

From
1647Q **MORPHINE**, morphine sulfate 30 mg/mL injection, 5 x 1 mL ampoules *(Hospira Pty Limited)*
To
1647Q **MORPHINE**, morphine sulfate pentahydrate 30 mg/mL injection, 5 x 1 mL ampoules *(Hospira Pty Limited)*

From
5170D **MORPHINE**, morphine sulfate 30 mg/mL injection, 5 x 1 mL ampoules *(Hospira Pty Limited)*
To
5170D **MORPHINE**, morphine sulfate pentahydrate 30 mg/mL injection, 5 x 1 mL ampoules *(Hospira Pty Limited)*

From
10869C **MORPHINE**, morphine hydrochloride 50 mg/5 mL injection, 5 x 5 mL ampoules *(Morphine Juno)*
To
10869C **MORPHINE**, morphine hydrochloride trihydrate 50 mg/5 mL injection, 5 x 5 mL ampoules *(Morphine Juno)*

From
10878M **MORPHINE**, morphine hydrochloride 100 mg/5 mL injection, 5 x 5 mL ampoules *(Morphine Juno)*
To
10878M **MORPHINE**, morphine hydrochloride trihydrate 100 mg/5 mL injection, 5 x 5 mL ampoules *(Morphine Juno)*

From
2122Q **MORPHINE**, morphine hydrochloride 2 mg/mL oral liquid, 200 mL *(Ordine 2)*
To
2122Q **MORPHINE**, morphine hydrochloride trihydrate 2 mg/mL oral liquid, 200 mL *(Ordine 2)*

From
5237P **MORPHINE**, morphine hydrochloride 2 mg/mL oral liquid, 200 mL *(Ordine 2)*
To
5237P **MORPHINE**, morphine hydrochloride trihydrate 2 mg/mL oral liquid, 200 mL *(Ordine 2)*

From
2123R **MORPHINE**, morphine hydrochloride 5 mg/mL oral liquid, 200 mL *(Ordine 5)*
To
2123R **MORPHINE**, morphine hydrochloride trihydrate 5 mg/mL oral liquid, 200 mL *(Ordine 5)*

From
5238Q **MORPHINE**, morphine hydrochloride 5 mg/mL oral liquid, 200 mL *(Ordine 5)*
To
5238Q **MORPHINE**, morphine hydrochloride trihydrate 5 mg/mL oral liquid, 200 mL *(Ordine 5)*

From
2124T **MORPHINE**, morphine hydrochloride 10 mg/mL oral liquid, 200 mL *(Ordine 10)*
To
2124T **MORPHINE**, morphine hydrochloride trihydrate 10 mg/mL oral liquid, 200 mL *(Ordine 10)*

From
5239R **MORPHINE**, morphine hydrochloride 10 mg/mL oral liquid, 200 mL *(Ordine 10)*
To
5239R **MORPHINE**, morphine hydrochloride trihydrate 10 mg/mL oral liquid, 200 mL *(Ordine 10)*

From
8490W **MORPHINE**, morphine sulfate 20 mg modified release granules, 28 sachets *(MS Contin Suspension 20 mg)*
To
8490W **MORPHINE**, morphine sulfate pentahydrate 20 mg modified release granules, 28 sachets *(MS Contin Suspension 20 mg)*

From
8146R **MORPHINE**, morphine Sachet containing controlled release granules for oral suspension, 30 mg per sachet, 28 *(MS Contin Suspension 30 mg)*
To
8146R **MORPHINE**, morphine sulfate pentahydrate 30 mg modified release granules, 28 sachets *(MS Contin Suspension 30 mg)*

From
8305D **MORPHINE**, morphine Sachet containing controlled release granules for oral suspension, 60 mg per sachet, 28 *(MS Contin Suspension 60 mg)*
To
8305D **MORPHINE**, morphine sulfate pentahydrate 60 mg modified release granules, 28 sachets *(MS Contin Suspension 60 mg)*

From
8306E **MORPHINE**, morphine sulfate 100 mg modified release granules, 28 sachets *(MS Contin Suspension 100 mg)*
To
8306E **MORPHINE**, morphine sulfate pentahydrate 100 mg modified release granules, 28 sachets *(MS Contin Suspension 100 mg)*

From
8454Y **MORPHINE**, morphine sulfate 200 mg modified release granules, 28 sachets *(MS Contin Suspension 200 mg)*
To
8454Y **MORPHINE**, morphine sulfate pentahydrate 200 mg modified release granules, 28 sachets *(MS Contin Suspension 200 mg)*

From
8035X **MORPHINE**, morphine sulfate 5 mg modified release tablet, 28 *(MS Contin)*
To
8035X **MORPHINE**, morphine sulfate pentahydrate 5 mg modified release tablet, 28 *(MS Contin)*

From
1653B **MORPHINE**, morphine sulfate 10 mg modified release tablet, 28 *(MORPHINE MR APOTEX, MS Contin, Momex SR 10, Morphine MR AN, Morphine MR Mylan)*
To
1653B **MORPHINE**, morphine sulfate pentahydrate 10 mg modified release tablet, 28 *(MORPHINE MR APOTEX, MS Contin, Momex SR 10, Morphine MR AN, Morphine MR Mylan)*

From
8669G **MORPHINE**, morphine sulfate 10 mg tablet, 20 *(Sevredol)*
To
8669G **MORPHINE**, morphine sulfate pentahydrate 10 mg tablet, 20 *(Sevredol)*

From
8489T **MORPHINE**, morphine sulfate 15 mg modified release tablet, 28 *(MS Contin)*
To
8489T **MORPHINE**, morphine sulfate pentahydrate 15 mg modified release tablet, 28 *(MS Contin)*

From
8670H **MORPHINE**, morphine sulfate 20 mg tablet, 20 *(Sevredol)*
To
8670H **MORPHINE**, morphine sulfate pentahydrate 20 mg tablet, 20 *(Sevredol)*

From
1646P **MORPHINE**, morphine sulfate 30 mg tablet, 20 *(Anamorph)*
To
1646P **MORPHINE**, morphine sulfate pentahydrate 30 mg tablet, 20 *(Anamorph)*

From
1654C **MORPHINE**, morphine sulfate 30 mg modified release tablet, 28 *(MORPHINE MR APOTEX, MS Contin, Momex SR 30, Morphine MR AN, Morphine MR Mylan)*
To
1654C **MORPHINE**, morphine sulfate pentahydrate 30 mg modified release tablet, 28 *(MORPHINE MR APOTEX, MS Contin, Momex SR 30, Morphine MR AN, Morphine MR Mylan)*

From

5163R **MORPHINE**, morphine sulfate 30 mg tablet, 20 *(Anamorph)*

To

5163R **MORPHINE**, morphine sulfate pentahydrate 30 mg tablet, 20 *(Anamorph)*

From

1655D **MORPHINE**, morphine sulfate 60 mg modified release tablet, 28 *(MORPHINE MR APOTEX, MS Contin, Momex SR 60, Morphine MR AN, Morphine MR Mylan)*

To

1655D **MORPHINE**, morphine sulfate pentahydrate 60 mg modified release tablet, 28 *(MORPHINE MR APOTEX, MS Contin, Momex SR 60, Morphine MR AN, Morphine MR Mylan)*

From

1656E **MORPHINE**, morphine sulfate 100 mg modified release tablet, 28 *(MORPHINE MR APOTEX, MS Contin, Momex SR 100, Morphine MR AN, Morphine MR Mylan)*

To

1656E **MORPHINE**, morphine sulfate pentahydrate 100 mg modified release tablet, 28 *(MORPHINE MR APOTEX, MS Contin, Momex SR 100, Morphine MR AN, Morphine MR Mylan)*

From

8453X **MORPHINE**, morphine sulfate 200 mg modified release tablet, 28 *(MS Contin)*

To

8453X **MORPHINE**, morphine sulfate pentahydrate 200 mg modified release tablet, 28 *(MS Contin)*

From

3012M **POTASSIUM CHLORIDE + POTASSIUM BICARBONATE + POTASSIUM CARBONATE**, potassium chloride 595 mg + potassium bicarbonate 384 mg + potassium carbonate 152 mg effervescent tablet, 60 *(Chlorvescent)*

To

3012M **POTASSIUM CHLORIDE + POTASSIUM BICARBONATE + POTASSIUM CARBONATE**, potassium chloride 595 mg + potassium bicarbonate 384 mg + potassium carbonate 152 mg (total potassium 14 mmol) effervescent tablet, 60 *(Chlorvescent)*

From

1975Y **QUININE**, quinine sulfate 300 mg tablet, 50 *(Quinate)*

To

1975Y **QUININE**, quinine sulfate dihydrate 300 mg tablet, 50 *(Quinate)*

From

8354Q **SALBUTAMOL**, salbutamol Oral pressurised inhalation in breath actuated device 100 micrograms (base) per dose (200 doses), CFC-free formulation, 1 *(Airomir Autohaler)*

To

8354Q **SALBUTAMOL**, salbutamol 100 microgram/actuation breath activated inhalation, 200 actuations *(Airomir Autohaler)*

From

2091C **SORBITOL + CITRIC ACID + LAURYL SULFOACETATE SODIUM**, sorbitol 3.125 g/5 mL + citrate sodium dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 12 x 5 mL *(Micolette)*

To

2091C **SORBITOL + CITRIC ACID + LAURYL SULFOACETATE SODIUM**, sorbitol 3.125 g/5 mL + sodium citrate dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 12 x 5 mL *(Micolette)*

From

1109J **BENZHEXOL**, benzhexol hydrochloride 2 mg tablet, 200 *(Artane)*

To

1109J **TRIHEXYPHENIDYL (BENZHEXOL)**, trihexyphenidyl (benzhexol) hydrochloride 2 mg tablet, 200 *(Artane)*

From

1110K **BENZHEXOL**, benzhexol hydrochloride 5 mg tablet, 200 *(Artane)*

To

1110K **TRIHEXYPHENIDYL (BENZHEXOL)**, trihexyphenidyl (benzhexol) hydrochloride 5 mg tablet, 200 *(Artane)*

Alteration – Note

2034C **PAZOPANIB**, pazopanib 200 mg tablet, 90 *(Votrient)*

2035D **PAZOPANIB**, pazopanib 400 mg tablet, 60 *(Votrient)*

9420T **SUNITINIB**, sunitinib 12.5 mg capsule, 28 *(Sutent)*

9421W **SUNITINIB**, sunitinib 25 mg capsule, 28 *(Sutent)*

10459L **SUNITINIB**, sunitinib 37.5 mg capsule, 28 *(Sutent)*

9422X **SUNITINIB**, sunitinib 50 mg capsule, 28 *(Sutent)*

Alteration – Restriction

9186L	**ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL syringes *(Humira)*
9187M	**ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL cartridges *(Humira)*
9188N	**ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes *(Humira)*
9190Q	**ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges *(Humira)*
10539Q	**AXITINIB**, axitinib 1 mg tablet, 28 *(Inlyta)*
10556N	**AXITINIB**, axitinib 5 mg tablet, 28 *(Inlyta)*
10047T	**PAZOPANIB**, pazopanib 200 mg tablet, 90 *(Votrient)*
10054E	**PAZOPANIB**, pazopanib 200 mg tablet, 30 *(Votrient)*
2034C	**PAZOPANIB**, pazopanib 200 mg tablet, 90 *(Votrient)*
2232L	**PAZOPANIB**, pazopanib 200 mg tablet, 30 *(Votrient)*
10043N	**PAZOPANIB**, pazopanib 400 mg tablet, 60 *(Votrient)*
10052C	**PAZOPANIB**, pazopanib 400 mg tablet, 30 *(Votrient)*
2035D	**PAZOPANIB**, pazopanib 400 mg tablet, 60 *(Votrient)*
2201W	**PAZOPANIB**, pazopanib 400 mg tablet, 30 *(Votrient)*
10242C	**SORAFENIB**, sorafenib 200 mg tablet, 60 *(Nexavar)*
10009T	**SUNITINIB**, sunitinib 12.5 mg capsule, 28 *(Sutent)*
9420T	**SUNITINIB**, sunitinib 12.5 mg capsule, 28 *(Sutent)*
2842N	**SUNITINIB**, sunitinib 25 mg capsule, 28 *(Sutent)*
9421W	**SUNITINIB**, sunitinib 25 mg capsule, 28 *(Sutent)*
10459L	**SUNITINIB**, sunitinib 37.5 mg capsule, 28 *(Sutent)*
10473F	**SUNITINIB**, sunitinib 37.5 mg capsule, 28 *(Sutent)*
10010W	**SUNITINIB**, sunitinib 50 mg capsule, 28 *(Sutent)*
9422X	**SUNITINIB**, sunitinib 50 mg capsule, 28 *(Sutent)*
11178H	**USTEKINUMAB**, ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial *(Stelara)*
9129L	**VARENICLINE**, varenicline 1 mg tablet, 56 *(Champix)*

