Australian Government
Department of Health

PBS

Schedule of Pharmaceutical Benefits

Summary of Changes

Effective 1 April 2022

Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 April 2022 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	$7.78
	Dangerous drug fee	$4.82
	Extemporaneously-prepared	$9.82
	Allowable additional patient charge*	$4.54
Additional Fees (for safety net prices):	Ready-prepared	$1.30
	Extemporaneously-prepared	$1.67
Patient Co-payments:	General	$42.50
	Concessional	$6.80
Safety Net Thresholds:	General	$1542.10
	Concessional	$326.40
Safety Net Card Issue Fee:		$10.65

* 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 April 2022. The Schedule is updated on the first day of each month and is available on the internet at www.pbs.gov.au.

Prescriber Bag

Deletions

Deletion – Brand

12222G *Lasix-M, SW* – **FUROSEMIDE (FRUSEMIDE)**, furosemide (frusemide) 20 mg tablet, 50

General Pharmaceutical Benefits

Additions

Addition – Item

12915R **BUDESONIDE**, budesonide 3 mg modified release capsule, 90 *(Entocort)*

12918X **EMPAGLIFLOZIN**, empagliflozin 10 mg tablet, 30 *(Jardiance)*

12917W **FLUTICASONE FUROATE + UMECLIDINIUM + VILANTEROL**, fluticasone furoate 200 microgram/actuation + umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations *(Trelegy Ellipta 200/62.5/25)*

12911M **IMATINIB**, imatinib 600 mg tablet, 30 *(Imatab)*

12912N **IMATINIB**, imatinib 600 mg tablet, 30 *(Imatab)*

12919Y **IMATINIB**, imatinib 600 mg tablet, 30 *(Imatab)*

12920B **IMATINIB**, imatinib 600 mg tablet, 30 *(Imatab)*

12923E **IMATINIB**, imatinib 600 mg tablet, 30 *(Imatab)*

12924F **IMATINIB**, imatinib 600 mg tablet, 30 *(Imatab)*

12926H **IMATINIB**, imatinib 600 mg tablet, 30 *(Imatab)*

12927J **IMATINIB**, imatinib 600 mg tablet, 30 *(Imatab)*

12928K **IMATINIB**, imatinib 600 mg tablet, 30 *(Imatab)*

12935T **IMATINIB**, imatinib 600 mg tablet, 30 *(Imatab)*

12931N **MYCOBACTERIUM BOVIS (BACILLUS CALMETTE AND GUERIN (BCG)) DANISH 1331 STRAIN**, Mycobacterium bovis (Bacillus Calmette and Guerin (BCG)) Danish 1331 strain 250 million CFU 30 mg, 4 vials *(BCG Culture SSI)*

12921C **OLAPARIB**, olaparib 100 mg tablet, 56 *(Lynparza)*

12932P **OLAPARIB**, olaparib 100 mg tablet, 56 *(Lynparza)*

12913P **OLAPARIB**, olaparib 150 mg tablet, 56 *(Lynparza)*

12929L **OLAPARIB**, olaparib 150 mg tablet, 56 *(Lynparza)*

12914Q **PANCRELIPASE**, pancrelipase 25 000 units capsule, 100 *(Panzytrat 25 000 (Allergan))*

12933Q **PANCRELIPASE**, pancrelipase 25 000 units capsule, 100 *(Panzytrat 25 000 (Allergan))*

Addition – Brand

8213G *ATOMED, DZ* – **ATORVASTATIN**, atorvastatin 10 mg tablet, 30

9230T *ATOMED, DZ* – **ATORVASTATIN**, atorvastatin 10 mg tablet, 30

8214H *ATOMED, DZ* – **ATORVASTATIN**, atorvastatin 20 mg tablet, 30

9231W *ATOMED, DZ* – **ATORVASTATIN**, atorvastatin 20 mg tablet, 30

8215J *ATOMED, DZ* – **ATORVASTATIN**, atorvastatin 40 mg tablet, 30

9232X *ATOMED, DZ* – **ATORVASTATIN**, atorvastatin 40 mg tablet, 30

8521L *ATOMED, DZ* – **ATORVASTATIN**, atorvastatin 80 mg tablet, 30

9233Y *ATOMED, DZ* – **ATORVASTATIN**, atorvastatin 80 mg tablet, 30

8295N *NOUMED CANDESARTAN, VO* – **CANDESARTAN**, candesartan cilexetil 4 mg tablet, 30

8296P *NOUMED CANDESARTAN, VO* – **CANDESARTAN**, candesartan cilexetil 8 mg tablet, 30

8297Q *NOUMED CANDESARTAN, VO* – **CANDESARTAN**, candesartan cilexetil 16 mg tablet, 30

8889W *NOUMED CANDESARTAN, VO* – **CANDESARTAN**, candesartan cilexetil 32 mg tablet, 30