Alteration – Restriction Level

		From	*To*
8213G	**ATORVASTATIN**, atorvastatin 10 mg tablet, 30 *(APO-Atorvastatin, Atorvastatin Amneal, Atorvastatin GH, Atorvastatin SCP 10, Atorvastatin SZ, Atorvastatin Sandoz, Blooms the Chemist Atorvastatin, Chem mart Atorvastatin, Lipitor, Lorstat 10, Pharmacor Atorvastatin, Terry White Chemists Atorvastatin, Torvastat 10, Trovas)*	restricted	unrestricted
8214H	**ATORVASTATIN**, atorvastatin 20 mg tablet, 30 *(APO-Atorvastatin, Atorvastatin Amneal, Atorvastatin GH, Atorvastatin SCP 20, Atorvastatin SZ, Atorvastatin Sandoz, Blooms the Chemist Atorvastatin, Chem mart Atorvastatin, Lipitor, Lorstat 20, Pharmacor Atorvastatin, Terry White Chemists Atorvastatin, Torvastat 20, Trovas)*	restricted	unrestricted
8215J	**ATORVASTATIN**, atorvastatin 40 mg tablet, 30 *(APO-Atorvastatin, Atorvastatin Amneal, Atorvastatin GH, Atorvastatin SCP 40, Atorvastatin SZ, Atorvastatin Sandoz, Blooms the Chemist Atorvastatin, Chem mart Atorvastatin, Lipitor, Lorstat 40, Pharmacor Atorvastatin, Terry White Chemists Atorvastatin, Torvastat 40, Trovas)*	restricted	unrestricted
8521L	**ATORVASTATIN**, atorvastatin 80 mg tablet, 30 *(APO-Atorvastatin, Atorvastatin Amneal, Atorvastatin GH, Atorvastatin SCP 80, Atorvastatin SZ, Atorvastatin Sandoz, Blooms the Chemist Atorvastatin, Chem mart Atorvastatin, Lipitor, Lorstat 80, Pharmacor Atorvastatin, Terry White Chemists Atorvastatin, Torvastat 80, Trovas)*	restricted	unrestricted
10539Q	**AXITINIB**, axitinib 1 mg tablet, 28 *(Inlyta)*	authority-required	streamlined
10556N	**AXITINIB**, axitinib 5 mg tablet, 28 *(Inlyta)*	authority-required	streamlined
10028T	**ERLOTINIB**, erlotinib 25 mg tablet, 30 *(Tarceva)*	authority-required	streamlined
10019H	**ERLOTINIB**, erlotinib 100 mg tablet, 30 *(Tarceva)*	authority-required	streamlined

10025P	**ERLOTINIB**, erlotinib 150 mg tablet, 30 *(Tarceva)*	authority-required	streamlined
2863Q	**FLUVASTATIN**, fluvastatin 80 mg modified release tablet, 28 *(Lescol XL)*	restricted	unrestricted
10047T	**PAZOPANIB**, pazopanib 200 mg tablet, 90 *(Votrient)*	authority-required	streamlined
10054E	**PAZOPANIB**, pazopanib 200 mg tablet, 30 *(Votrient)*	authority-required	streamlined
2232L	**PAZOPANIB**, pazopanib 200 mg tablet, 30 *(Votrient)*	authority-required	streamlined
10043N	**PAZOPANIB**, pazopanib 400 mg tablet, 60 *(Votrient)*	authority-required	streamlined
10052C	**PAZOPANIB**, pazopanib 400 mg tablet, 30 *(Votrient)*	authority-required	streamlined
2201W	**PAZOPANIB**, pazopanib 400 mg tablet, 30 *(Votrient)*	authority-required	streamlined
2833D	**PRAVASTATIN**, pravastatin sodium 10 mg tablet, 30 *(APO-Pravastatin, Auro-Pravastatin 10, Chem mart Pravastatin, Cholstat 10, Lipostat 10, Pravachol, Pravastatin AN, Pravastatin Sandoz, Pravastatin generichealth, Terry White Chemists Pravastatin)*	restricted	unrestricted
2834E	**PRAVASTATIN**, pravastatin sodium 20 mg tablet, 30 *(APO-Pravastatin, Auro-Pravastatin 20, Chem mart Pravastatin, Cholstat 20, Cholvastin, Lipostat 20, Pravachol, Pravastatin AN, Pravastatin Sandoz, Pravastatin generichealth, Terry White Chemists Pravastatin)*	restricted	unrestricted
8197K	**PRAVASTATIN**, pravastatin sodium 40 mg tablet, 30 *(APO-Pravastatin, Auro-Pravastatin 40, Chem mart Pravastatin, Cholstat 40, Cholvastin, Lipostat 40, Pravachol, Pravastatin AN, Pravastatin Sandoz, Pravastatin generichealth, Terry White Chemists Pravastatin)*	restricted	unrestricted
8829Q	**PRAVASTATIN**, pravastatin sodium 80 mg tablet, 30 *(APO-Pravastatin, Auro-Pravastatin 80, Chem mart Pravastatin, Lipostat 80, Pravachol, Pravastatin AN, Pravastatin Sandoz, Pravastatin generichealth, Terry White Chemists Pravastatin)*	restricted	unrestricted
2606E	**ROSUVASTATIN**, rosuvastatin 5 mg tablet, 30 *(APO-Rosuvastatin, Blooms the Chemist Rosuvastatin, Cavstat, Chem mart Rosuvastatin, Crestor, Crosuva 5, Pharmacor Rosuvastatin 5, Rosuvastatin AMNEAL, , Rosuvastatin generichealth, Rosuvastatin-DRLA, Terry White Chemists Rosuvastatin)*	restricted	unrestricted
2628H	**ROSUVASTATIN**, rosuvastatin 10 mg tablet, 30 *(APO-Rosuvastatin, Blooms the Chemist Rosuvastatin, Cavstat, Chem mart Rosuvastatin, Crestor, Crosuva 10, Pharmacor Rosuvastatin 10, Rosuvastatin AMNEAL, , Rosuvastatin generichealth, Rosuvastatin-DRLA, Terry White Chemists Rosuvastatin)*	restricted	unrestricted
2574L	**ROSUVASTATIN**, rosuvastatin 20 mg tablet, 30 *(APO-Rosuvastatin, Blooms the Chemist Rosuvastatin, Cavstat, Chem mart Rosuvastatin, Crestor, Crosuva 20, Pharmacor Rosuvastatin 20, Rosuvastatin AMNEAL, , Rosuvastatin generichealth, Rosuvastatin-DRLA, Terry White Chemists Rosuvastatin)*	restricted	unrestricted
2594M	**ROSUVASTATIN**, rosuvastatin 40 mg tablet, 30 *(APO-Rosuvastatin, Blooms the Chemist Rosuvastatin, Cavstat, Chem mart Rosuvastatin, Crestor, Crosuva 40, Pharmacor Rosuvastatin 40, Rosuvastatin AMNEAL, , Rosuvastatin generichealth, Rosuvastatin-DRLA, Terry White Chemists Rosuvastatin)*	restricted	unrestricted
2013Y	**SIMVASTATIN**, simvastatin 5 mg tablet, 30 *(Simvastatin Sandoz, Zimstat)*	restricted	unrestricted
2011W	**SIMVASTATIN**, simvastatin 10 mg tablet, 30 *(APO-Simvastatin, Auro-Simvastatin 10, Chem mart Simvastatin, Lipex 10, Ransim, Simvacor 10, Simvar 10, Simvastatin AN, Simvastatin Sandoz, Simvastatin generichealth, Terry White Chemists Simvastatin, Zimstat, Zocor)*	restricted	unrestricted
2012X	**SIMVASTATIN**, simvastatin 20 mg tablet, 30 *(APO-Simvastatin, Auro-Simvastatin 20, Chem mart Simvastatin, Lipex 20, Ransim, Simvacor 20, Simvar 20, Simvastatin AN, Simvastatin Sandoz, Simvastatin generichealth, Terry White Chemists Simvastatin, Zimstat, Zocor)*	restricted	unrestricted
8173E	**SIMVASTATIN**, simvastatin 40 mg tablet, 30 *(APO-Simvastatin, Auro-Simvastatin 40, Chem mart Simvastatin, Lipex 40, Ransim, Simvacor 40, Simvar 40, Simvastatin AN, Simvastatin Sandoz, Simvastatin generichealth, Terry White Chemists Simvastatin, Zimstat, Zocor)*	restricted	unrestricted

8313M	**SIMVASTATIN**, simvastatin 80 mg tablet, 30 *(APO-Simvastatin, Auro-Simvastatin 80, Chem mart Simvastatin, Lipex 80, Ransim, Simvacor 80, Simvar 80, Simvastatin AN, Simvastatin Sandoz, Simvastatin generichealth, Terry White Chemists Simvastatin, Zimstat, Zocor)*	restricted	unrestricted
10242C	**SORAFENIB**, sorafenib 200 mg tablet, 60 *(Nexavar)*	authority-required	streamlined
10009T	**SUNITINIB**, sunitinib 12.5 mg capsule, 28 *(Sutent)*	authority-required	streamlined
9420T	**SUNITINIB**, sunitinib 12.5 mg capsule, 28 *(Sutent)*	authority-required	streamlined
2842N	**SUNITINIB**, sunitinib 25 mg capsule, 28 *(Sutent)*	authority-required	streamlined
9421W	**SUNITINIB**, sunitinib 25 mg capsule, 28 *(Sutent)*	authority-required	streamlined
10459L	**SUNITINIB**, sunitinib 37.5 mg capsule, 28 *(Sutent)*	authority-required	streamlined
10473F	**SUNITINIB**, sunitinib 37.5 mg capsule, 28 *(Sutent)*	authority-required	streamlined
10010W	**SUNITINIB**, sunitinib 50 mg capsule, 28 *(Sutent)*	authority-required	streamlined
9422X	**SUNITINIB**, sunitinib 50 mg capsule, 28 *(Sutent)*	authority-required	streamlined
2832C	**TETRACOSACTIDE (TETRACOSACTRIN)**, tetracosactide (tetracosactrin) 1 mg/mL modified release injection, 1 mL ampoule *(Synacthen Depot 1 mg/1 mL)*	unrestricted	restricted

Alteration – Manufacturer Code

		From	*To*
8406K	*Qvar 50* – **BECLOMETASONE**, beclometasone dipropionate 50 microgram/actuation pressurised inhalation, 200 actuations	IA	IL
8408M	*Qvar 50 Autohaler* – **BECLOMETASONE**, beclometasone dipropionate 50 microgram/actuation breath activated inhalation, 200 actuations	IA	IL
8407L	*Qvar 100* – **BECLOMETASONE**, beclometasone dipropionate 100 microgram/actuation pressurised inhalation, 200 actuations	IA	IL
8409N	*Qvar 100 Autohaler* – **BECLOMETASONE**, beclometasone dipropionate 100 microgram/actuation breath activated inhalation, 200 actuations	IA	IL
1121B	*Difflam* – **BENZYDAMINE**, benzydamine hydrochloride 0.15% mouthwash, 500 mL	IA	IL
5032W	*Difflam* – **BENZYDAMINE**, benzydamine hydrochloride 0.15% mouthwash, 500 mL	IA	IL
5504Q	*Viscotears Gel PF* – **CARBOMER-980**, carbomer-980 0.2% eye drops, 30 x 0.6 mL unit doses	IV	IM
8578L	*Viscotears Gel PF* – **CARBOMER-980**, carbomer-980 0.2% eye drops, 30 x 0.6 mL unit doses	IV	IM
5503P	*PAA* – **CARBOMER-980**, carbomer-980 0.2% eye gel, 10 g	IA	IL
5503P	*Viscotears* – **CARBOMER-980**, carbomer-980 0.2% eye gel, 10 g	IV	IM
8384G	*PAA* – **CARBOMER-980**, carbomer-980 0.2% eye gel, 10 g	IA	IL
8384G	*Viscotears* – **CARBOMER-980**, carbomer-980 0.2% eye gel, 10 g	IV	IM
9210R	*PAA* – **CARBOMER-980**, carbomer-980 0.2% eye gel, 10 g	IA	IL
9210R	*Viscotears* – **CARBOMER-980**, carbomer-980 0.2% eye gel, 10 g	IV	IM
2501P	*Lofenoxal* – **DIPHENOXYLATE + ATROPINE SULFATE MONOHYDRATE**, diphenoxylate hydrochloride 2.5 mg + atropine sulfate monohydrate 25 microgram tablet, 20	IA	IL
2501P	*Lomotil* – **DIPHENOXYLATE + ATROPINE SULFATE MONOHYDRATE**, diphenoxylate hydrochloride 2.5 mg + atropine sulfate monohydrate 25 microgram tablet, 20	IV	IM
1088G	*Tambocor* – **FLECAINIDE**, flecainide acetate 50 mg tablet, 60	IA	IL
1090J	*Tambocor* – **FLECAINIDE**, flecainide acetate 100 mg tablet, 60	IA	IL
8027L	*Minitran 5* – **GLYCERYL TRINITRATE**, glyceryl trinitrate 5 mg/24 hours patch, 30	IA	IL
8028M	*Minitran 10* – **GLYCERYL TRINITRATE**, glyceryl trinitrate 10 mg/24 hours patch, 30	IA	IL

8119H	*Minitran 15* – **GLYCERYL TRINITRATE**, glyceryl trinitrate 15 mg/24 hours patch, 30	IA	IL
2637T	*Aldara Pump* – **IMIQUIMOD**, imiquimod 5% cream, 2 x 2 g	IA	IL
2546B	*Aldara* – **IMIQUIMOD**, imiquimod 5% cream, 12 x 250 mg sachets	IA	IL
3124K	*Hiprex* – **METHENAMINE HIPPURATE**, methenamine hippurate 1 g tablet, 100	IA	IL
1206L	*Maxolon* – **METOCLOPRAMIDE**, metoclopramide hydrochloride 10 mg/2 mL injection, 10 x 2 mL ampoules	IA	IL
5153F	*Maxolon* – **METOCLOPRAMIDE**, metoclopramide hydrochloride 10 mg/2 mL injection, 10 x 2 mL ampoules	IA	IL
1207M	*Maxolon* – **METOCLOPRAMIDE**, metoclopramide hydrochloride 10 mg tablet, 25	IA	IL
5151D	*Maxolon* – **METOCLOPRAMIDE**, metoclopramide hydrochloride 10 mg tablet, 25	IA	IL
2723H	*Mogadon* – **NITRAZEPAM**, nitrazepam 5 mg tablet, 25	IA	IL
2732T	*Mogadon* – **NITRAZEPAM**, nitrazepam 5 mg tablet, 25	IA	IL
5189D	*Mogadon* – **NITRAZEPAM**, nitrazepam 5 mg tablet, 25	IA	IL
1705R	*LPV* – **PHENOXYMETHYLPENICILLIN**, phenoxymethylpenicillin 250 mg capsule, 50	IA	IL
1789E	*LPV* – **PHENOXYMETHYLPENICILLIN**, phenoxymethylpenicillin 250 mg capsule, 50	IA	IL
3363B	*LPV* – **PHENOXYMETHYLPENICILLIN**, phenoxymethylpenicillin 250 mg capsule, 50	IA	IL
2965C	*LPV* – **PHENOXYMETHYLPENICILLIN**, phenoxymethylpenicillin 500 mg capsule, 50	IA	IL
3364C	*LPV* – **PHENOXYMETHYLPENICILLIN**, phenoxymethylpenicillin 500 mg capsule, 50	IA	IL
1917X	*Solone* – **PREDNISOLONE**, prednisolone 5 mg tablet, 60	IA	IL
1916W	*Solone* – **PREDNISOLONE**, prednisolone 25 mg tablet, 30	IA	IL
1935W	*Sone* – **PREDNISONE**, prednisone 5 mg tablet, 60	IA	IL
1936X	*Sone* – **PREDNISONE**, prednisone 25 mg tablet, 30	IA	IL
2724J	*Mestinon* – **PYRIDOSTIGMINE**, PYRIDOSTIGMINE BROMIDE Tablet 10 mg, 50	IA	IL
1959D	*Mestinon* – **PYRIDOSTIGMINE**, pyridostigmine bromide 60 mg tablet, 150	IA	IL
2608G	*Mestinon Timespan* – **PYRIDOSTIGMINE**, pyridostigmine bromide 180 mg modified release tablet, 50	IA	IL
8354Q	*Airomir Autohaler* –**SALBUTAMOL**, salbutamol 100 microgram/actuation breath activated inhalation, 200 actuations	IA	IL
1330B	*iNova Pharmaceuticals (Australia) Pty Ltd* – **TETRABENAZINE**, tetrabenazine 25 mg tablet, 112	IA	IL
2614N	*Nuelin* – **THEOPHYLLINE**, theophylline 133.3 mg/25 mL oral liquid, 500 mL	IA	IL
8230E	*Nuelin-SR 200* – **THEOPHYLLINE**, theophylline 200 mg modified release tablet, 100	IA	IL
2634P	*Nuelin-SR 250* – **THEOPHYLLINE**, theophylline 250 mg modified release tablet, 100	IA	IL
8231F	*Nuelin-SR 300* – **THEOPHYLLINE**, theophylline 300 mg modified release tablet, 100	IA	IL

Advance Notices

1 April 2018

Deletion – Brand

8358X *Clopidogrel RBX, RA* – **CLOPIDOGREL**, clopidogrel 75 mg tablet, 28

2412Y *Frusemide RBX, RA* – **FUROSEMIDE (FRUSEMIDE)**, furosemide (frusemide) 40 mg tablet, 100

2414C *Frusemide RBX, RA* – **FUROSEMIDE (FRUSEMIDE)**, furosemide (frusemide) 20 mg tablet, 100

8535F *Chem mart Gliclazide MR, CH* – **GLICLAZIDE**, gliclazide 30 mg modified release tablet, 100

8535F *Terry White Chemists Gliclazide MR, TW* – **GLICLAZIDE**, gliclazide 30 mg modified release tablet, 100

8247C *Irbesartan RBX, RA* – **IRBESARTAN**, irbesartan 150 mg tablet, 30

8248D *Irbesartan RBX, RA* – **IRBESARTAN**, irbesartan 300 mg tablet, 30

2136K *Irbesartan/HCTZ RBX 300/25, RA* – **IRBESARTAN + HYDROCHLOROTHIAZIDE**, irbesartan 300 mg + hydrochlorothiazide 25 mg tablet, 30

8404H *Irbesartan/HCTZ RBX 150/12.5, RA* – **IRBESARTAN + HYDROCHLOROTHIAZIDE**, irbesartan 150 mg + hydrochlorothiazide 12.5 mg tablet, 30

9120B *Chem mart Ramipril, CH* – **RAMIPRIL**, ramipril 1.25 mg capsule, 30

9120B *Terry White Chemists Ramipril, TW* – **RAMIPRIL**, ramipril 1.25 mg capsule, 30

2012X *Ransim, RA* – **SIMVASTATIN**, simvastatin 20 mg tablet, 30

8173E *Ransim, RA* – **SIMVASTATIN**, simvastatin 40 mg tablet, 30

9243L *Ransim, RA* – **SIMVASTATIN**, simvastatin 20 mg tablet, 30

9244M *Ransim, RA* – **SIMVASTATIN**, simvastatin 40 mg tablet, 30

2185B *Stelazine, GH* – **TRIFLUOPERAZINE**, trifluoperazine 1 mg tablet, 100

2186C *Stelazine, GH* – **TRIFLUOPERAZINE**, trifluoperazine 5 mg tablet, 100

2386N *Stelazine, GH* – **TRIFLUOPERAZINE**, trifluoperazine 2 mg tablet, 100

1 May 2018

Deletion – Brand

9049G *Caduet 5/10, PF* – **AMLODIPINE + ATORVASTATIN**, amlodipine 5 mg + atorvastatin 10 mg tablet, 30

9050H *Caduet 5/20, PF* – **AMLODIPINE + ATORVASTATIN**, amlodipine 5 mg + atorvastatin 20 mg tablet, 30

8974H *Actonel EC Combi D, UA* – **RISEDRONATE (&) CALCIUM CARBONATE + COLECALCIFEROL**, RISEDRONATE SODIUM and CALCIUM CARBONATE with COLECALCIFEROL Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms, 1

Palliative Care

Alterations

Alteration – Item Description

From
5393W **MORPHINE**, morphine sulfate 10 mg tablet, 20 *(Sevredol)*
To
5393W **MORPHINE**, morphine sulfate pentahydrate 10 mg tablet, 20 *(Sevredol)*

From
5394X **MORPHINE**, morphine sulfate 20 mg tablet, 20 *(Sevredol)*
To
5394X **MORPHINE**, morphine sulfate pentahydrate 20 mg tablet, 20 *(Sevredol)*

From
5391R **MORPHINE**, morphine sulfate 200 mg modified release tablet, 28 *(MS Contin)*
To
5391R **MORPHINE**, morphine sulfate pentahydrate 200 mg modified release tablet, 28 *(MS Contin)*

From
5331N **SORBITOL + CITRIC ACID + LAURYL SULFOACETATE SODIUM**, sorbitol 3.125 g/5 mL + citrate sodium dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 12 x 5 mL *(Micolette)*
To
5331N **SORBITOL + CITRIC ACID + LAURYL SULFOACETATE SODIUM**, sorbitol 3.125 g/5 mL + sodium citrate dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 12 x 5 mL *(Micolette)*

Alteration – Manufacturer Code

		From	*To*
5385K	*Difflam* – **BENZYDAMINE**, benzydamine hydrochloride 0.15% mouthwash, 500 mL	IA	IL
10762K	*Maxolon* – **METOCLOPRAMIDE**, metoclopramide hydrochloride 10 mg/2 mL injection, 10 x 2 mL ampoules	IA	IL
5359C	*Mogadon* – **NITRAZEPAM**, nitrazepam 5 mg tablet, 25	IA	IL

Highly Specialised Drugs Program (Private Hospital)

Additions

Addition – Item

11236J **DEFERASIROX**, deferasirox 125 mg dispersible tablet, 28 *(Exjade)*

11241P **DEFERASIROX**, deferasirox 125 mg dispersible tablet, 28 *(Exjade)*

11238L **DEFERASIROX**, deferasirox 250 mg dispersible tablet, 28 *(Exjade)*

11244T **DEFERASIROX**, deferasirox 250 mg dispersible tablet, 28 *(Exjade)*

11232E **DEFERASIROX**, deferasirox 500 mg dispersible tablet, 28 *(Exjade)*

11243R **DEFERASIROX**, deferasirox 500 mg dispersible tablet, 28 *(Exjade)*

Deletions

Deletion – Item

10554L **ZOLEDRONIC ACID**, zoledronic acid 4 mg/100 mL injection, 100 mL vial *(Zometa)*

Alterations

Alteration – Item Description

From

9744W **LEVODOPA + CARBIDOPA ANHYDROUS**, levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL *(Duodopa)*

To

9744W **LEVODOPA + CARBIDOPA**, levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL *(Duodopa)*

From

10084R **PLERIXAFOR**, plerixafor 24 mg/1.2 mL subcutaneous infusion injection, 1.2 mL vial *(Mozobil)*

To

10084R **PLERIXAFOR**, plerixafor 24 mg/1.2 mL injection, 1.2 mL vial *(Mozobil)*

Alteration – Restriction

6499C **DEFERASIROX**, deferasirox 125 mg dispersible tablet, 28 *(Exjade)*

6500D **DEFERASIROX**, deferasirox 250 mg dispersible tablet, 28 *(Exjade)*

9600G **DEFERASIROX**, deferasirox 500 mg dispersible tablet, 28 *(Exjade)*

9613Y **INFLIXIMAB**, infliximab 100 mg injection, 1 vial *(Inflectra, Remicade, Renflexis)*

11003D **MEPOLIZUMAB**, mepolizumab 100 mg injection, 1 vial *(Nucala)*

11164N **USTEKINUMAB**, ustekinumab 130 mg/26 mL injection, 26 mL vial *(Stelara)*

10415E **VEDOLIZUMAB**, vedolizumab 300 mg injection, 1 vial *(Entyvio)*

Highly Specialised Drugs Program (Public Hospital)

Additions

Addition – Item

11235H **DEFERASIROX**, deferasirox 125 mg dispersible tablet, 28 *(Exjade)*

11247Y **DEFERASIROX**, deferasirox 125 mg dispersible tablet, 28 *(Exjade)*

11239M **DEFERASIROX**, deferasirox 250 mg dispersible tablet, 28 *(Exjade)*

11240N **DEFERASIROX**, deferasirox 250 mg dispersible tablet, 28 *(Exjade)*

11231D **DEFERASIROX**, deferasirox 500 mg dispersible tablet, 28 *(Exjade)*

11234G **DEFERASIROX**, deferasirox 500 mg dispersible tablet, 28 *(Exjade)*

Addition – Note

5654N **DEFERASIROX**, deferasirox 125 mg dispersible tablet, 28 *(Exjade)*

5655P **DEFERASIROX**, deferasirox 250 mg dispersible tablet, 28 *(Exjade)*

5656Q **DEFERASIROX**, deferasirox 500 mg dispersible tablet, 28 *(Exjade)*

Deletions

Deletion – Item

10548E **ZOLEDRONIC ACID**, zoledronic acid 4 mg/100 mL injection, 100 mL vial *(Zometa)*

Alterations

Alteration – Item Description

From

9743T **LEVODOPA + CARBIDOPA ANHYDROUS**, levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL *(Duodopa)*

To

9743T **LEVODOPA + CARBIDOPA**, levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL *(Duodopa)*

From

10083Q **PLERIXAFOR**, plerixafor 24 mg/1.2 mL subcutaneous infusion injection, 1.2 mL vial *(Mozobil)*

To

10083Q **PLERIXAFOR**, plerixafor 24 mg/1.2 mL injection, 1.2 mL vial *(Mozobil)*

Alteration – Restriction

5654N **DEFERASIROX**, deferasirox 125 mg dispersible tablet, 28 *(Exjade)*

5655P **DEFERASIROX**, deferasirox 250 mg dispersible tablet, 28 *(Exjade)*

5656Q **DEFERASIROX**, deferasirox 500 mg dispersible tablet, 28 *(Exjade)*

5754W **INFLIXIMAB**, infliximab 100 mg injection, 1 vial *(Inflectra, Remicade, Renflexis)*

10996R **MEPOLIZUMAB**, mepolizumab 100 mg injection, 1 vial *(Nucala)*

11182M **USTEKINUMAB**, ustekinumab 130 mg/26 mL injection, 26 mL vial *(Stelara)*

10390W **VEDOLIZUMAB**, vedolizumab 300 mg injection, 1 vial *(Entyvio)*

Alteration – Number of Repeats

		From	*To*
5654N	**DEFERASIROX**, deferasirox 125 mg dispersible tablet, 28 *(Exjade)*	5	2
5655P	**DEFERASIROX**, deferasirox 250 mg dispersible tablet, 28 *(Exjade)*	5	2
5656Q	**DEFERASIROX**, deferasirox 500 mg dispersible tablet, 28 *(Exjade)*	5	2

Highly Specialised Drugs Program (Community Access)

Additions

Addition – Brand

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

Growth Hormone Program

Advance Notices

1 April 2018

Deletion – Brand

10441M *Omnitrope, SZ* – **SOMATROPIN**, somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge

10481P *Omnitrope, SZ* – **SOMATROPIN**, somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge

6311E *Omnitrope, SZ* – **SOMATROPIN**, somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge

Repatriation Pharmaceutical Benefits

Deletions

Deletion – Item

2220W **RISEDRONATE (&) CALCIUM CARBONATE**, RISEDRONATE SODIUM and CALCIUM CARBONATE Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium), 1 *(Actonel EC Combi)*

Alterations

Alteration – Item Description

From

4434J **ACETIC ACID + HYDROXYQUINOLINE + RICINOLEIC ACID**, acetic acid 0.94% + hydroxyquinoline sulfate 0.025% + ricinoleic acid 0.75% vaginal gel, 100 g *(Aci-Jel)*

To

4434J **ACETIC ACID + HYDROXYQUINOLINE + RICINOLEIC ACID**, acetic acid 0.94% + oxyquinoline sulfate 0.025% + ricinoleic acid 0.75% vaginal gel, 100 g *(Aci-Jel)*

From

10594N **FERROUS FUMARATE**, ferrous fumarate 200 mg (equivalent to 65.7 mg of elemental iron) tablet, 60 *(Ferro-tab)*

To

10594N **FERROUS FUMARATE**, ferrous fumarate 200 mg (iron 65.7 mg) tablet, 60 *(Ferro-tab)*

From

10579T **FERROUS FUMARATE + FOLIC ACID**, ferrous fumarate 310 mg (equivalent to 100 mg elemental iron) + folic acid 350 microgram tablet, 60 *(Ferro-f-tab)*

To

10579T **FERROUS FUMARATE + FOLIC ACID**, ferrous fumarate 310 mg (iron 100 mg) + folic acid 350 microgram tablet, 60 *(Ferro-f-tab)*

From

4308R **LIGNOCAINE**, lignocaine hydrochloride anhydrous 2% oral liquid, 200 mL *(Xylocaine Viscous)*

To

4308R **LIDOCAINE (LIGNOCAINE)**, lidocaine (lignocaine) hydrochloride 2% oral liquid, 200 mL *(Xylocaine Viscous)*

From

4493L **FERRIC PYROPHOSPHATE + THIAMINE + PYRIDOXINE + CYANOCOBALAMIN + LYSINE**, cyanocobalamin 25 microgram/10 mL + iron (as ferric pyrophosphate) 10 mg/10 mL + lysine hydrochloride 300 mg/10 mL + pyridoxine hydrochloride 5 mg/10 mL + thiamine hydrochloride 10 mg/10 mL oral liquid, 200 mL *(Accomin Adult Tonic)*

To

4493L **LYSINE + THIAMINE + PYRIDOXINE + CYANOCOBALAMIN + FERRIC PYROPHOSPHATE**, lysine hydrochloride 300 mg/10 mL + thiamine hydrochloride 10 mg/10 mL + pyridoxine hydrochloride 5 mg/10 mL + cyanocobalamin 25 microgram/10 mL + iron (as ferric pyrophosphate) 10 mg/10 mL oral liquid, 200 mL *(Accomin Adult Tonic)*

From

4321K **MAGNESIUM ASPARTATE DIHYDRATE**, magnesium aspartate dihydrate 500 mg (equivalent to 37.4 mg of magnesium) tablet, 50 *(Mag-Sup, Magmin)*

To

4321K **MAGNESIUM ASPARTATE DIHYDRATE**, magnesium aspartate dihydrate 500 mg (magnesium 37.4 mg) tablet, 50 *(Mag-Sup, Magmin)*

From

4022Q **EUCALYPTUS OIL + MENTHOL + METHYL SALICYLATE**, eucalyptus oil 10% + menthol 4% + methyl salicylate 25% cream, 100 g *(Gold Cross)*

To

4022Q **METHYL SALICYLATE + EUCALYPTUS OIL + MENTHOL**, methyl salicylate 25% + eucalyptus oil 10% + menthol 4% cream, 100 g *(Gold Cross)*

From

4349X **MORPHINE**, morphine sulfate 200 mg modified release tablet, 28 *(MS Contin)*

To

4349X **MORPHINE**, morphine sulfate pentahydrate 200 mg modified release tablet, 28 *(MS Contin)*

From

4180B **DICHLOROBENZENE WITH CHLORBUTOL AND ARACHIS OIL**, DICHLOROBENZENE with CHLORBUTOL and ARACHIS OIL Ear drops, ortho-dichlorobenzene 140 mg per mL, para-dichlorobenzene 20 mg per mL, chlorbutol 50 mg per mL, arachis oil 573 mg per mL, 10 mL, 1 *(Cerumol)*

To

4180B **ORTHO-DICHLOROBENZENE + PARA-DICHLOROBENZENE + CHLOROBUTANOL + ARACHIS OIL**, ortho-dichlorobenzene 14% + para-dichlorobenzene 2% + chlorobutanol hemihydrate 5% + arachis oil 57% ear drops, 10 mL *(Cerumol)*

From

4462W **SORBITOL + CITRIC ACID + LAURYL SULFOACETATE SODIUM**, sorbitol 3.125 g/5 mL + citrate sodium dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 4 x 5 mL *(Micolette)*

To

4462W **SORBITOL + CITRIC ACID + LAURYL SULFOACETATE SODIUM**, sorbitol 3.125 g/5 mL + sodium citrate dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 4 x 5 mL *(Micolette)*

From

4447C **COAL TAR SOLUTION + TAR + SALICYLIC ACID**, coal tar solution 1% + tar 1% + salicylic acid 2% solution, 250 mL *(Sebitar)*

To

4447C **TAR + COAL TAR SOLUTION + SALICYLIC ACID**, tar 1% + coal tar solution 1% + salicylic acid 2% solution, 250 mL *(Sebitar)*

From

4408B **TAR + TRIETHANOLAMINE LAURYL SULFATE**, tar 2.3% + triethanolamine lauryl sulfate 6% solution, 500 mL *(Pinetarsol)*

To

4408B **TAR + TROLAMINE LAURIL SULFATE**, tar 2.3% + trolamine lauril sulfate 6% solution, 500 mL *(Pinetarsol)*

Alteration – Manufacturer Code

		From	*To*
4222F	*Efudix* – **FLUOROURACIL**, fluorouracil 5% cream, 20 g	IA	IL
10106X	*Aldara Pump* – **IMIQUIMOD**, imiquimod 5% cream, 2 x 2 g	IA	IL
4134N	*Aldara* – **IMIQUIMOD**, imiquimod 5% cream, 12 x 250 mg sachets	IA	IL
4559Y	*Aldara* – **IMIQUIMOD**, imiquimod 5% cream, 12 x 250 mg sachets	IA	IL
4071G	*Duro-Tuss* – **PHOLCODINE**, pholcodine 1 mg/mL oral liquid, 100 mL	IA	IL

Advance Notices

1 May 2018

Deletion – Brand

2254P *Actonel EC Combi D, UA* – **RISEDRONATE (&) CALCIUM CARBONATE + COLECALCIFEROL**, RISEDRONATE SODIUM and CALCIUM CARBONATE with COLECALCIFEROL Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms, 1

Prescriber Bag

- **BENZATROPINE**

benzatropine mesilate 2 mg/2 mL injection, 5 x 2 mL vials

11265X	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
NP	1	115.99	Benzatropine Injection [PL]

General Pharmaceutical Benefits

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying drugs (bDMDs) for adult patients with severe Crohn disease. Where the term bDMDs appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).

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

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab, vedolizumab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab,or vedolizumab treatment prior to 1 September 2017 is considered to be in their first cycle as of 1 September 2017.

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

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

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

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

(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised therapy with adalimumab, infliximab, vedolizumab or ustekinumab in this treatment cycle and wishes to commence such therapy (Initial 1 - new patients); or

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

(iii) a patient wishes to re-commence treatment with adalimumab, infliximab, vedolizumab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - Change or Re-commencement).

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

From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, 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 bDMD therapy.

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

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.

Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the

subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.
(b) Continuing treatment.
Following the completion of an initial treatment course with adalimumab, infliximab, vedolizumab or ustekinumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.
Assessments of response to a course of PBS-subsidised therapy must be 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 drug.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMD therapy is approved, a patient may swap if eligible to the alternate adalimumab, infliximab, vedolizumab or ustekinumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.
A patient may trial the alternate bDMD therapy at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab, vedolizumab or ustekinumab at the time of the application. However, they cannot swap to a particular bDMD therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to adalimumab, infliximab, vedolizumab or ustekinumab (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the therapy 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 CDAI or evidence of intestinal inflammation submitted with the first authority application for adalimumab, infliximab, vedolizumab or ustekinumab. 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 provided for all subsequent continuing treatment applications.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised bDMD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with vedolizumab.
A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.
(6) Patients 'grandfathered' onto PBS-subsidised treatment with ustekinumab.
A patient who commenced treatment with ustekinumab for severe Crohn disease prior to 1 September 2017 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Note No applications for increased maximum quantities will be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Special Pricing Arrangements apply.

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment (new patient - initial 1)

Treatment criteria:

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

Clinical criteria:

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more months.

Population criteria:

- Patient must be aged 18 years or older.

Clinical criteria:

- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.

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

(a) two completed authority prescription forms; and

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

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

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

(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iv) the date of the most recent clinical assessment; and

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

Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:(a) patient must have evidence of intestinal inflammation;(b) patient must be assessed clinically as being in a high faecal output state; (c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.Evidence of intestinal inflammation includes: (i) blood: higher than normal platelet count, or, 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; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;

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

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting the Department of Human Services.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

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.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity and number of repeats to provide for an initial 16 week course of this drug will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may

be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

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

This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this 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 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 continuation criterion for PBS-subsidised treatment with this drug.

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

Authority required

Severe Crohn disease

Treatment Phase: Change or Re-commencement of treatment (initial 2)

Treatment criteria:

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

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological disease modifying drug for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle.

Population criteria:

- Patient must be aged 18 years or older.

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

(a) two completed authority prescription forms; and

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

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment; and

(iv) the details of prior biological disease modifying drug treatment including the 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 disease modifying drug (bDMD) therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised bDMD 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 vedolizumab 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 bDMD treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of bDMD.

A maximum quantity and number of repeats to provide for an initial 16 week course of this drug will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

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

This assessment, 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 timeframes, 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.

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

Authority required

Severe Crohn disease

Treatment Phase: Balance of supply

Treatment criteria:

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

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the initial dose (i.e. the initial infusion regimen at weeks 0 and 2); OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 2 doses (new patients) or 5 repeats (Continuing treatment).

Population criteria:

- Patient must be aged 18 years or older.

Authority approval for sufficient therapy to complete a maximum of 2 initial doses or 5 repeats may be requested by telephone by contacting the Department of Human Services

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

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

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9187M	1	..	..	3989.10	39.50	Humira [VE]

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

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9190Q	1	2	..	1401.83	39.50	Humira [VE]

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

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9188N	1	2	..	1401.83	39.50	Humira [VE]

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

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9186L	1	..	..	3989.10	39.50	Humira [VE]

▪ AXITINIB

Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

7433

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

Clinical criteria:

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Prescribers may request an increased maximum quantity sufficient to provide up to one month's supply for patients who require dose adjustment.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

axitinib 1 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10539Q	2	5	..	*1120.45	39.50	Inlyta [PF]

axitinib 5 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10556N	2	5	..	*5189.53	39.50	Inlyta [PF]

▪ BENZATROPINE

benzatropine mesilate 2 mg/2 mL injection, 5 x 2 mL vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11249C (DP)	1	..	..	115.99	39.50	Benzatropine Injection [PL]

benzatropine mesilate 2 mg/2 mL injection, 5 x 2 mL vials

11255J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	115.99	39.50	Benzatropine Injection [PL]

▪ DESVENLAFAXINE

Note Pharmaceutical benefits that have the forms desvenlafaxine tablet (modified release) 100 mg, desvenlafaxine tablet (modified release) 100 mg (as benzoate) and desvenlafaxine tablet (extended release) 100 mg (as succinate) are equivalent for the purposes of substitution.

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

Restricted benefit
Major depressive disorders

desvenlafaxine 100 mg modified release tablet, 28

10231L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	28.61	29.82	[a] Desfax [AF] [a] Desvenlafaxine Actavis [EA]	[a] DESVEN [RW] [a] Desvenlafaxine Sandoz [SZ]

desvenlafaxine 100 mg modified release tablet, 28

10245F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	28.61	29.82	[a] APO-Desvenlafaxine MR [TX]	[a] Desvenlafaxine GH XR [GQ]

desvenlafaxine 100 mg modified release tablet, 28

9367B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	28.61	29.82	[a] Pristiq [PF]

▪ DESVENLAFAXINE

Note Pharmaceutical benefits that have the forms desvenlafaxine tablet (modified release) 50 mg, desvenlafaxine tablet (modified release) 50 mg (as benzoate) and desvenlafaxine tablet (extended release) 50 mg (as succinate) are equivalent for the purposes of substitution.

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

Restricted benefit
Major depressive disorders

desvenlafaxine 50 mg modified release tablet, 28

10234P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	25.36	26.57	[a] APO-Desvenlafaxine MR [TX]	[a] Desvenlafaxine GH XR [GQ]

desvenlafaxine 50 mg modified release tablet, 28

10241B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	25.36	26.57	[a] Desfax [AF] [a] Desvenlafaxine Actavis [EA]	[a] DESVEN [RW] [a] Desvenlafaxine Sandoz [SZ]

desvenlafaxine 50 mg modified release tablet, 28

9366Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	25.36	26.57	[a] Pristiq [PF]

▪ ERLOTINIB

Authority required (STREAMLINED)
7446
Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)
Treatment Phase: Continuing treatment
Clinical criteria:

- The treatment must be as monotherapy, **AND**
- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must not have progressive disease.