10293R *Lacosam, AF* – **LACOSAMIDE**, lacosamide 50 mg tablet, 14

10293R *Lacosamide ARX, XT* – **LACOSAMIDE**, lacosamide 50 mg tablet, 14

10293R *Lacosamide Lupin, GQ* – **LACOSAMIDE**, lacosamide 50 mg tablet, 14

10293R *Lacosamide Sandoz, SZ* – **LACOSAMIDE**, lacosamide 50 mg tablet, 14

10293R *Vimcosa, CR* – **LACOSAMIDE**, lacosamide 50 mg tablet, 14

12626M *Lacosamide Sandoz, SZ* – **LACOSAMIDE**, lacosamide 50 mg tablet, 14

12626M *Vimcosa, CR* – **LACOSAMIDE**, lacosamide 50 mg tablet, 14

9333F *Lacosam, AF* – **LACOSAMIDE**, lacosamide 50 mg tablet, 14

9333F *Lacosamide ARX, XT* – **LACOSAMIDE**, lacosamide 50 mg tablet, 14

9333F *Lacosamide Lupin, GQ* – **LACOSAMIDE**, lacosamide 50 mg tablet, 14

9333F *Lacosamide Sandoz, SZ* – **LACOSAMIDE**, lacosamide 50 mg tablet, 14

9333F *Vimcosa, CR* – **LACOSAMIDE**, lacosamide 50 mg tablet, 14

12633X *Lacosamide Sandoz, SZ* – **LACOSAMIDE**, lacosamide 100 mg tablet, 14

12633X *Vimcosa, CR* – **LACOSAMIDE**, lacosamide 100 mg tablet, 14

12634Y *Lacosamide Sandoz, SZ* – **LACOSAMIDE**, lacosamide 100 mg tablet, 56

12634Y *Vimcosa, CR* – **LACOSAMIDE**, lacosamide 100 mg tablet, 56

9334G *Lacosamide Sandoz, SZ* – **LACOSAMIDE**, lacosamide 100 mg tablet, 14

9334G *Vimcosa, CR* – **LACOSAMIDE**, lacosamide 100 mg tablet, 14

9335H *Lacosam, AF* – **LACOSAMIDE**, lacosamide 100 mg tablet, 56

9335H *Lacosamide ARX, XT* – **LACOSAMIDE**, lacosamide 100 mg tablet, 56

9335H *Lacosamide Lupin, GQ* – **LACOSAMIDE**, lacosamide 100 mg tablet, 56

9335H *Lacosamide Sandoz, SZ* – **LACOSAMIDE**, lacosamide 100 mg tablet, 56

9335H *Vimcosa, CR* – **LACOSAMIDE**, lacosamide 100 mg tablet, 56

12627N *Lacosamide Sandoz, SZ* – **LACOSAMIDE**, lacosamide 150 mg tablet, 56

12627N *Vimcosa, CR* – **LACOSAMIDE**, lacosamide 150 mg tablet, 56

12649R *Vimcosa, CR* – **LACOSAMIDE**, lacosamide 150 mg tablet, 14

9336J *Vimcosa, CR* – **LACOSAMIDE**, lacosamide 150 mg tablet, 14

9337K *Lacosam, AF* – **LACOSAMIDE**, lacosamide 150 mg tablet, 56

9337K *Lacosamide ARX, XT* – **LACOSAMIDE**, lacosamide 150 mg tablet, 56

9337K *Lacosamide Lupin, GQ* – **LACOSAMIDE**, lacosamide 150 mg tablet, 56

9337K *Lacosamide Sandoz, SZ* – **LACOSAMIDE**, lacosamide 150 mg tablet, 56

9337K *Vimcosa, CR* – **LACOSAMIDE**, lacosamide 150 mg tablet, 56

12658F *Lacosamide Sandoz, SZ* – **LACOSAMIDE**, lacosamide 200 mg tablet, 56

12658F *Vimcosa, CR* – **LACOSAMIDE**, lacosamide 200 mg tablet, 56

9338L *Lacosam, AF* – **LACOSAMIDE**, lacosamide 200 mg tablet, 56

9338L *Lacosamide ARX, XT* – **LACOSAMIDE**, lacosamide 200 mg tablet, 56

9338L *Lacosamide Lupin, GQ* – **LACOSAMIDE**, lacosamide 200 mg tablet, 56

9338L *Lacosamide Sandoz, SZ* – **LACOSAMIDE**, lacosamide 200 mg tablet, 56

9338L *Vimcosa, CR* – **LACOSAMIDE**, lacosamide 200 mg tablet, 56

1692C *ARX-Nitrofurantoin, XT* – **NITROFURANTOIN**, nitrofurantoin 50 mg capsule, 30

1693D *ARX-Nitrofurantoin, XT* – **NITROFURANTOIN**, nitrofurantoin 100 mg capsule, 30

5295Q *Palonosetron Dr.Reddy's, RZ* – **PALONOSETRON**, palonosetron 250 microgram/5 mL injection, 5 mL vial

8470T *APX-Ramipril, TY* – **RAMIPRIL**, ramipril 10 mg capsule, 30

Addition – Equivalence Indicator

11202N *Brenzys, RF* – **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL pen devices

11215G *Brenzys, RF* – **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL pen devices

11218K *Brenzys, RF* – **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL pen devices

11221N *Brenzys, RF* – **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL pen devices

11211C *Brenzys, RF* – **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL syringes

11216H *Brenzys, RF* – **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL syringes

11217J *Brenzys, RF* – **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL syringes

11225T *Brenzys, RF* – **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL syringes

10293R *Vimpat, UC* – **LACOSAMIDE**, lacosamide 50 mg tablet, 14

12626M *Vimpat, UC* – **LACOSAMIDE**, lacosamide 50 mg tablet, 14

9333F *Vimpat, UC* – **LACOSAMIDE**, lacosamide 50 mg tablet, 14

12633X *Vimpat, UC* – **LACOSAMIDE**, lacosamide 100 mg tablet, 14

12634Y *Vimpat, UC* – **LACOSAMIDE**, lacosamide 100 mg tablet, 56

9334G *Vimpat, UC* – **LACOSAMIDE**, lacosamide 100 mg tablet, 14

9335H *Vimpat, UC* – **LACOSAMIDE**, lacosamide 100 mg tablet, 56

12627N *Vimpat, UC* – **LACOSAMIDE**, lacosamide 150 mg tablet, 56

12649R *Vimpat, UC* – **LACOSAMIDE**, lacosamide 150 mg tablet, 14

9336J *Vimpat, UC* – **LACOSAMIDE**, lacosamide 150 mg tablet, 14

9337K *Vimpat, UC* – **LACOSAMIDE**, lacosamide 150 mg tablet, 56

12658F *Vimpat, UC* – **LACOSAMIDE**, lacosamide 200 mg tablet, 56

9338L *Vimpat, UC* – **LACOSAMIDE**, lacosamide 200 mg tablet, 56

5295Q *Aloxi, MF* – **PALONOSETRON**, palonosetron 250 microgram/5 mL injection, 5 mL vial

8366H *Panzytrat 25000, TM* – **PANCRELIPASE**, pancrelipase 25 000 units capsule, 100

9229R *Panzytrat 25000, TM* – **PANCRELIPASE**, pancrelipase 25 000 units capsule, 100

Addition – Note

11215G **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL pen devices *(Brenzys)*

11218K **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL pen devices *(Brenzys)*

11221N **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL pen devices *(Brenzys)*

11211C **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL syringes *(Brenzys)*

11217J **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL syringes *(Brenzys)*

11225T **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL syringes *(Brenzys)*

8366H **PANCRELIPASE**, pancrelipase 25 000 units capsule, 100 *(Panzytrat 25000)*

9229R **PANCRELIPASE**, pancrelipase 25 000 units capsule, 100 *(Panzytrat 25000)*

Addition – Restriction

2868Y **IVERMECTIN**, ivermectin 3 mg tablet, 4 *(Stromectol)*

Deletions

Deletion – Item

10040K **DOCOSAHEXAENOIC ACID WITH CARBOHYDRATE**, docosahexaenoic acid with carbohydrate containing 200 mg docosahexaenoic acid powder for oral liquid, 30 x 4 g sachets *(docomega)*

8748K **ETACRYNIC ACID**, etacrynic acid 25 mg tablet, 100 *(Edecrin)*

Deletion – Brand

1810G *Lasix-M, SW* – **FUROSEMIDE (FRUSEMIDE)**, furosemide (frusemide) 20 mg tablet, 50

2412Y *Lasix, SW* – **FUROSEMIDE (FRUSEMIDE)**, furosemide (frusemide) 40 mg tablet, 100

8450R *Dimirel, AV* – **GLIMEPIRIDE**, glimepiride 1 mg tablet, 30

1394J *Nordette 28, PF* – **LEVONORGESTREL + ETHINYLESTRADIOL**, levonorgestrel 150 microgram + ethinylestradiol 30 microgram tablet [21] (&) inert substance tablet [7], 4 x 28

1621H *Metronide 400, AV* – **METRONIDAZOLE**, metronidazole 400 mg tablet, 21

5155H *Metronide 400, AV* – **METRONIDAZOLE**, metronidazole 400 mg tablet, 21

1692C *Macrodantin, PF* – **NITROFURANTOIN**, nitrofurantoin 50 mg capsule, 30

1693D *Macrodantin, PF* – **NITROFURANTOIN**, nitrofurantoin 100 mg capsule, 30

Deletion – Equivalence Indicator

1394J *Monofeme 28, FZ* – **LEVONORGESTREL + ETHINYLESTRADIOL**, levonorgestrel 150 microgram + ethinylestradiol 30 microgram tablet [21] (&) inert substance tablet [7], 4 x 28

Deletion – Note

12826C **ACALABRUTINIB**, acalabrutinib 100 mg capsule, 56 *(Calquence)*

12295D **INDACATEROL + GLYCOPYRRONIUM + MOMETASONE**, indacaterol 114 microgram + glycopyrronium 46 microgram + mometasone furoate 136 microgram powder for inhalation, 30 capsules *(Enerzair Breezhaler)*

12298G **INDACATEROL + GLYCOPYRRONIUM + MOMETASONE**, indacaterol 114 microgram + glycopyrronium 46 microgram + mometasone furoate 68 microgram powder for inhalation, 30 capsules *(Enerzair Breezhaler)*

12633X **LACOSAMIDE**, lacosamide 100 mg tablet, 14 *(Lacosamide Sandoz, Vimcosa, Vimpat)*

12634Y **LACOSAMIDE**, lacosamide 100 mg tablet, 56 *(Lacosamide Sandoz, Vimcosa, Vimpat)*

12627N **LACOSAMIDE**, lacosamide 150 mg tablet, 56 *(Lacosamide Sandoz, Vimcosa, Vimpat)*

12649R **LACOSAMIDE**, lacosamide 150 mg tablet, 14 *(Vimcosa, Vimpat)*

12658F **LACOSAMIDE**, lacosamide 200 mg tablet, 56 *(Lacosamide Sandoz, Vimcosa, Vimpat)*