Population criteria:

- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.

erlotinib 150 mg tablet, 30

11259N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	3	..	1433.50	39.50	Tarceva [RO]

erlotinib 25 mg tablet, 30

11263T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	3	..	329.57	39.50	Tarceva [RO]

erlotinib 100 mg tablet, 30

11260P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	3	..	1173.53	39.50	Tarceva [RO]

▪ EVEROLIMUS

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

7431

Tuberous sclerosis complex (TSC)

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; OR
- The condition must be visceral tumours associated with TSC, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have demonstrated a response to prior treatment.

everolimus 5 mg tablet, 30

11254H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	2714.52	39.50	Afinitor [NV]

everolimus 2.5 mg tablet, 30

11258M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	1404.57	39.50	Afinitor [NV]

everolimus 10 mg tablet, 30

11267B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	5279.52	39.50	Afinitor [NV]

▪ EVEROLIMUS

Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

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 (STREAMLINED)

7432

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

Clinical criteria:

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

everolimus 5 mg tablet, 30

11257L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	2714.52	39.50	Afinitor [NV]

everolimus 10 mg tablet, 30

11262R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	5279.52	39.50	Afinitor [NV]

▪ GEFITINIB

Authority required (STREAMLINED)

7447

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

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must not have progressive disease.

gefitinib 250 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11264W	1	3	..	1433.50	39.50	Iressa [AP]

▪ LAPATINIB

Note No applications for increased maximum quantities will be authorised.

Note No applications for increased repeats will be authorised.

Authority required (STREAMLINED)

7441

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- The treatment must be in combination with capecitabine, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised anti-HER2 therapy for this condition, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), at 3 monthly intervals during treatment.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

The treatment must not exceed a lifetime total of one continuous course.

lapatinib 250 mg tablet, 70

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11251E	2	2	..	*3228.57	39.50	Tykerb [NV]

▪ MELOXICAM

Note Pharmaceutical benefits that have the form meloxicam tablet 7.5 mg and pharmaceutical benefits that have the form meloxicam capsule 7.5 mg are equivalent for the purposes of substitution.

Note The use of this drug for the treatment of the following conditions is not subsidised through the PBS:
(a) acute pain;
(b) soft tissue injury;
(c) arthrosis without an inflammatory component.

Restricted benefit

Osteoarthritis

Clinical criteria:

- The treatment must be for symptomatic treatment.

Restricted benefit

Rheumatoid arthritis

Clinical criteria:

- The treatment must be for symptomatic treatment.

meloxicam 7.5 mg capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8887R NP	1	3	..	13.89	15.10	[a] APO-Meloxicam [TX] [a] Meloxicam Sandoz [SZ] [a] Moxicam [AF]	[a] Chem mart Meloxicam [CH] [a] Movalis 7.5 [RW] [a] Terry White Chemists Meloxicam [TW]
			[B]2.50	16.39	15.10	[a] Mobic [BY]	

meloxicam 7.5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8561N NP	1	3	..	13.89	15.10	[a] APO-Meloxicam [TX]	[a] Chem mart Meloxicam 7.5 mg [CH]

				[a] Meloxiauro 7.5 [DO]	[a] Meloxibell [GQ]
				[a] Meloxicam AN [EA]	[a] Meloxicam-GA [ED]
				[a] Meloxicam Ranbaxy [RA]	[a] Meloxicam Sandoz [SZ]
				[a] Movalis 7.5 [RW]	[a] Moxicam 7.5 [AF]
				[a] Pharmacor Meloxicam 7.5 [CR]	[a] Terry White Chemists Meloxicam 7.5 mg [TW]
	[B]2.50	16.39	15.10	[a] Mobic [BY]	

▪ MELOXICAM

Note Pharmaceutical benefits that have the form meloxicam tablet 15 mg and pharmaceutical benefits that have the form meloxicam capsule 15 mg are equivalent for the purposes of substitution.

Note The use of this drug for the treatment of the following conditions is not subsidised through the PBS:
(a) acute pain;
(b) soft tissue injury;
(c) arthrosis without an inflammatory component.

Restricted benefit

Osteoarthritis

Clinical criteria:

- The treatment must be for symptomatic treatment.

Restricted benefit

Rheumatoid arthritis

Clinical criteria:

- The treatment must be for symptomatic treatment.

meloxicam 15 mg capsule, 30

8888T (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	15.18	16.39	[a] APO-Meloxicam [TX]	[a] Chem mart Meloxicam [CH]
					[a] Meloxicam Sandoz [SZ]	[a] Movalis 15 [RW]
					[a] Moxicam [AF]	[a] Terry White Chemists Meloxicam [TW]
		[B]2.50	17.68	16.39	[a] Mobic [BY]	

meloxicam 15 mg tablet, 30

8562P (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	15.18	16.39	[a] APO-Meloxicam [TX]	[a] Chem mart Meloxicam 15 mg [CH]
					[a] Meloxiauro 15 [DO]	[a] Meloxibell [GQ]
					[a] Meloxicam AN [EA]	[a] Meloxicam-GA [ED]
					[a] Meloxicam Ranbaxy [RA]	[a] Meloxicam Sandoz [SZ]
					[a] Movalis 15 [RW]	[a] Moxicam 15 [AF]
					[a] Pharmacor Meloxicam 15 [CR]	[a] Terry White Chemists Meloxicam 15 mg [TW]
		[B]2.50	17.68	16.39	[a] Mobic [BY]	

▪ PAZOPANIB

Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

7422

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

Clinical criteria:

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- Patient must require dose adjustment, **AND**
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

Patients who have progressive disease on sunitinib are not eligible to receive PBS-subsidised pazopanib.

pazopanib 400 mg tablet, 30

2201W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	2413.16	39.50	Votrient [NV]

pazopanib 200 mg tablet, 30

2232L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1248.61	39.50	Votrient [NV]

▪ PAZOPANIB

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

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have been receiving treatment with pazopanib prior to 1 October 2012, **AND**
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

pazopanib 200 mg tablet, 90

2034C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	3544.98	39.50	Votrient [NV]

pazopanib 400 mg tablet, 60

2035D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	4676.80	39.50	Votrient [NV]

▪ PAZOPANIB

Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.
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 (STREAMLINED)

7423

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

Clinical criteria:

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

Patients who have progressive disease on sunitinib are not eligible to receive PBS-subsidised pazopanib.

pazopanib 200 mg tablet, 90

11252F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	3544.98	39.50	Votrient [NV]

pazopanib 400 mg tablet, 60

11261Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	4676.80	39.50	Votrient [NV]

▪ PAZOPANIB

Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.
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 (STREAMLINED)

7458

Advanced (unresectable and/or metastatic) soft tissue sarcoma

Treatment Phase: Continuing treatment beyond 3 months

Clinical criteria:

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

pazopanib 200 mg tablet, 90

10047T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	3544.98	39.50	Votrient [NV]

pazopanib 400 mg tablet, 60

10043N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	4676.80	39.50	Votrient [NV]

▪ PAZOPANIB

Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

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 (STREAMLINED)

7459

Advanced (unresectable and/or metastatic) soft tissue sarcoma

Treatment Phase: Continuing treatment beyond 3 months

Clinical criteria:

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- Patient must require dose adjustment, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

pazopanib 400 mg tablet, 30

10052C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	2413.16	39.50	Votrient [NV]

pazopanib 200 mg tablet, 30

10054E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	1248.61	39.50	Votrient [NV]

▪ SORAFENIB

Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

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 (STREAMLINED)

7487

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

Clinical criteria:

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

sorafenib 200 mg tablet, 60

10242C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	..	*6144.71	39.50	Nexavar [BN]

▪ SUNITINIB

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 (STREAMLINED)

7471

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)
Treatment Phase: Continuing treatment
Clinical criteria:

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must not have disease progression, **AND**
- The treatment must be as monotherapy.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

sunitinib 25 mg capsule, 28

2842N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	3356.15	39.50	Sutent [PF]

sunitinib 50 mg capsule, 28

10010W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	6563.05	39.50	Sutent [PF]

sunitinib 12.5 mg capsule, 28

10009T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	1736.75	39.50	Sutent [PF]

sunitinib 37.5 mg capsule, 28

10473F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	4959.60	39.50	Sutent [PF]

▪ SUNITINIB

Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.
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 (STREAMLINED)

7466

Stage IV clear cell variant renal cell carcinoma (RCC)
Treatment Phase: Continuing treatment beyond 3 months
Clinical criteria:

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.
Patients who have developed progressive disease on pazopanib are not eligible to receive PBS-subsidised sunitinib.

sunitinib 25 mg capsule, 28

9421W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	3	..	3356.15	39.50	Sutent [PF]

sunitinib 50 mg capsule, 28

9422X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	3	..	6563.05	39.50	Sutent [PF]

sunitinib 12.5 mg capsule, 28

9420T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	3	..	1736.75	39.50	Sutent [PF]

sunitinib 37.5 mg capsule, 28

10459L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	3	..	4959.60	39.50	Sutent [PF]

▪ SUNITINIB

Note A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

Note Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS subsidised imatinib after progression on this drug

Note Sunitinib malate is not PBS-subsidised for the treatment of patients with resectable malignant gastrointestinal stromal tumours.

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

7430

Metastatic or unresectable malignant gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- The treatment must be as monotherapy, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must not have progressive disease.

sunitinib 25 mg capsule, 28

11253G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	3356.15	39.50	Sutent [PF]

sunitinib 50 mg capsule, 28

11250D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	6563.05	39.50	Sutent [PF]

sunitinib 12.5 mg capsule, 28

11266Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	1736.75	39.50	Sutent [PF]

sunitinib 37.5 mg capsule, 28

11256K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	4959.60	39.50	Sutent [PF]

▪ TETRACOSACTIDE (TETRACOSACTRIN)

Restricted benefit

Hypsarrhythmia and/or infantile spasms

tetracosactide (tetracosactrin) 1 mg/mL modified release injection, 1 mL ampoule

2832C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	5	5	..	*449.95	39.50	Synacthen Depot 1 mg/1 mL [LM]

▪ USTEKINUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying drugs (bDMDs) for adult patients with severe Crohn disease. Where the term bDMDs appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).

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

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab, vedolizumab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab,or vedolizumab treatment prior to 1 September 2017 is

considered to be in their first cycle as of 1 September 2017.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab more than once.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab, vedolizumab or ustekinumab under the new treatment cycle.
A patient who has failed fewer than 3 trials of bDMD 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 fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised therapy with adalimumab, infliximab, vedolizumab or ustekinumab in this treatment cycle and wishes to commence such therapy (Initial 1 - new patients); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab, vedolizumab or ustekinumab and wishes to trial an alternate agent (Initial 2 - Change or recommencement) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with adalimumab, infliximab, vedolizumab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - Change or Re-commencement).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab, 14 weeks of therapy for vedolizumab and 16 weeks for ustekinumab.
From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, 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 bDMD therapy.
For second and subsequent courses of PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
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.
Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.
(b) Continuing treatment.
Following the completion of an initial treatment course with adalimumab, infliximab, vedolizumab or ustekinumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.
Assessments of response to a course of PBS-subsidised therapy must be 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 drug.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMD therapy is approved, a patient may swap if eligible to the alternate adalimumab, infliximab, vedolizumab or ustekinumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.
A patient may trial the alternate bDMD therapy at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab, vedolizumab or ustekinumab at the time of the application. However, they cannot swap to a particular bDMD therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to adalimumab, infliximab, vedolizumab or ustekinumab (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the therapy 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 CDAI or evidence of intestinal inflammation submitted with the first authority application for adalimumab, infliximab, vedolizumab or ustekinumab. 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 provided for all subsequent continuing treatment applications.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised bDMD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with vedolizumab.
A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.
(6) Patients 'grandfathered' onto PBS-subsidised treatment with ustekinumab.
A patient who commenced treatment with ustekinumab for severe Crohn disease prior to 1 September 2017 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment (new patient - initial 1)

Treatment criteria:

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

Clinical criteria:

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more months, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.

Population criteria:

- Patient must be aged 18 years or older.

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

(a) two completed authority prescription forms; and

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

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

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

(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iv) the date of the most recent clinical assessment; and

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

Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:(a) patient must have evidence of intestinal inflammation;(b) patient must be assessed clinically as being in a high faecal output state; (c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.Evidence of intestinal inflammation includes: (i) blood: higher than normal platelet count, or, 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; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

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.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

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

This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this 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 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 continuation criterion for PBS-subsidised treatment with this drug.

Note Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

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

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Change or Re-commencement of treatment (initial 2)

Treatment criteria:

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

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological disease modifying drug for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle.

Population criteria:

- Patient must be aged 18 years or older.

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

(a) two completed authority prescription forms; and

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

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment; and

(iv) the details of prior biological disease modifying drug treatment including the details of date and duration of treatment.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological disease modifying drug (bDMD) therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised bDMD 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 vedolizumab 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 bDMD treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of bDMD.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

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

This assessment, 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 timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

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

Note Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

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

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Continuing treatment

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 or sustained an adequate response to treatment with this drug, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.

Population criteria:

- Patient must be aged 18 years or older.