12160B **SIPONIMOD**, siponimod 250 microgram tablet, 120 *(Mayzent)*

12172P **SIPONIMOD**, siponimod 250 microgram tablet, 12 *(Mayzent)*

12158X **SIPONIMOD**, siponimod 2 mg tablet, 28 *(Mayzent)*

Deletion – Caution

11503K **OLAPARIB**, olaparib 100 mg tablet, 56 *(Lynparza)*

11522K **OLAPARIB**, olaparib 100 mg tablet, 56 *(Lynparza)*

12169L **OLAPARIB**, olaparib 100 mg tablet, 56 *(Lynparza)*

12170M **OLAPARIB**, olaparib 100 mg tablet, 56 *(Lynparza)*

11528R **OLAPARIB**, olaparib 150 mg tablet, 56 *(Lynparza)*

11539H **OLAPARIB**, olaparib 150 mg tablet, 56 *(Lynparza)*

12157W **OLAPARIB**, olaparib 150 mg tablet, 56 *(Lynparza)*

12161C **OLAPARIB**, olaparib 150 mg tablet, 56 *(Lynparza)*

Deletion – Restriction

12160B **SIPONIMOD**, siponimod 250 microgram tablet, 120 *(Mayzent)*

12172P **SIPONIMOD**, siponimod 250 microgram tablet, 12 *(Mayzent)*

12158X **SIPONIMOD**, siponimod 2 mg tablet, 28 *(Mayzent)*

Alterations

Alteration – Item Description

From

1433K **FLUDROCORTISONE ACETATE**, fludrocortisone acetate 100 microgram tablet, 100 *(FLUDROCORTISONE MEDSURGE, Florinef)*

To

1433K **FLUDROCORTISONE**, fludrocortisone acetate 100 microgram tablet, 100 *(FLUDROCORTISONE MEDSURGE, Florinef)*

Alteration – Note

12773G **VENETOCLAX**, venetoclax 50 mg tablet, 7 *(Venclexta)*

12803W **VENETOCLAX**, venetoclax 100 mg tablet, 120 *(Venclexta)*

Alteration – Restriction

12295D **INDACATEROL + GLYCOPYRRONIUM + MOMETASONE**, indacaterol 114 microgram + glycopyrronium 46 microgram + mometasone furoate 136 microgram powder for inhalation, 30 capsules *(Enerzair Breezhaler)*

12298G **INDACATEROL + GLYCOPYRRONIUM + MOMETASONE**, indacaterol 114 microgram + glycopyrronium 46 microgram + mometasone furoate 68 microgram powder for inhalation, 30 capsules *(Enerzair Breezhaler)*

11043F **TIOTROPIUM**, tiotropium 2.5 microgram/actuation inhalation solution, 60 actuations *(Spiriva Respimat)*

Alteration – Restriction Level

		From	*To*
12295D	**INDACATEROL + GLYCOPYRRONIUM + MOMETASONE**, indacaterol 114 microgram + glycopyrronium 46 microgram + mometasone furoate 136 microgram powder for inhalation, 30 capsules *(Enerzair Breezhaler)*	authority-required	streamlined
12298G	**INDACATEROL + GLYCOPYRRONIUM + MOMETASONE**, indacaterol 114 microgram + glycopyrronium 46 microgram + mometasone furoate 68 microgram powder for inhalation, 30 capsules *(Enerzair Breezhaler)*	authority-required	streamlined

Alteration – Manufacturer Code

		From	*To*
12849G	*TE-DASATINIB* – **DASATINIB**, dasatinib 20 mg tablet, 60	TI	AF
12850H	*TE-DASATINIB* – **DASATINIB**, dasatinib 20 mg tablet, 60	TI	AF
12869H	*TE-DASATINIB* – **DASATINIB**, dasatinib 20 mg tablet, 60	TI	AF
12888H	*TE-DASATINIB* – **DASATINIB**, dasatinib 20 mg tablet, 60	TI	AF
1354G	*TE-DASATINIB* – **DASATINIB**, dasatinib 20 mg tablet, 60	TI	AF
2478K	*TE-DASATINIB* – **DASATINIB**, dasatinib 20 mg tablet, 60	TI	AF
9125G	*TE-DASATINIB* – **DASATINIB**, dasatinib 20 mg tablet, 60	TI	AF
12843Y	*TE-DASATINIB* – **DASATINIB**, dasatinib 50 mg tablet, 60	TI	AF
12857Q	*TE-DASATINIB* – **DASATINIB**, dasatinib 50 mg tablet, 60	TI	AF
12860W	*TE-DASATINIB* – **DASATINIB**, dasatinib 50 mg tablet, 60	TI	AF
12865D	*TE-DASATINIB* – **DASATINIB**, dasatinib 50 mg tablet, 60	TI	AF
1381Q	*TE-DASATINIB* – **DASATINIB**, dasatinib 50 mg tablet, 60	TI	AF
2482P	*TE-DASATINIB* – **DASATINIB**, dasatinib 50 mg tablet, 60	TI	AF
9126H	*TE-DASATINIB* – **DASATINIB**, dasatinib 50 mg tablet, 60	TI	AF
12866E	*TE-DASATINIB* – **DASATINIB**, dasatinib 70 mg tablet, 60	TI	AF
12886F	*TE-DASATINIB* – **DASATINIB**, dasatinib 70 mg tablet, 60	TI	AF
12890K	*TE-DASATINIB* – **DASATINIB**, dasatinib 70 mg tablet, 60	TI	AF
12903D	*TE-DASATINIB* – **DASATINIB**, dasatinib 70 mg tablet, 60	TI	AF
1415L	*TE-DASATINIB* – **DASATINIB**, dasatinib 70 mg tablet, 60	TI	AF
2485T	*TE-DASATINIB* – **DASATINIB**, dasatinib 70 mg tablet, 60	TI	AF
9127J	*TE-DASATINIB* – **DASATINIB**, dasatinib 70 mg tablet, 60	TI	AF

12842X	*TE-DASATINIB* – **DASATINIB**, dasatinib 100 mg tablet, 30	TI	AF
12859T	*TE-DASATINIB* – **DASATINIB**, dasatinib 100 mg tablet, 30	TI	AF
12889J	*TE-DASATINIB* – **DASATINIB**, dasatinib 100 mg tablet, 30	TI	AF
12902C	*TE-DASATINIB* – **DASATINIB**, dasatinib 100 mg tablet, 30	TI	AF
1416M	*TE-DASATINIB* – **DASATINIB**, dasatinib 100 mg tablet, 30	TI	AF
9342Q	*TE-DASATINIB* – **DASATINIB**, dasatinib 100 mg tablet, 30	TI	AF
9343R	*TE-DASATINIB* – **DASATINIB**, dasatinib 100 mg tablet, 30	TI	AF

Alteration – Maximum Quantity

		From	*To*
12465C	**PROGESTERONE**, progesterone 200 mg pessary, 15 *(Oripro)*	2	3

Alteration – Number of Repeats

		From	*To*
12465C	**PROGESTERONE**, progesterone 200 mg pessary, 15 *(Oripro)*	5	3

Supply Only

From 1 November 2020 when a product is deleted from the Schedule it may now be available under new Supply Only rules. Supply Only items/brands are available on the Schedule for dispensing but not for prescribing, usually for a period of up to 12 months from when it is deleted.
Substitution of Supply Only items/brands with products flagged as "equivalent for substitution" still apply as specified in the Schedule at the time the script was written. Further information on Supply Only arrangements is available at www.pbs.gov.au

9351E **ALENDRONATE + COLECALCIFEROL (&) CALCIUM CARBONATE**, alendronate 70 mg + colecalciferol 140 microgram tablet [4] (&) calcium (as carbonate) 500 mg tablet [48], 1 pack *(ReddyMax Plus D-Cal)*

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

1914R **AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE**, amino acid formula with vitamins and minerals without valine, leucine and isoleucine powder for oral liquid, 30 x 34 g sachets *(MSUD express 20)*

8334P **CROMOGLYCATE**, sodium cromoglycate 5 mg/actuation inhalation, 112 actuations *(Intal Forte CFC-Free)*

9412J **PANCREATIC EXTRACT**, pancreatic extract 40 000 units modified release capsule, 100 *(Creon 40,000)*

9413K **PANCREATIC EXTRACT**, pancreatic extract 40 000 units modified release capsule, 100 *(Creon 40,000)*

11049M **SODIUM CHLORIDE + POTASSIUM CHLORIDE + GLUCOSE MONOHYDRATE + CITRIC ACID**, sodium chloride 470 mg + potassium chloride 300 mg (potassium 4 mmol) + glucose monohydrate 3.56 g + sodium acid citrate 530 mg powder for oral liquid, 10 x 4.9 g sachets *(restore O.R.S.)*

Advance Notices

1 May 2022

Deletion – Brand

12280H *Desmopressin Acetate (Medsurge), DZ* – **DESMOPRESSIN**, desmopressin acetate 10 microgram/actuation nasal spray, 50 actuations

12288R *Desmopressin Acetate (Medsurge), DZ* – **DESMOPRESSIN**, desmopressin acetate 10 microgram/actuation nasal spray, 50 actuations

8450R *Diapride 1, RW* – **GLIMEPIRIDE**, glimepiride 1 mg tablet, 30

8451T *Diapride 2, RW* – **GLIMEPIRIDE**, glimepiride 2 mg tablet, 30

8452W *Diapride 4, RW* – **GLIMEPIRIDE**, glimepiride 4 mg tablet, 30

8533D *Diapride 3, RW* – **GLIMEPIRIDE**, glimepiride 3 mg tablet, 30

1324Q *Lopresor 50, NV* – **METOPROLOL TARTRATE**, METOPROLOL TARTRATE Tablet 50 mg, 100

1325R *Lopresor 100, NV* – **METOPROLOL TARTRATE**, METOPROLOL TARTRATE Tablet 100 mg, 60

1653B *Momex SR 10, RW* – **MORPHINE**, morphine sulfate pentahydrate 10 mg modified release tablet, 28

1654C *Momex SR 30, RW* – **MORPHINE**, morphine sulfate pentahydrate 30 mg modified release tablet, 28

1655D *Momex SR 60, RW* – **MORPHINE**, morphine sulfate pentahydrate 60 mg modified release tablet, 28

1656E *Momex SR 100, RW* – **MORPHINE**, morphine sulfate pentahydrate 100 mg modified release tablet, 28

5458G *QUEPINE XR, RW* – **QUETIAPINE**, quetiapine 150 mg modified release tablet, 60

8458E *Quetiapine GH 200, GQ* – **QUETIAPINE**, quetiapine 200 mg tablet, 60

9202H *QUEPINE XR, RF* – **QUETIAPINE**, quetiapine 50 mg modified release tablet, 60

9203J *QUEPINE XR, RF* – **QUETIAPINE**, quetiapine 200 mg modified release tablet, 60

9204K *QUEPINE XR, RF* – **QUETIAPINE**, quetiapine 300 mg modified release tablet, 60

9205L *QUEPINE XR, RF* – **QUETIAPINE**, quetiapine 400 mg modified release tablet, 60

1977C *Ausran, RW* – **RANITIDINE**, ranitidine 300 mg tablet, 30

1978D *Ausran, RW* – **RANITIDINE**, ranitidine 150 mg tablet, 60

2011W *Lipex 10, AL* – **SIMVASTATIN**, simvastatin 10 mg tablet, 30

2011W *Simvastatin generichealth, GQ* – **SIMVASTATIN**, simvastatin 10 mg tablet, 30

2011W *Zocor, MQ* – **SIMVASTATIN**, simvastatin 10 mg tablet, 30

2012X *Simvastatin generichealth, GQ* – **SIMVASTATIN**, simvastatin 20 mg tablet, 30

8173E *Simvastatin generichealth, GQ* – **SIMVASTATIN**, simvastatin 40 mg tablet, 30

9242K *Lipex 10, AL* – **SIMVASTATIN**, simvastatin 10 mg tablet, 30

9242K *Simvastatin generichealth, GQ* – **SIMVASTATIN**, simvastatin 10 mg tablet, 30

9242K *Zocor, MQ* – **SIMVASTATIN**, simvastatin 10 mg tablet, 30

9243L *Simvastatin generichealth, GQ* – **SIMVASTATIN**, simvastatin 20 mg tablet, 30

9244M *Simvastatin generichealth, GQ* – **SIMVASTATIN**, simvastatin 40 mg tablet, 30

1 June 2022
Deletion – Brand

9296G *CoPlavix, SW* – **CLOPIDOGREL + ASPIRIN**, clopidogrel 75 mg + aspirin 100 mg tablet, 30

8452W *Dimirel, AV* – **GLIMEPIRIDE**, glimepiride 4 mg tablet, 30

1636D *Flagyl, SW* – **METRONIDAZOLE**, metronidazole 200 mg tablet, 21

3339R *Flagyl, SW* – **METRONIDAZOLE**, metronidazole 200 mg tablet, 21

1 July 2022
Deletion – Brand

8533D *Dimirel, AV* – **GLIMEPIRIDE**, glimepiride 3 mg tablet, 30

Palliative Care

Advance Notices

1 May 2022
Deletion – Brand

12483B *Momex SR 100, RW* – **MORPHINE**, morphine sulfate pentahydrate 100 mg modified release tablet, 28

12500X *Momex SR 30, RW* – **MORPHINE**, morphine sulfate pentahydrate 30 mg modified release tablet, 28

12544F *Momex SR 60, RW* – **MORPHINE**, morphine sulfate pentahydrate 60 mg modified release tablet, 28

12547J *Momex SR 10, RW* – **MORPHINE**, morphine sulfate pentahydrate 10 mg modified release tablet, 28

Highly Specialised Drugs Program (Private Hospital)

Additions

Addition – Item

12938Y **ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**, elexacaftor 100 mg + tezacaftor 50 mg + ivacaftor 75 mg tablet [56] (&) ivacaftor 150 mg tablet [28], 84 *(Trikafta)*

12930M **SILTUXIMAB**, siltuximab 100 mg injection, 1 vial *(Sylvant)*

12934R **SILTUXIMAB**, siltuximab 400 mg injection, 1 vial *(Sylvant)*

Addition – Brand

12784W *Azacitidine MSN, JU* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

6100C *Azacitidine MSN, JU* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

6138C *Azacitidine MSN, JU* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

Deletions

Deletion – Brand

6363X *Neulasta, JU* – **PEGFILGRASTIM**, pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe

6363X *Tezmota, JX* – **PEGFILGRASTIM**, pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe

Alterations

Alteration – Note

12784W **AZACITIDINE**, azacitidine 100 mg injection, 1 vial *(AZACITIDINE DR.REDDY'S, Azacitidine Accord, Azacitidine Juno, Azacitidine MSN, Azacitidine-Teva, Azadine)*

11097C **IVACAFTOR**, ivacaftor 50 mg granules, 56 sachets *(Kalydeco)*

11109Q **IVACAFTOR**, ivacaftor 75 mg granules, 56 sachets *(Kalydeco)*

10175M **IVACAFTOR**, ivacaftor 150 mg tablet, 56 *(Kalydeco)*

11841F **LUMACAFTOR + IVACAFTOR**, lumacaftor 100 mg + ivacaftor 125 mg granules, 56 sachets *(Orkambi)*

11848N **LUMACAFTOR + IVACAFTOR**, lumacaftor 150 mg + ivacaftor 188 mg granules, 56 sachets *(Orkambi)*

11464J **LUMACAFTOR + IVACAFTOR**, lumacaftor 100 mg + ivacaftor 125 mg tablet, 112 *(Orkambi)*

11463H **LUMACAFTOR + IVACAFTOR**, lumacaftor 200 mg + ivacaftor 125 mg tablet, 112 *(Orkambi)*

11833T **TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**, tezacaftor 100 mg + ivacaftor 150 mg tablet [28] (&) ivacaftor 150 mg tablet [28], 56 *(Symdeko)*

11834W **TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**, tezacaftor 100 mg + ivacaftor 150 mg tablet [28] (&) ivacaftor 150 mg tablet [28], 56 *(Symdeko)*