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)].

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 which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

If the application is the first application for continuing treatment with this drug, an assessment of the patient's response to the initial course of treatment must be made up to 12 weeks after the first dose 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.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats; up to 1 repeat will be authorised for patients whose dosing frequency is every 12 weeks. Up to a maximum of 2 repeats will be authorised for patients whose dosing frequency is every 8 weeks.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

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

Note Increase in the maximum number of repeats of up to 2 may be authorised in patients whose dosing frequency is every 8 weeks.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Initial PBS-subsidised treatment (Grandfather)

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously received non-PBS-subsidised therapy with this drug for this condition prior to 1 September 2017, **AND**
- Patient must be receiving treatment with ustekinumab at the time of application, **AND**
- Patient must have had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with this drug; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.

Population criteria:

- Patient must be aged 18 years or older.

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)].

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

(a) a completed authority prescription form; and

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

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

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

(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iv) the date of the most recent clinical assessment; and

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

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.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats; up to 1 repeat will be authorised for patients whose dosing frequency is every 12 weeks. Up to a maximum of 2 repeats will be authorised for patients whose dosing frequency is every 8 weeks

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

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

Note No applications for increased maximum quantities will be authorised.

Note Increase in the maximum number of repeats of up to two may be authorised in patients whose dosing frequency is every 8 weeks.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Balance of supply for Initial treatment, Continuing treatment or Grandfathered treatment

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 16 weeks of treatment; OR
- 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 therapy with this drug under the Grandfathered treatment restriction to complete 24 weeks of treatment.

Population criteria:

- Patient must be aged 18 years or older.

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)].

Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services

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

Note Applications for authority to prescribe may be made by phone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial

11178H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*8614.15	39.50	Stelara [JC]

▪ VARENICLINE

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

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

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

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

Authority required (STREAMLINED)

7483

Nicotine dependence

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

Clinical criteria:

- The treatment must be as an aid to achieving abstinence from smoking, **AND**

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

Treatment criteria:

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

varenicline 1 mg tablet, 56

9129L

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*208.61	39.50	Champix [PF]

Highly Specialised Drugs Program (Private Hospital)

▪ DEFERASIROX

Note Special Pricing Arrangements apply.

Authority required

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be transfusion dependent, **AND**
- Patient must not have a malignant disorder of erythropoiesis.

Authority required

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not be transfusion dependent, **AND**
- The condition must be thalassaemia.

deferasirox 500 mg dispersible tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
9600G	6	5	..	*5372.71	Exjade [NV]

deferasirox 250 mg dispersible tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
6500D	6	5	..	*2709.91	Exjade [NV]

deferasirox 125 mg dispersible tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
6499C	6	5	..	*1378.57	Exjade [NV]

▪ DEFERASIROX

Note A patient's median life expectancy is determined by the severity of their underlying disease.

Note Patients with underlying myelodysplastic syndrome are considered to have a median life expectancy exceeding five years if they are classified as:
- low risk according to the International Prognostic Scoring System (IPSS); or
- very low and low risk according to the Revised International Prognostic Scoring System (IPSS-R); or
- very low and low risk according to the WHO classification based Prognostic Scoring System (WPSS).

Note Patients with underlying myelofibrosis have a median life expectancy exceeding five years if they are classified as:
- low or intermediate risk according to the International Prognostic Scoring System (IPSS); or
- low or intermediate-1 risk according to Dynamic International Prognostic Scoring System (DIPSS).

Note Special Pricing Arrangements apply.

Authority required

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be red blood cell transfusion dependent, **AND**
- Patient must have a serum ferritin level of greater than 1000 microgram/L, **AND**
- Patient must have a malignant disorder of haemopoiesis, **AND**
- Patient must have a median life expectancy exceeding five years.

deferasirox 500 mg dispersible tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
11232E	6	2	..	*5372.71	Exjade [NV]

deferasirox 250 mg dispersible tablet, 28

11244T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	6	2	..	*2709.91	Exjade [NV]

deferasirox 125 mg dispersible tablet, 28

11241P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	6	2	..	*1378.57	Exjade [NV]

▪ DEFERASIROX

Note Special Pricing Arrangements apply.

Authority required

Chronic iron overload

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must be transfusion dependent, **AND**
- Patient must not have a malignant disorder of erythropoiesis, **AND**
- Patient must have previously received PBS-subsidised therapy with this drug for this condition.

Authority required

Chronic iron overload

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must not be transfusion dependent, **AND**
- The condition must be thalassaemia, **AND**
- Patient must have previously received PBS-subsidised therapy with this drug for this condition.

Authority required

Chronic iron overload

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must be red blood cell transfusion dependent, **AND**
- Patient must have a malignant disorder of haemopoieisis, **AND**
- Patient must have previously received PBS-subsidised therapy with this drug for this condition.

Note Interruption of treatment should be considered if serum ferritin levels fall consistently below 500 microgram/ml.

deferasirox 500 mg dispersible tablet, 28

11243R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	6	2	..	*5372.71	Exjade [NV]

deferasirox 250 mg dispersible tablet, 28

11238L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	6	2	..	*2709.91	Exjade [NV]

deferasirox 125 mg dispersible tablet, 28

11236J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	6	2	..	*1378.57	Exjade [NV]

▪ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying drugs (bDMDs) for adult patients with severe Crohn disease. Where the term bDMDs appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).

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

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab, vedolizumab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab,or vedolizumab treatment prior to 1 September 2017 is considered to be in their first cycle as of 1 September 2017.

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

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

treatment with adalimumab, infliximab, vedolizumab or ustekinumab under the new treatment cycle.
A patient who has failed fewer than 3 trials of bDMD 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 fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised therapy with adalimumab, infliximab, vedolizumab or ustekinumab in this treatment cycle and wishes to commence such therapy (Initial 1 - new patients); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab, vedolizumab or ustekinumab and wishes to trial an alternate agent (Initial 2 - Change or recommencement) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with adalimumab, infliximab, vedolizumab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - Change or Re-commencement).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab, 14 weeks of therapy for vedolizumab and 16 weeks for ustekinumab.
From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, 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 bDMD therapy.
For second and subsequent courses of PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
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.
Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.
(b) Continuing treatment.
Following the completion of an initial treatment course with adalimumab, infliximab, vedolizumab or ustekinumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.
Assessments of response to a course of PBS-subsidised therapy must be 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 drug.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMD therapy is approved, a patient may swap if eligible to the alternate adalimumab, infliximab, vedolizumab or ustekinumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.
A patient may trial the alternate bDMD therapy at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab, vedolizumab or ustekinumab at the time of the application. However, they cannot swap to a particular bDMD therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to adalimumab, infliximab, vedolizumab or ustekinumab (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the therapy 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 CDAI or evidence of intestinal inflammation submitted with the first authority application for adalimumab, infliximab, vedolizumab or ustekinumab. 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 provided for all subsequent continuing treatment applications.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised bDMD

therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with vedolizumab.
A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.
(6) Patients 'grandfathered' onto PBS-subsidised treatment with ustekinumab.
A patient who commenced treatment with ustekinumab for severe Crohn disease prior to 1 September 2017 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

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
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 patient - initial 1)

Treatment criteria:

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

Clinical criteria:

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more months.

Population criteria:

- Patient must be aged 18 years or older.

Clinical criteria:

- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.

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 which includes the following:

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

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

(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iv) the date of the most recent clinical assessment; and

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

Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:(a) patient must have evidence of intestinal inflammation;(b) patient must be assessed clinically as being in a high faecal output state; (c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.Evidence of intestinal inflammation includes: (i) blood: higher than normal platelet count, or, 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; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

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.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

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.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The 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 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 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 continuation criterion for PBS-subsidised treatment with this drug.

Authority required

Severe Crohn disease

Treatment Phase: Change or Re-commencement of treatment (initial 2)

Treatment criteria:

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

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological disease modifying drug for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle.

Population criteria:

- Patient must be aged 18 years or older.

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, which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment; and

(iv) the details of prior biological disease modifying drug treatment including the 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 disease modifying drug (bDMD) therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised bDMD 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 vedolizumab 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 bDMD treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of bDMD.

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.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction.

Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The 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 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 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 continuation criterion for PBS-subsidised treatment with this drug.

Authority required

Severe Crohn disease

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 3 doses (new patients) or 2 repeats (Continuing treatment).

Treatment criteria:

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

Population criteria:

- Patient must be aged 18 years or older.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services.

Authority required

Severe Crohn disease

Treatment Phase: Continuing treatment

Treatment criteria:

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

Clinical criteria:

- Patient must have 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 or sustained an adequate response to treatment with this drug.

Population criteria:

- Patient must be aged 18 years or older.

Clinical criteria:

- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.

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 which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

If the application is the first application for continuing treatment with this drug, an assessment of the patient's response to the initial course of treatment must be made up to 12 weeks after the first dose 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.

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 sufficient for a single infusion at a dose of 5 mg per kg.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

Up to a maximum of 2 repeats will be authorised.

infliximab 100 mg injection, 1 vial

9613Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	534.87	[a] Inflectra [PF] [a] Renflexis [MK]	[a] Remicade [JC]

▪ MEPOLIZUMAB

Note The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note For copies of the ACQ, please contact GlaxoSmithKline Medical Information on 1800 033 109.

Note It is recommended that an application for continuing treatment is submitted at the time of the 26 to 30 week assessment, to ensure continuity of treatment for those patients who meet the continuation criteria for PBS-subsidised mepolizumab treatment.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE EOSINOPHILIC ASTHMA
Patients are eligible to commence a 'mepolizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.
Once a patient has either failed to achieve or maintain a response to mepolizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised mepolizumab therapy before they are eligible to commence the next mepolizumab treatment cycle, or if eligible, an 'omalizumab treatment cycle'. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised mepolizumab is stopped to the date of the first application for initial treatment with mepolizumab under the 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 mepolizumab therapy:
(a) Initial treatment:
Applications for initial treatment should be made where:
i) A patient has received no prior PBS-subsidised mepolizumab treatment and wishes to commence such therapy; or
ii) A patient wishes to recommence treatment with mepolizumab following a break in PBS-subsidised therapy of more than 6 months; or
iii) A patient has received prior PBS-subsidised omalizumab and wishes to commence treatment with mepolizumab after a treatment break of 6 months.
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 32 weeks of therapy for mepolizumab.
(b) Grandfather patients:
For patients who commenced treatment with mepolizumab for uncontrolled severe eosinophilic asthma prior to 1 January 2017 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment with mepolizumab will be authorised under this criterion. Approval will be based on the criteria included in the relevant restriction. Following completion of the Initial PBS-subsidised course, further applications for treatment with mepolizumab will be assessed under the continuing treatment restriction.
'Grandfather' arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). If a 'Grandfathered' patient recommences on second and subsequent cycles after a treatment break, the 'Grandfathered' patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 6 month break in PBS-subsidised therapy' below for further details.
(c) Continuing treatment:

Following the completion of the initial treatment course with mepolizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with mepolizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing mepolizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) 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 Asthma Control Questionnaire (ACQ; 5 item version) and oral corticosteroid dose, submitted with the Initial authority application for mepolizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent mepolizumab treatment cycle, or an initial omalizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

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

Uncontrolled severe eosinophilic asthma

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must be under the care of the same physician for at least 12 months, **AND**
- Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have forced expiratory volume (FEV1) less than or equal to 80% predicted, documented on 1 or more occasions in the previous 12 months, **AND**
- Patient must have blood eosinophil count greater than or equal to 300 cells per microlitre in the last 12 months, **AND**
- Patient must have signed a patient or parent/guardian acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
- The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised omalizumab.

Population criteria:

- Patient must be aged 12 years or older.

Optimised asthma therapy includes:

(i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; AND

(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

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

(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND

(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) assessment of the patient must be made at time of application for treatment (to establish baseline score) and again around 26 to 30 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment at around 26 to 30 weeks, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current

treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with mepolizumab.

A patient who fails to respond to a course of PBS-subsidised mepolizumab for the treatment of uncontrolled severe eosinophilic asthma will not be eligible to receive further PBS-subsidised treatment with mepolizumab or omalizumab within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request 7 repeats to provide for an initial course of mepolizumab sufficient for 32 weeks of therapy.

Mepolizumab and omalizumab may not be used concurrently or within 6 months of each other. A patient is required to have ceased treatment with omalizumab for 6 months prior to initiating treatment with mepolizumab.