Alteration – Restriction

11097C **IVACAFTOR**, ivacaftor 50 mg granules, 56 sachets *(Kalydeco)*

11109Q **IVACAFTOR**, ivacaftor 75 mg granules, 56 sachets *(Kalydeco)*

10175M **IVACAFTOR**, ivacaftor 150 mg tablet, 56 *(Kalydeco)*

11841F **LUMACAFTOR + IVACAFTOR**, lumacaftor 100 mg + ivacaftor 125 mg granules, 56 sachets *(Orkambi)*

11848N **LUMACAFTOR + IVACAFTOR**, lumacaftor 150 mg + ivacaftor 188 mg granules, 56 sachets *(Orkambi)*

11464J **LUMACAFTOR + IVACAFTOR**, lumacaftor 100 mg + ivacaftor 125 mg tablet, 112 *(Orkambi)*

11463H **LUMACAFTOR + IVACAFTOR**, lumacaftor 200 mg + ivacaftor 125 mg tablet, 112 *(Orkambi)*

12895Q **RAVULIZUMAB**, ravulizumab 300 mg/3 mL injection, 3 mL vial *(Ultomiris)*

12897T **RAVULIZUMAB**, ravulizumab 1.1 g/11 mL injection, 11 mL vial *(Ultomiris)*

11833T **TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**, tezacaftor 100 mg + ivacaftor 150 mg tablet [28] (&) ivacaftor 150 mg tablet [28], 56 *(Symdeko)*

11834W **TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**, tezacaftor 100 mg + ivacaftor 150 mg tablet [28] (&) ivacaftor 150 mg tablet [28], 56 *(Symdeko)*

Highly Specialised Drugs Program (Public Hospital)

Additions

Addition – Item

12936W **ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**, elexacaftor 100 mg + tezacaftor 50 mg + ivacaftor 75 mg tablet [56] (&) ivacaftor 150 mg tablet [28], 84 *(Trikafta)*

12916T **SILTUXIMAB**, siltuximab 100 mg injection, 1 vial *(Sylvant)*

12922D **SILTUXIMAB**, siltuximab 400 mg injection, 1 vial *(Sylvant)*

Addition – Brand

12771E *Azacitidine MSN, JU* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

9597D *Azacitidine MSN, JU* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

9598E *Azacitidine MSN, JU* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

Deletions

Deletion – Brand

9514R *Neulasta, JU* – **PEGFILGRASTIM**, pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe

9514R *Tezmota, JX* – **PEGFILGRASTIM**, pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe

Alterations

Alteration – Note

12771E **AZACITIDINE**, azacitidine 100 mg injection, 1 vial *(AZACITIDINE DR.REDDY'S, Azacitidine Accord, Azacitidine Juno, Azacitidine MSN, Azacitidine-Teva, Azadine)*

11105L **IVACAFTOR**, ivacaftor 50 mg granules, 56 sachets *(Kalydeco)*

11098D **IVACAFTOR**, ivacaftor 75 mg granules, 56 sachets *(Kalydeco)*

10170G **IVACAFTOR**, ivacaftor 150 mg tablet, 56 *(Kalydeco)*

11866M **LUMACAFTOR + IVACAFTOR**, lumacaftor 100 mg + ivacaftor 125 mg granules, 56 sachets *(Orkambi)*

11851R **LUMACAFTOR + IVACAFTOR**, lumacaftor 150 mg + ivacaftor 188 mg granules, 56 sachets *(Orkambi)*

11465K **LUMACAFTOR + IVACAFTOR**, lumacaftor 100 mg + ivacaftor 125 mg tablet, 112 *(Orkambi)*

11466L **LUMACAFTOR + IVACAFTOR**, lumacaftor 200 mg + ivacaftor 125 mg tablet, 112 *(Orkambi)*

11854X **TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**, tezacaftor 100 mg + ivacaftor 150 mg tablet [28] (&) ivacaftor 150 mg tablet [28], 56 *(Symdeko)*

11863J **TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**, tezacaftor 100 mg + ivacaftor 150 mg tablet [28] (&) ivacaftor 150 mg tablet [28], 56 *(Symdeko)*

Alteration – Restriction

11105L **IVACAFTOR**, ivacaftor 50 mg granules, 56 sachets *(Kalydeco)*

11098D **IVACAFTOR**, ivacaftor 75 mg granules, 56 sachets *(Kalydeco)*

10170G **IVACAFTOR**, ivacaftor 150 mg tablet, 56 *(Kalydeco)*

11866M **LUMACAFTOR + IVACAFTOR**, lumacaftor 100 mg + ivacaftor 125 mg granules, 56 sachets *(Orkambi)*

11851R **LUMACAFTOR + IVACAFTOR**, lumacaftor 150 mg + ivacaftor 188 mg granules, 56 sachets *(Orkambi)*

11465K **LUMACAFTOR + IVACAFTOR**, lumacaftor 100 mg + ivacaftor 125 mg tablet, 112 *(Orkambi)*

11466L **LUMACAFTOR + IVACAFTOR**, lumacaftor 200 mg + ivacaftor 125 mg tablet, 112 *(Orkambi)*

12884D **RAVULIZUMAB**, ravulizumab 300 mg/3 mL injection, 3 mL vial *(Ultomiris)*

12883C **RAVULIZUMAB**, ravulizumab 1.1 g/11 mL injection, 11 mL vial *(Ultomiris)*

11854X **TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**, tezacaftor 100 mg + ivacaftor 150 mg tablet [28] (&) ivacaftor 150 mg tablet [28], 56 *(Symdeko)*

11863J **TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**, tezacaftor 100 mg + ivacaftor 150 mg tablet [28] (&) ivacaftor 150 mg tablet [28], 56 *(Symdeko)*

Highly Specialised Drugs Program (Community Access)

Additions

Addition – Item

12939B **CABOTEGRAVIR**, cabotegravir 30 mg tablet, 30 *(Vocabria)*

12937X **CABOTEGRAVIR (&) RILPIVIRINE**, cabotegravir 600 mg/3 mL modified release injection [3 mL vial] (&) rilpivirine 900 mg/3 mL modified release injection [3 mL vial], 1 pack *(Cabenuva)*

Growth Hormone Program

Alterations

Alteration – Item Description

From

10435F **SOMATROPIN**, SOMATROPIN (Recombinant human growth hormone) Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative), 1 *(Genotropin GoQuick)*

To

10435F **SOMATROPIN**, somatropin 5 mg injection [1 chamber] (&) inert substance diluent [1 mL chamber], 1 dual chamber pen device *(Genotropin GoQuick)*

From

10443P **SOMATROPIN**, SOMATROPIN (Recombinant human growth hormone) Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative), 1 *(Genotropin GoQuick)*

To

10443P **SOMATROPIN**, somatropin 5 mg injection [1 chamber] (&) inert substance diluent [1 mL chamber], 1 dual chamber pen device *(Genotropin GoQuick)*

From

11493X **SOMATROPIN**, SOMATROPIN (Recombinant human growth hormone) Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative), 1 *(Genotropin GoQuick)*

To

11493X **SOMATROPIN**, somatropin 5 mg injection [1 chamber] (&) inert substance diluent [1 mL chamber], 1 dual chamber pen device *(Genotropin GoQuick)*

From

9585L **SOMATROPIN**, SOMATROPIN (Recombinant human growth hormone) Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative), 1 *(Genotropin GoQuick)*

To

9585L **SOMATROPIN**, somatropin 5 mg injection [1 chamber] (&) inert substance diluent [1 mL chamber], 1 dual chamber pen device *(Genotropin GoQuick)*

From

10426R **SOMATROPIN**, SOMATROPIN (Recombinant human growth hormone) Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative), 1 *(Genotropin GoQuick)*

To

10426R **SOMATROPIN**, somatropin 12 mg injection [1 chamber] (&) inert substance diluent [1 mL chamber], 1 dual chamber pen device *(Genotropin GoQuick)*

From

10431B **SOMATROPIN**, SOMATROPIN (Recombinant human growth hormone) Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative), 1 *(Genotropin GoQuick)*

To

10431B **SOMATROPIN**, somatropin 12 mg injection [1 chamber] (&) inert substance diluent [1 mL chamber], 1 dual chamber pen device *(Genotropin GoQuick)*

From

11495B **SOMATROPIN**, SOMATROPIN (Recombinant human growth hormone) Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative), 1 *(Genotropin GoQuick)*

To

11495B **SOMATROPIN**, somatropin 12 mg injection [1 chamber] (&) inert substance diluent [1 mL chamber], 1 dual chamber pen device *(Genotropin GoQuick)*

From

9586M **SOMATROPIN**, SOMATROPIN (Recombinant human growth hormone) Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative), 1 *(Genotropin GoQuick)*

To

9586M **SOMATROPIN**, somatropin 12 mg injection [1 chamber] (&) inert substance diluent [1 mL chamber], 1 dual chamber pen device *(Genotropin GoQuick)*

Alteration – Note

11493X **SOMATROPIN**, somatropin 5 mg injection [1 chamber] (&) inert substance diluent [1 mL chamber], 1 dual chamber pen device *(Genotropin GoQuick)*

11495B **SOMATROPIN**, somatropin 12 mg injection [1 chamber] (&) inert substance diluent [1 mL chamber], 1 dual chamber pen device *(Genotropin GoQuick)*

11895C **SOMATROPIN**, somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge *(Norditropin FlexPro)*

11650E **SOMATROPIN**, somatropin 10 mg/2 mL injection, 2 mL cartridge *(NutropinAq)*

Alteration – Restriction

11493X **SOMATROPIN**, somatropin 5 mg injection [1 chamber] (&) inert substance diluent [1 mL chamber], 1 dual chamber pen device *(Genotropin GoQuick)*

11495B **SOMATROPIN**, somatropin 12 mg injection [1 chamber] (&) inert substance diluent [1 mL chamber], 1 dual chamber pen device *(Genotropin GoQuick)*

11895C **SOMATROPIN**, somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge *(Norditropin FlexPro)*

11650E **SOMATROPIN**, somatropin 10 mg/2 mL injection, 2 mL cartridge *(NutropinAq)*

Repatriation Pharmaceutical Benefits

Advance Notices

1 June 2022

Deletion – Brand

4089F *Atrovent Nasal Aqueous, VZ* – **IPRATROPIUM**, ipratropium bromide monohydrate 22 microgram/actuation nasal spray, 180 actuations

4090G *Atrovent Nasal Forte, VZ* – **IPRATROPIUM**, ipratropium bromide monohydrate 44 microgram/actuation nasal spray, 180 actuations

General Pharmaceutical Benefits

▪ BUDESONIDE

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

Authority required (STREAMLINED)

12607

Mild to moderate Crohn disease

Clinical criteria:

- The condition must affect the ileum; OR
- The condition must affect the ascending colon; OR
- The condition must affect the ileum and ascending colon.

The total duration of therapy should be no more than 12 weeks in any single course.

budesonide 3 mg modified release capsule, 90

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12915R NP	1	2	..	53.85	42.50	Entocort [EU]

▪ EMPAGLIFLOZIN

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.

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)

12477

Chronic heart failure

Clinical criteria:

- Patient must be symptomatic with NYHA classes II, III or IV, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor.

empagliflozin 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12918X NP	1	5	..	60.10	42.50	Jardiance [BY]

▪ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor

(tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).
A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised biological medicines for the treatment of rheumatoid arthritis.
A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.
A patient who has failed fewer than 5 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.
(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 24 months).
(iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months)
Initial applications for a new patient (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, baricitinib, etanercept, golimumab, tocilizumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab (either treatment with infliximab intravenous (IV) form alone or a combination of IV and subcutaneous form) and 2 infusions of rituximab.
Patients must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy, and this assessment must be conducted no later than 4 weeks from the completion of that course.
Where a response assessment is not provided with subsequent applications, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Abatacept patients:
A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. Two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats.
The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Infliximab subcutaneous form only:
Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide form weeks 6, 8, 10, 12, 14 and 16 will be authorised.
Rituximab patients:
Subsequent applications may be submitted to Services Australia with new baselines if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine 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 for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
Adalimumab and Infliximab only:
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
Infliximab patients:

A patient may swap between the intravenous form and subcutaneous form of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.
(2) Swapping therapy
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug.
Abatacept:
A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
Rituximab:
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they be assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.
(3) Baseline measurements to determine response.
Determination of whether a response to treatment has been demonstrated must be based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

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 Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL cartridges are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

7276

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

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

Population criteria:

- Patient must be aged 18 years or older.

Clinical criteria:

- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition, **AND**

- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

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

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

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

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

etanercept 50 mg/mL injection, 4 x 1 mL syringes

11211C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1050.14	42.50	[a] Brenzys [RF]

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

11218K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1050.14	42.50	[a] Brenzys [RF]

▪ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab and upadacitinib for adult patients with ankylosing spondylitis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab and upadacitinib only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 8 biological medicines at any 1 time.

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

A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine 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 biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

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

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

(1) How to prescribe PBS-subsidised biological medicine treatment with adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab and upadacitinib.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient)

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

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

Grandfather patients (upadacitinib only)

A patient who commenced treatment with upadacitinib for ankylosing spondylitis prior to 1 October 2021 and who continues

to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed 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 qualify for continuing treatment under the criteria that apply to a continuing patient.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
Assessment of the patient's response to treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the cessation of the most recent course of biological medicine therapy. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug 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.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(3) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine.
For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response.
Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(4) Recommencement 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 biological medicine therapy of at least 5 years, must qualify under the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

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 Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL cartridges are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

9481

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

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

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be used to determine response for all subsequent continuing treatments.

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

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

etanercept 50 mg/mL injection, 4 x 1 mL syringes

11217J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1050.14	42.50	[a] Brenzys [RF]

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

11215G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1050.14	42.50	[a] Brenzys [RF]

ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

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

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response 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 biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines 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 under Initial 2 treatment restriction.

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

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of

more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
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.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

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 Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL cartridges are equivalent for the purposes of substitution.

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

Authority required (STREAMLINED)

8887

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, whole body

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**

- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

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

Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug.

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

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required (STREAMLINED)

8955

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, face, hand, foot

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

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

Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

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

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

etanercept 50 mg/mL injection, 4 x 1 mL syringes

11225T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1050.14	42.50	[a] Brenzys [RF]

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

11221N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1050.14	42.50	[a] Brenzys [RF]

▪ FLUTICASONE FUROATE + UMECLIDINIUM + VILANTEROL

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.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 This pharmaceutical benefit is not for the treatment of chronic obstructive pulmonary disease (COPD).

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

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

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

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

Note An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

Authority required (STREAMLINED)

12603

Severe asthma

Clinical criteria:

- Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of: (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique.

Population criteria:

- Patient must be at least 18 years of age.

Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.

fluticasone furoate 200 microgram/actuation + umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations

12917W (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	91.66	42.50	Trelegy Ellipta 200/62.5/25 [GK]

▪ IMATINIB

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)

9208

Malignant gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be metastatic; OR
- The condition must be unresectable, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given at a dose not exceeding 600 mg per day.

Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib

Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

imatinib 600 mg tablet, 30

12919Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	978.46	42.50	Imatab [JU]

▪ IMATINIB

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)

9209

Dermatofibrosarcoma protuberans

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be unresectable; OR
- The condition must be locally recurrent; OR
- The condition must be metastatic, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to the PBS-subsidised treatment, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 800 mg per day.

Evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

imatinib 600 mg tablet, 30

12923E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	978.46	42.50	Imatab [JU]

▪ IMATINIB

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

Dermatofibrosarcoma protuberans

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be unresectable; OR
- The condition must be locally recurrent; OR
- The condition must be metastatic, **AND**
- The treatment must not exceed a maximum dose of 800 mg per day.

Details of unresectable tumour or site of the local recurrence or site(s) of metastatic disease must be documented in the patient's medical records.

imatinib 600 mg tablet, 30

12927J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	978.46	42.50	Imatab [JU]

▪ IMATINIB

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

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

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

Authority required

Malignant gastrointestinal stromal tumour

Treatment Phase: Initial Treatment

Clinical criteria:

- The condition must be metastatic; OR
- The condition must be unresectable, **AND**
- The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining, **AND**
- The treatment must be commenced at a dose not exceeding 400 mg per day, **AND**
- The treatment must not exceed 3 months under this restriction.