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

(a) a completed authority prescription form; and

(b) a completed Severe Eosinophilic Asthma Initial PBS Authority Application - Supporting Information Form,

which includes the following:

(i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and

(ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and

(iii) the signed patient or parent/guardian acknowledgement; and

(c) a copy of the eosinophil pathology report; and

(d) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms.

mepolizumab 100 mg injection, 1 vial

11003D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	7	..	1685.15	Nucala [GK]

▪ USTEKINUMAB

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

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

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying drugs (bDMDs) for adult patients with severe Crohn disease. Where the term bDMDs appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).
Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological disease modifying drugs at any one time.
From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab, vedolizumab or ustekinumab while they continue to show a response to therapy.
A patient who received PBS-subsidised adalimumab, infliximab,or vedolizumab treatment prior to 1 September 2017 is considered to be in their first cycle as of 1 September 2017.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab more than once.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab, vedolizumab or ustekinumab under the new treatment cycle.
A patient who has failed fewer than 3 trials of bDMD 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 fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised therapy with adalimumab, infliximab, vedolizumab or ustekinumab in this treatment cycle and wishes to commence such therapy (Initial 1 - new patients); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab, vedolizumab or ustekinumab

and wishes to trial an alternate agent (Initial 2 - Change or recommencement) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with adalimumab, infliximab, vedolizumab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - Change or Re-commencement).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab, 14 weeks of therapy for vedolizumab and 16 weeks for ustekinumab.
From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, 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 bDMD therapy.
For second and subsequent courses of PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
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.
Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.
(b) Continuing treatment.
Following the completion of an initial treatment course with adalimumab, infliximab, vedolizumab or ustekinumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.
Assessments of response to a course of PBS-subsidised therapy must be 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 drug.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMD therapy is approved, a patient may swap if eligible to the alternate adalimumab, infliximab, vedolizumab or ustekinumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.
A patient may trial the alternate bDMD therapy at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab, vedolizumab or ustekinumab at the time of the application. However, they cannot swap to a particular bDMD therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to adalimumab, infliximab, vedolizumab or ustekinumab (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the therapy 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 CDAI or evidence of intestinal inflammation submitted with the first authority application for adalimumab, infliximab, vedolizumab or ustekinumab. 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 provided for all subsequent continuing treatment applications.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised bDMD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with vedolizumab.
A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-

commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.
(6) Patients 'grandfathered' onto PBS-subsidised treatment with ustekinumab.
A patient who commenced treatment with ustekinumab for severe Crohn disease prior to 1 September 2017 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment (new patient - initial 1)

Treatment criteria:

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

Clinical criteria:

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more months, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.

Population criteria:

- Patient must be aged 18 years or older.

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

(a) two completed authority prescription forms; and

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

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

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

(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iv) the date of the most recent clinical assessment; and

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

Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:(a) patient must have evidence of intestinal inflammation;(b) patient must be assessed clinically as being in a high faecal output state; (c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.Evidence of intestinal inflammation includes: (i) blood: higher than normal platelet count, or, 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; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

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.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

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

This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this 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 Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

Authority required

Severe Crohn disease

Treatment Phase: Change or Re-commencement of treatment (initial 2)

Treatment criteria:

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

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological disease modifying drug for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle.

Population criteria:

- Patient must be aged 18 years or older.

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

(a) two completed authority prescription forms; and

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

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment; and

(iv) the details of prior biological disease modifying drug treatment including the details of date and duration of treatment.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological disease modifying drug (bDMD) therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised bDMD 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 vedolizumab 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 bDMD treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of bDMD.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

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

This assessment, 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 timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Note Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

ustekinumab 130 mg/26 mL injection, 26 mL vial

11164N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
4	..	..	*16976.39	Stelara [JC]

▪ VEDOLIZUMAB

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
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Special Pricing Arrangements apply.

Note **TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE**
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying drugs (bDMDs) for adult patients with severe Crohn disease. Where the term bDMDs appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).
Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological disease modifying drugs at any one time.
From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab, vedolizumab or ustekinumab while they continue to show a response to therapy.
A patient who received PBS-subsidised adalimumab, infliximab,or vedolizumab treatment prior to 1 September 2017 is considered to be in their first cycle as of 1 September 2017.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab more than once.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab, vedolizumab or ustekinumab under the new treatment cycle.
A patient who has failed fewer than 3 trials of bDMD 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 fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised therapy with adalimumab, infliximab, vedolizumab or ustekinumab in this treatment cycle and wishes to commence such therapy (Initial 1 - new patients); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab, vedolizumab or ustekinumab and wishes to trial an alternate agent (Initial 2 - Change or recommencement) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with adalimumab, infliximab, vedolizumab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - Change or Re-commencement).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab, 14 weeks of therapy for vedolizumab and 16 weeks for ustekinumab.
From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, 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 bDMD therapy.
For second and subsequent courses of PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
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.
Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.
(b) Continuing treatment.
Following the completion of an initial treatment course with adalimumab, infliximab, vedolizumab or ustekinumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure

uninterrupted supply of treatment.
Assessments of response to a course of PBS-subsidised therapy must be 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 drug.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMD therapy is approved, a patient may swap if eligible to the alternate adalimumab, infliximab, vedolizumab or ustekinumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.
A patient may trial the alternate bDMD therapy at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab, vedolizumab or ustekinumab at the time of the application. However, they cannot swap to a particular bDMD therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to adalimumab, infliximab, vedolizumab or ustekinumab (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the therapy 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 CDAI or evidence of intestinal inflammation submitted with the first authority application for adalimumab, infliximab, vedolizumab or ustekinumab. 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 provided for all subsequent continuing treatment applications.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised bDMD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with vedolizumab.
A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.
(6) Patients 'grandfathered' onto PBS-subsidised treatment with ustekinumab.
A patient who commenced treatment with ustekinumab for severe Crohn disease prior to 1 September 2017 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment (new patient - initial 1)

Treatment criteria:

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

Clinical criteria:

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; OR

- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more months, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Population criteria:

- Patient must be aged 18 years or older.

Clinical criteria:

- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.

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 which includes the following:

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

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

(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iv) the date of the most recent clinical assessment; and

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

Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:(a) patient must have evidence of intestinal inflammation;(b) patient must be assessed clinically as being in a high faecal output state; (c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.Evidence of intestinal inflammation includes: (i) blood: higher than normal platelet count, or, 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; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 1 month following cessation of the most recent prior 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, 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.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The 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.

Note 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 timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

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

Authority required

Severe Crohn disease

Treatment Phase: Change or Re-commencement of treatment (initial 2)

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological disease modifying drug for this condition in this treatment cycle, **AND**

- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Population criteria:

- Patient must be aged 18 years or older.

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)].

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, which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment; and

(iv) the details of prior biological disease modifying drug treatment including the 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 disease modifying drug (bDMD) therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised bDMD 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 vedolizumab 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 bDMD treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of bDMD.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The 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 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 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 continuation criterion for PBS-subsidised treatment with this drug.

Authority required

Severe Crohn disease

Treatment Phase: Initial PBS-subsidised treatment (Grandfather)

Treatment criteria:

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

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously received non-PBS-subsidised therapy with this drug for this condition prior to 1 August 2015.

Population criteria:

- Patient must be aged 18 years or older.

Clinical criteria:

- Patient must have had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with this drug; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the

need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**

- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

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 which includes the following:

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

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

(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iv) the date of the most recent clinical assessment; and

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

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.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide sufficient for a single infusion of 300 mg vedolizumab per dose. Up to a maximum of 2 repeats will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

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

Authority required

Severe Crohn disease

Treatment Phase: Balance of supply

Treatment criteria:

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

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR
- 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 therapy with this drug to complete 24 weeks of treatment under the Initial PBS-subsidised treatment restriction for patients who had previously received non-PBS subsidised treatment (Grandfathered patient), **AND**
- The treatment must provide no more than the balance of up to 3 doses (new patients) or 2 repeats (Continuing or Grandfathered patients), **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Population criteria:

- Patient must be aged 18 years or older.

Note Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats 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 Crohn disease

Treatment Phase: Continuing treatment

Treatment criteria:

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

Clinical criteria:

- Patient must have 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 or sustained an adequate response to treatment with this drug.

Population criteria:

- Patient must be aged 18 years or older.

Clinical criteria:

- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.

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 which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment.

All assessments, pathology tests and diagnostic imaging studies, must be made within 1 month of the date of application.

If the application is the first application for continuing treatment with this drug, an assessment of the patient's response to the initial course of treatment must be made up to 12 weeks after the first dose 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.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide sufficient for a single infusion of 300 mg vedolizumab per dose. Up to a maximum of 2 repeats will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

vedolizumab 300 mg injection, 1 vial

10415E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	3152.34	Entyvio [TK]

Highly Specialised Drugs Program (Public Hospital)

▪ DEFERASIROX

Note Special Pricing Arrangements apply.

Authority required

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be transfusion dependent, **AND**
- Patient must not have a malignant disorder of erythropoiesis.

Authority required

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not be transfusion dependent, **AND**
- The condition must be thalassaemia.

deferasirox 500 mg dispersible tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
11234G	6	5	..	*5325.54	Exjade [NV]

deferasirox 250 mg dispersible tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
11240N	6	5	..	*2662.74	Exjade [NV]

deferasirox 125 mg dispersible tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
11247Y	6	5	..	*1331.40	Exjade [NV]

▪ DEFERASIROX

Note A patient's median life expectancy is determined by the severity of their underlying disease.

Note Patients with underlying myelodysplastic syndrome are considered to have a median life expectancy exceeding five years if they are classified as:
- low risk according to the International Prognostic Scoring System (IPSS); or
- very low and low risk according to the Revised International Prognostic Scoring System (IPSS-R); or
- very low and low risk according to the WHO classification based Prognostic Scoring System (WPSS).

Note Patients with underlying myelofibrosis have a median life expectancy exceeding five years if they are classified as:
- low or intermediate risk according to the International Prognostic Scoring System (IPSS); or
- low or intermediate-1 risk according to Dynamic International Prognostic Scoring System (DIPSS).

Note Special Pricing Arrangements apply.

Authority required

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be red blood cell transfusion dependent, **AND**
- Patient must have a serum ferritin level of greater than 1000 microgram/L, **AND**
- Patient must have a malignant disorder of haemopoiesis, **AND**
- Patient must have a median life expectancy exceeding five years.

deferasirox 500 mg dispersible tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
11231D	6	2	..	*5325.54	Exjade [NV]

deferasirox 250 mg dispersible tablet, 28

11239M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	6	2	..	*2662.74	Exjade [NV]

deferasirox 125 mg dispersible tablet, 28

11235H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	6	2	..	*1331.40	Exjade [NV]

▪ DEFERASIROX

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

7384

Chronic iron overload

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must be transfusion dependent, **AND**
- Patient must not have a malignant disorder of erythropoiesis, **AND**
- Patient must have previously received PBS-subsidised therapy with this drug for this condition.

Authority required (STREAMLINED)

7372

Chronic iron overload

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must not be transfusion dependent, **AND**
- The condition must be thalassaemia, **AND**
- Patient must have previously received PBS-subsidised therapy with this drug for this condition.

Authority required (STREAMLINED)

7395

Chronic iron overload

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must be red blood cell transfusion dependent, **AND**
- Patient must have a malignant disorder of haemopoieisis, **AND**
- Patient must have previously received PBS-subsidised therapy with this drug for this condition.

Note Interruption of treatment should be considered if serum ferritin levels fall consistently below 500 microgram/ml.

deferasirox 500 mg dispersible tablet, 28

5656Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	6	2	..	*5325.54	Exjade [NV]

deferasirox 250 mg dispersible tablet, 28

5655P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	6	2	..	*2662.74	Exjade [NV]

deferasirox 125 mg dispersible tablet, 28

5654N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	6	2	..	*1331.40	Exjade [NV]

▪ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying drugs (bDMDs) for adult patients with severe Crohn disease. Where the term bDMDs appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).

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

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab, vedolizumab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab,or vedolizumab treatment prior to 1 September 2017 is considered to be in their first cycle as of 1 September 2017.

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

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment

cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab, vedolizumab or ustekinumab under the new treatment cycle.
A patient who has failed fewer than 3 trials of bDMD 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 fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised therapy with adalimumab, infliximab, vedolizumab or ustekinumab in this treatment cycle and wishes to commence such therapy (Initial 1 - new patients); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab, vedolizumab or ustekinumab and wishes to trial an alternate agent (Initial 2 - Change or recommencement) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with adalimumab, infliximab, vedolizumab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - Change or Re-commencement).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab, 14 weeks of therapy for vedolizumab and 16 weeks for ustekinumab.
From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, 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 bDMD therapy.
For second and subsequent courses of PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
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.
Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.
(b) Continuing treatment.
Following the completion of an initial treatment course with adalimumab, infliximab, vedolizumab or ustekinumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.
Assessments of response to a course of PBS-subsidised therapy must be 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 drug.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMD therapy is approved, a patient may swap if eligible to the alternate adalimumab, infliximab, vedolizumab or ustekinumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.
A patient may trial the alternate bDMD therapy at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab, vedolizumab or ustekinumab at the time of the application. However, they cannot swap to a particular bDMD therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to adalimumab, infliximab, vedolizumab or ustekinumab (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the therapy 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 CDAI or evidence of intestinal inflammation submitted with the first authority application for adalimumab, infliximab, vedolizumab or ustekinumab. 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 provided for all subsequent continuing treatment

applications.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised bDMD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with vedolizumab.
A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.
(6) Patients 'grandfathered' onto PBS-subsidised treatment with ustekinumab.
A patient who commenced treatment with ustekinumab for severe Crohn disease prior to 1 September 2017 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

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
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 patient - initial 1)

Treatment criteria:

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

Clinical criteria:

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more months.

Population criteria:

- Patient must be aged 18 years or older.

Clinical criteria:

- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.

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 which includes the following:

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

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

(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iv) the date of the most recent clinical assessment; and

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

Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:(a) patient must have evidence of intestinal inflammation;(b) patient must be assessed clinically as being in a high faecal output state; (c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.Evidence of intestinal inflammation includes: (i) blood: higher than normal platelet count, or, 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; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

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.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

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.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The 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 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 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 continuation criterion for PBS-subsidised treatment with this drug.

Authority required

Severe Crohn disease

Treatment Phase: Change or Re-commencement of treatment (initial 2)

Treatment criteria:

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

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological disease modifying drug for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle.