Authority prescriptions for a higher dose will not be approved during this initial 3 month treatment period.

Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

A pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining must be documented in the patient's medical records.

Details of the most recent (within 2 months of the application) computed tomography (CT) scan, magnetic resonance imaging (MRI) or ultrasound assessment of the tumour(s), including whether or not there is evidence of metastatic disease must be documented in the patient's medical records.

Where the application for authority to prescribe is being sought on the basis of an unresectable tumour, written evidence must be documented in the patient's medical records.

imatinib 600 mg tablet, 30

12926H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	978.46	42.50	Imatab [JU]

▪ IMATINIB

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

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

Authority required

Acute lymphoblastic leukaemia

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be newly diagnosed, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- The treatment must be for induction and consolidation therapy, **AND**
- The treatment must be in combination with chemotherapy or corticosteroids, **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised first-line treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first-line therapy for this condition.

A pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report

documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

imatinib 600 mg tablet, 30

12911M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	978.46	42.50	Imatab [JU]

▪ IMATINIB

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

Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - FIRST-LINE THERAPY

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia (CML) in the first line treatment setting.
Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib.
Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.
1. Initial First-line treatment
A patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.
During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond.
2. Continuing First-line treatment
Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% on the international scale (Blood 108:28-37,2006) to receive continuing therapy.
For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.
During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents.
Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.
3. Authority approval requirements
Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with imatinib, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).
4. Definitions of response
A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.
5. Definitions of loss of response
Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

Authority required (STREAMLINED)

12536

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment - first-line therapy

Clinical criteria:

- The condition must be in the chronic phase, **AND**
- Patient must have received initial continuing PBS-subsidised treatment with this drug as a first-line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with dasatinib for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with nilotinib for this condition, **AND**

- Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR
- Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

imatinib 600 mg tablet, 30

12912N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	978.46	42.50	Imatab [JU]

▪ IMATINIB

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

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

Authority required (STREAMLINED)

9207

Acute lymphoblastic leukaemia

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised treatment with dasatinib as a first-line therapy for this condition, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- The treatment must be for maintenance of first complete remission, **AND**
- The treatment must be in combination with chemotherapy or corticosteroids.

Dasatinib and imatinib are available with a lifetime maximum of 24 months for continuing treatment for patients with acute lymphoblastic leukaemia reimbursed through the PBS in this treatment setting.

imatinib 600 mg tablet, 30

12920B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	978.46	42.50	Imatab [JU]

▪ IMATINIB

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 Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - first-line therapy

Clinical criteria:

- The condition must be a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the accelerated phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Accelerated phase is defined by the presence of 1 or more of the following:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or

3. Peripheral basophils greater than or equal to 20%; or

4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report

documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records.

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - first-line therapy

Clinical criteria:

- The condition must be a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the blast phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Blast crisis is defined as either:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or

2. Extramedullary involvement other than spleen and liver.

A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records.

imatinib 600 mg tablet, 30

12924F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	978.46	42.50	Imatab [JU]

▪ IMATINIB

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 Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required (STREAMLINED)

12542

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received initial PBS-subsidised treatment with this drug as a first-line therapy for this condition, **AND**
- The condition must be in the accelerated phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR).

Authority required (STREAMLINED)

12525

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received initial PBS-subsidised treatment with this drug as a first-line therapy for this condition, **AND**
- The condition must be in the blast phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR).

imatinib 600 mg tablet, 30

12928K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	978.46	42.50	Imatab [JU]

▪ IMATINIB

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 Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - FIRST-LINE THERAPY

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia (CML) in the first line treatment setting.

Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial First-line treatment

A patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.

During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond.

2. Continuing First-line treatment

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% on the international scale (Blood 108:28-37,2006) to receive continuing therapy.

For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents.

Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

3. Authority approval requirements

Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with imatinib, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

4. Definitions of response

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

5. Definitions of loss of response

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - first-line therapy

Clinical criteria:

- The condition must be a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the chronic phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first-line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with nilotinib as a first-line therapy for this condition, **AND**
- The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.

Patients should be commenced on a dose of imatinib mesilate of 400 mg (base) daily. Continuing therapy is dependent on patients demonstrating a response to imatinib mesilate therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records.

imatinib 600 mg tablet, 30

12935T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	978.46	42.50	Imatab [JU]

▪ INDACATEROL + GLYCOPYRRONIUM + MOMETASONE

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

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

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

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

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

Note An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

Authority required (STREAMLINED)

12603

Severe asthma

Clinical criteria:

- Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of: (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique.

Population criteria:

- Patient must be at least 18 years of age.

Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.

indacaterol 114 microgram + glycopyrronium 46 microgram + mometasone furoate 68 microgram powder for inhalation, 30 capsules

12298G

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	74.99	42.50	Enerzair Breezhaler [NV]

indacaterol 114 microgram + glycopyrronium 46 microgram + mometasone furoate 136 microgram powder for inhalation, 30 capsules

12295D

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	91.66	42.50	Enerzair Breezhaler [NV]

▪ IVERMECTIN

Authority required (STREAMLINED)

4328

Strongyloidiasis

Authority required (STREAMLINED)

4565

Crusted (Norwegian) scabies

Clinical criteria:

- The condition must be established by clinical and/or parasitological examination, **AND**
- Patient must be undergoing topical therapy for this condition; OR
- Patient must have a contraindication to topical treatment.

Population criteria:

- Patient must weigh 15 kg or over, **AND**
- Patient must be 5 years of age or older.

Authority required (STREAMLINED)

4566

Human sarcoptic scabies

Clinical criteria:

- The condition must be established by clinical and/or parasitological examination, **AND**

- Patient must have completed and failed sequential treatment with topical permethrin and benzyl benzoate and finished the most recent course of topical therapy at least 4 weeks prior to initiating oral therapy; OR
- Patient must have a contraindication to topical treatment.

Population criteria:

- Patient must weigh 15 kg or over, **AND**
- Patient must be 5 years of age or older.

Note This drug is not PBS-subsidised for first line treatment of typical scabies.

Authority required (STREAMLINED)

12604

Human sarcoptic scabies

Clinical criteria:

- The condition must be established by clinical and/or parasitological examination.

Population criteria:

- Patient must identify as Aboriginal or Torres Strait Islander, **AND**
- Patient must weigh 15 kg or over, **AND**
- Patient must be 5 years of age or older.

ivermectin 3 mg tablet, 4

2868Y NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*47.24	42.50	Stromectol [MK]

▪ MYCOBACTERIUM BOVIS (BACILLUS CALMETTE AND GUERIN (BCG)) DANISH 1331 STRAIN

Restricted benefit

Primary and relapsing superficial urothelial carcinoma of the bladder

Mycobacterium bovis (Bacillus Calmette and Guerin (BCG)) Danish 1331 strain 250 million CFU 30 mg, 4 vials

12931N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡3	1	..	*1446.79	42.50	BCG Culture SSI [LM]

▪ OLAPARIB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) darolutamide, (iii) enzalutamide.

Note Special Pricing Arrangements apply.

Authority required

Castration resistant metastatic carcinoma of the prostate

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must not be subsidised in combination with: (i) chemotherapy, (ii) a novel hormonal drug.

olaparib 100 mg tablet, 56

12921C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*6630.72	42.50	Lynparza [AP]

olaparib 150 mg tablet, 56

12913P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*6630.72	42.50	Lynparza [AP]

▪ OLAPARIB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) darolutamide, (iii) enzalutamide.

Note Special Pricing Arrangements apply.

Authority required

Castration resistant metastatic carcinoma of the prostate

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene mutation, **AND**
- The treatment must not be subsidised in combination with: (i) chemotherapy, (ii) a novel hormonal drug, **AND**
- The condition must have progressed following prior treatment that included a novel hormonal drug for this condition (metastatic/non-metastatic disease), **AND**
- Patient must have a WHO performance status of 2 or less.