Population criteria:

- Patient must be aged 18 years or older.

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, which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment; and

(iv) the details of prior biological disease modifying drug treatment including the 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 disease modifying drug (bDMD) therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised bDMD 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 vedolizumab 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 bDMD treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of bDMD.

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.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction.

Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The 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 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 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 continuation criterion for PBS-subsidised treatment with this drug.

Authority required

Severe Crohn disease

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 3 doses (new patients) or 2 repeats (Continuing treatment).

Treatment criteria:

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

Population criteria:

- Patient must be aged 18 years or older.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services.

Authority required

Severe Crohn disease

Treatment Phase: Continuing treatment

Treatment criteria:

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

Clinical criteria:

- Patient must have 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 or sustained an adequate response to treatment with this drug.

Population criteria:

- Patient must be aged 18 years or older.

Clinical criteria:

- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.

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 which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

If the application is the first application for continuing treatment with this drug, an assessment of the patient's response to the initial course of treatment must be made up to 12 weeks after the first dose 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.

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 sufficient for a single infusion at a dose of 5 mg per kg.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

Up to a maximum of 2 repeats will be authorised.

infliximab 100 mg injection, 1 vial

5754W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	507.42	[a] Inflectra [PF] [a] Renflexis [MK]	[a] Remicade [JC]

▪ MEPOLIZUMAB

Note The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note For copies of the ACQ, please contact GlaxoSmithKline Medical Information on 1800 033 109.

Note It is recommended that an application for continuing treatment is submitted at the time of the 26 to 30 week assessment, to ensure continuity of treatment for those patients who meet the continuation criteria for PBS-subsidised mepolizumab treatment.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE EOSINOPHILIC ASTHMA
Patients are eligible to commence a 'mepolizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.
Once a patient has either failed to achieve or maintain a response to mepolizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised mepolizumab therapy before they are eligible to commence the next mepolizumab treatment cycle, or if eligible, an 'omalizumab treatment cycle'. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised mepolizumab is stopped to the date of the first application for initial treatment with mepolizumab under the 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 mepolizumab therapy:
(a) Initial treatment:
Applications for initial treatment should be made where:
i) A patient has received no prior PBS-subsidised mepolizumab treatment and wishes to commence such therapy; or
ii) A patient wishes to recommence treatment with mepolizumab following a break in PBS-subsidised therapy of more than 6 months; or
iii) A patient has received prior PBS-subsidised omalizumab and wishes to commence treatment with mepolizumab after a treatment break of 6 months.
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 32 weeks of therapy for mepolizumab.
(b) Grandfather patients:
For patients who commenced treatment with mepolizumab for uncontrolled severe eosinophilic asthma prior to 1 January 2017 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment with mepolizumab will be authorised under this criterion. Approval will be based on the criteria included in the relevant restriction. Following completion of the Initial PBS-subsidised course, further applications for treatment with mepolizumab will be assessed under the continuing treatment restriction.
'Grandfather' arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). If a 'Grandfathered' patient recommences on second and subsequent cycles after a treatment break, the 'Grandfathered' patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See 'Re-

commencement of treatment after a 6 month break in PBS-subsidised therapy' below for further details.
(c) Continuing treatment:
Following the completion of the initial treatment course with mepolizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with mepolizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing mepolizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.
(2) 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 Asthma Control Questionnaire (ACQ; 5 item version) and oral corticosteroid dose, submitted with the Initial authority application for mepolizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:
A patient who wishes to trial a second or subsequent mepolizumab treatment cycle, or an initial omalizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

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

Uncontrolled severe eosinophilic asthma

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must be under the care of the same physician for at least 12 months, **AND**
- Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have forced expiratory volume (FEV1) less than or equal to 80% predicted, documented on 1 or more occasions in the previous 12 months, **AND**
- Patient must have blood eosinophil count greater than or equal to 300 cells per microlitre in the last 12 months, **AND**
- Patient must have signed a patient or parent/guardian acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
- The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised omalizumab.

Population criteria:

- Patient must be aged 12 years or older.

Optimised asthma therapy includes:

(i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; AND

(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

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

(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND

(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) assessment of the patient must be made at time of application for treatment (to establish baseline score) and again around 26 to 30 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment at around 26 to 30 weeks, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with mepolizumab.

A patient who fails to respond to a course of PBS-subsidised mepolizumab for the treatment of uncontrolled severe eosinophilic asthma will not be eligible to receive further PBS-subsidised treatment with mepolizumab or omalizumab within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request 7 repeats to provide for an initial course of mepolizumab sufficient for 32 weeks of therapy.

Mepolizumab and omalizumab may not be used concurrently or within 6 months of each other. A patient is required to have ceased treatment with omalizumab for 6 months prior to initiating treatment with mepolizumab.

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

(a) a completed authority prescription form; and

(b) a completed Severe Eosinophilic Asthma Initial PBS Authority Application - Supporting Information Form,

which includes the following:

(i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and

(ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and

(iii) the signed patient or parent/guardian acknowledgement; and

(c) a copy of the eosinophil pathology report; and

(d) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms.

mepolizumab 100 mg injection, 1 vial

10996R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	7	..	1638.00	Nucala [GK]

▪ USTEKINUMAB

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

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

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying drugs (bDMDs) for adult patients with severe Crohn disease. Where the term bDMDs appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).
Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological disease modifying drugs at any one time.
From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab, vedolizumab or ustekinumab while they continue to show a response to therapy.
A patient who received PBS-subsidised adalimumab, infliximab,or vedolizumab treatment prior to 1 September 2017 is considered to be in their first cycle as of 1 September 2017.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab more than once.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab, vedolizumab or ustekinumab under the new treatment cycle.
A patient who has failed fewer than 3 trials of bDMD 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 fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised therapy with adalimumab, infliximab, vedolizumab or ustekinumab in this

treatment cycle and wishes to commence such therapy (Initial 1 - new patients); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab, vedolizumab or ustekinumab and wishes to trial an alternate agent (Initial 2 - Change or recommencement) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with adalimumab, infliximab, vedolizumab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - Change or Re-commencement).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab, 14 weeks of therapy for vedolizumab and 16 weeks for ustekinumab.
From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, 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 bDMD therapy.
For second and subsequent courses of PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
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.
Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.
(b) Continuing treatment.
Following the completion of an initial treatment course with adalimumab, infliximab, vedolizumab or ustekinumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.
Assessments of response to a course of PBS-subsidised therapy must be 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 drug.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMD therapy is approved, a patient may swap if eligible to the alternate adalimumab, infliximab, vedolizumab or ustekinumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.
A patient may trial the alternate bDMD therapy at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab, vedolizumab or ustekinumab at the time of the application. However, they cannot swap to a particular bDMD therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to adalimumab, infliximab, vedolizumab or ustekinumab (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the therapy 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 CDAI or evidence of intestinal inflammation submitted with the first authority application for adalimumab, infliximab, vedolizumab or ustekinumab. 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 provided for all subsequent continuing treatment applications.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised bDMD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with vedolizumab.
A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.
(6) Patients 'grandfathered' onto PBS-subsidised treatment with ustekinumab.
A patient who commenced treatment with ustekinumab for severe Crohn disease prior to 1 September 2017 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment (new patient - initial 1)

Treatment criteria:

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

Clinical criteria:

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more months, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.

Population criteria:

- Patient must be aged 18 years or older.

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

(a) two completed authority prescription forms; and

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

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

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

(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iv) the date of the most recent clinical assessment; and

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

Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:(a) patient must have evidence of intestinal inflammation;(b) patient must be assessed clinically as being in a high faecal output state; (c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.Evidence of intestinal inflammation includes: (i) blood: higher than normal platelet count, or, 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; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

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.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

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

This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this 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 Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

Authority required

Severe Crohn disease

Treatment Phase: Change or Re-commencement of treatment (initial 2)

Treatment criteria:

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

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological disease modifying drug for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle.

Population criteria:

- Patient must be aged 18 years or older.

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

(a) two completed authority prescription forms; and

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

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment; and

(iv) the details of prior biological disease modifying drug treatment including the details of date and duration of treatment.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological disease modifying drug (bDMD) therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised bDMD 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 vedolizumab 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 bDMD treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of bDMD.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

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

This assessment, 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 timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Note Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

ustekinumab 130 mg/26 mL injection, 26 mL vial

11182M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
4	..	..	*16929.24	Stelara [JC]

▪ VEDOLIZUMAB

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
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Special Pricing Arrangements apply.

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying drugs (bDMDs) for adult patients with severe Crohn disease. Where the term bDMDs appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).
Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological disease modifying drugs at any one time.
From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab, vedolizumab or ustekinumab while they continue to show a response to therapy.
A patient who received PBS-subsidised adalimumab, infliximab,or vedolizumab treatment prior to 1 September 2017 is considered to be in their first cycle as of 1 September 2017.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab more than once.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab, vedolizumab or ustekinumab under the new treatment cycle.
A patient who has failed fewer than 3 trials of bDMD 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 fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised therapy with adalimumab, infliximab, vedolizumab or ustekinumab in this treatment cycle and wishes to commence such therapy (Initial 1 - new patients); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab, vedolizumab or ustekinumab and wishes to trial an alternate agent (Initial 2 - Change or recommencement) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with adalimumab, infliximab, vedolizumab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - Change or Re-commencement).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab, 14 weeks of therapy for vedolizumab and 16 weeks for ustekinumab.
From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, 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 bDMD therapy.
For second and subsequent courses of PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
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.
Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.
(b) Continuing treatment.
Following the completion of an initial treatment course with adalimumab, infliximab, vedolizumab or ustekinumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate

response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.
Assessments of response to a course of PBS-subsidised therapy must be 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 drug.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMD therapy is approved, a patient may swap if eligible to the alternate adalimumab, infliximab, vedolizumab or ustekinumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.
A patient may trial the alternate bDMD therapy at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab, vedolizumab or ustekinumab at the time of the application. However, they cannot swap to a particular bDMD therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to adalimumab, infliximab, vedolizumab or ustekinumab (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the therapy 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 CDAI or evidence of intestinal inflammation submitted with the first authority application for adalimumab, infliximab, vedolizumab or ustekinumab. 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 provided for all subsequent continuing treatment applications.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised bDMD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with vedolizumab.
A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.
(6) Patients 'grandfathered' onto PBS-subsidised treatment with ustekinumab.
A patient who commenced treatment with ustekinumab for severe Crohn disease prior to 1 September 2017 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment (new patient - initial 1)

Treatment criteria:

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

Clinical criteria:

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; OR

- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more months, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Population criteria:

- Patient must be aged 18 years or older.

Clinical criteria:

- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.

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 which includes the following:

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

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

(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iv) the date of the most recent clinical assessment; and

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

Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:(a) patient must have evidence of intestinal inflammation;(b) patient must be assessed clinically as being in a high faecal output state; (c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.Evidence of intestinal inflammation includes: (i) blood: higher than normal platelet count, or, 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; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 1 month following cessation of the most recent prior 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, 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.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The 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.

Note 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 timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

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

Authority required

Severe Crohn disease

Treatment Phase: Change or Re-commencement of treatment (initial 2)

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**

- Patient must have received prior PBS-subsidised treatment with a biological disease modifying drug for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Population criteria:

- Patient must be aged 18 years or older.

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)].

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, which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment; and

(iv) the details of prior biological disease modifying drug treatment including the 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 disease modifying drug (bDMD) therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised bDMD 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 vedolizumab 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 bDMD treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of bDMD.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The 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 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 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 continuation criterion for PBS-subsidised treatment with this drug.

Authority required

Severe Crohn disease

Treatment Phase: Initial PBS-subsidised treatment (Grandfather)

Treatment criteria:

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

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously received non-PBS-subsidised therapy with this drug for this condition prior to 1 August 2015.

Population criteria:

- Patient must be aged 18 years or older.

Clinical criteria:

- Patient must have had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with this drug; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces:

normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**

- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

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 which includes the following:

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

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

(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iv) the date of the most recent clinical assessment; and

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

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.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide sufficient for a single infusion of 300 mg vedolizumab per dose. Up to a maximum of 2 repeats will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

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

Authority required

Severe Crohn disease

Treatment Phase: Balance of supply

Treatment criteria:

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

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR
- 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 therapy with this drug to complete 24 weeks of treatment under the Initial PBS-subsidised treatment restriction for patients who had previously received non-PBS subsidised treatment (Grandfathered patient), **AND**
- The treatment must provide no more than the balance of up to 3 doses (new patients) or 2 repeats (Continuing or Grandfathered patients), **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Population criteria:

- Patient must be aged 18 years or older.

Note Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats 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 Crohn disease

Treatment Phase: Continuing treatment

Treatment criteria:

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

Clinical criteria:

- Patient must have 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 or sustained an adequate response to treatment with this drug.

Population criteria:

- Patient must be aged 18 years or older.

Clinical criteria:

- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.

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 which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment.

All assessments, pathology tests and diagnostic imaging studies, must be made within 1 month of the date of application.

If the application is the first application for continuing treatment with this drug, an assessment of the patient's response to the initial course of treatment must be made up to 12 weeks after the first dose 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.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide sufficient for a single infusion of 300 mg vedolizumab per dose. Up to a maximum of 2 repeats will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

vedolizumab 300 mg injection, 1 vial

10390W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	3105.19	Entyvio [TK]