Treatment criteria:

- Patient must be undergoing treatment with this drug for the first time.

Authority required

Castration resistant metastatic carcinoma of the prostate

Treatment Phase: Transitioning from non-PBS to PBS-subsided treatment - Grandfather arrangements

Clinical criteria:

- Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 April 2022, **AND**
- The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene mutation, **AND**
- The treatment must not be subsidised in combination with: (i) chemotherapy, (ii) a novel hormonal drug, **AND**
- The condition must have progressed following prior treatment that included a novel hormonal drug for this condition (metastatic/non-metastatic disease), prior to initiating non-PBS-subsidised treatment with this drug, **AND**
- Patient must have had a WHO performance status of 2 or less prior to initiating non-PBS-subsidised treatment.

Treatment criteria:

- Patient must be undergoing continuing treatment with this drug where non-PBS-subsidised treatment was for untreated (with this drug) disease which also has not progressed on non-PBS-subsidised treatment.

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

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

olaparib 100 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12932P	2	2	..	*6630.72	42.50	Lynparza [AP]

olaparib 150 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12929L	2	2	..	*6630.72	42.50	Lynparza [AP]

▪ PANCRELIPASE

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.

Note Pharmaceutical Benefits that have the brand Panzytrat 25 000 (Allergan) may be substituted for Pharmaceutical Benefits that have the brand Panzytrat 25 000 in the case of a shortage.

pancrelipase 25 000 units capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12914Q NP	2	10	..	*213.06	42.50	[a] Panzytrat 25 000 (Allergan) [DZ]

pancrelipase 25 000 units capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8366H NP	2	10	..	*109.14	42.50	[a] Panzytrat 25000 [TM]

▪ PANCRELIPASE

Note Pharmaceutical Benefits that have the brand Panzytrat 25 000 (Allergan) may be substituted for Pharmaceutical Benefits that have the brand Panzytrat 25 000 in the case of a shortage.

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

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

Restricted benefit

Cystic fibrosis

Clinical criteria:

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

pancrelipase 25 000 units capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12933Q	2	21	..	*213.06	42.50	[a] Panzytrat 25 000 (Allergan) [DZ]

pancrelipase 25 000 units capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9229R	2	21	..	*109.14	42.50	[a] Panzytrat 25000 [TM]

▪ TIOTROPIUM

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).

Restricted benefit

Severe asthma

Clinical criteria:

- Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of: (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique,

AND

- The treatment must be used in combination with a maintenance combination of an inhaled corticosteroid (ICS) and a long acting beta-2 agonist (LABA) unless a LABA is contraindicated.

Population criteria:

- Patient must be at least 18 years of age.

Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.

tiotropium 2.5 microgram/actuation inhalation solution, 60 actuations

11043F NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	43.07	42.50	Spiriva Respimat [BY]

▪ VENETOCLAX

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

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

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Acute Myeloid Leukaemia

Clinical criteria:

- The condition must be previously untreated at the time of initiation with this drug (except for essential treatment with hydroxyurea or leukapheresis), **AND**
- Patient must not be considered eligible for standard intensive remission induction chemotherapy at the time of initiation with this drug, **AND**
- The treatment must be used in combination with azacitidine (refer to Product Information for timing of azacitidine and venetoclax doses), **AND**
- Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition,

AND

- The condition must not be acute promyelocytic leukaemia.

Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.

If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.

venetoclax 50 mg tablet, 7

12773G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	2	..	*997.78	42.50	Venclexta [VE]

venetoclax 100 mg tablet, 120

12803W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	7784.24	42.50	Venclexta [VE]

Highly Specialised Drugs Program (Private Hospital)

▪ AZACITIDINE

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Acute Myeloid Leukaemia

Clinical criteria:

- The treatment must be used in combination with venetoclax (refer to Product Information for timing of azacitidine and venetoclax doses).

azacitidine 100 mg injection, 1 vial

12784W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
14	2	..	*1393.78	[a] Azacitidine Accord [OC]	[a] AZACITIDINE DR.REDDY'S [RI]
				[a] Azacitidine Juno [JO]	[a] Azacitidine MSN [JU]
				[a] Azacitidine-Teva [TB]	[a] Azadine [RZ]

▪ ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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 For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor and elexacaftor/ tezacaftor/ ivacaftor.

Note Special Pricing Arrangements apply.

Authority required

Cystic fibrosis

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have at least one F508del mutation in the cystic fibrosis transmembrane conductance (CFTR) gene, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, prior to initiating treatment with this drug.

Population criteria:

- Patient must be 12 years of age or older.

The patient must be registered in the Australian Cystic Fibrosis Database Registry.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Cystic Fibrosis elexacaftor, tezacaftor with ivacaftor Authority Application Supporting Information Form; and

(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and

(4) details of the name of the molecular testing for the patient having at least one F508del mutation including: (i) name of the pathology report provider (ii) date of pathology report (iii) unique identifying number/code that links the pathology result to the individual patient.

Authority required

Cystic fibrosis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be 12 years of age or older.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Cystic Fibrosis elexacaftor, tezacaftor with ivacaftor Authority Application Supporting Information Form; and

(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

elexacaftor 100 mg + tezacaftor 50 mg + ivacaftor 75 mg tablet [56] (&) ivacaftor 150 mg tablet [28], 84

12938Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	21422.78	Trikafta [VR]

▪ IVACAFTOR

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

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Cystic fibrosis

Treatment Phase: Initial treatment - New patients

Clinical criteria:

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

Population criteria:

- Patient must be aged 12 months or older.

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

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

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

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

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

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

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

The authority application must be in writing and must include:

(1) a completed authority prescription; and

(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and

(3) details of the pathology report substantiating G551D mutation or other gating (class III) mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and

(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and

(5) sweat chloride result.

Authority required

Cystic fibrosis

Treatment Phase: Continuing treatment

Clinical criteria:

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

Population criteria:

- Patient must be aged 12 months or older.

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

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

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

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

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

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

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

The authority application must be in writing and must include:

(1) a completed authority prescription; and

(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and

(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

ivacaftor 50 mg granules, 56 sachets

11097C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	21422.78	Kalydeco [VR]

ivacaftor 75 mg granules, 56 sachets

11109Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	21422.78	Kalydeco [VR]

ivacaftor 150 mg tablet, 56

10175M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	21422.78	Kalydeco [VR]

▪ LUMACAFTOR + IVACAFTOR

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 Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs

Reply Paid 9826
HOBART TAS 7001

Note For the purposes of this restriction, CFTR modulators, regardless if they are available as a single drug or in combination, are currently: elexacaftor, ivacaftor, lumacaftor, tezacaftor.

Authority required

Cystic fibrosis

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be 12 years of age or older.

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

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

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

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

The authority application must be in writing and must include:

(1) a completed authority prescription; and

(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and

(3) details of the pathology report substantiating the patient being homozygous for the F508del mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and

(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

Authority required

Cystic fibrosis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be 12 years of age or older.

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

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

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

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

The authority application must be in writing and must include:

(1) a completed authority prescription; and

(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and

(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

lumacaftor 200 mg + ivacaftor 125 mg tablet, 112

11463H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	17860.28	Orkambi [VR]

▪ LUMACAFTOR + IVACAFTOR

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note For the purposes of this restriction, CFTR modulators, regardless if they are available as a single drug or in combination, are currently: elexacaftor, ivacaftor, lumacaftor, tezacaftor.

Authority required

Cystic fibrosis

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be aged between 6 and 11 years inclusive.

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

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

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

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

The authority application must be in writing and must include:

(1) a completed authority prescription; and

(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and

(3) details of the pathology report substantiating the patient being homozygous for the F508del mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and

(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

Authority required

Cystic fibrosis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be aged between 6 and 11 years inclusive.

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

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

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

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

The authority application must be in writing and must include:

(1) a completed authority prescription; and

(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and

(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

lumacaftor 100 mg + ivacaftor 125 mg tablet, 112

11464J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	17860.28	Orkambi [VR]

▪ LUMACAFTOR + IVACAFTOR

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 Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note For the purposes of this restriction, CFTR modulators, regardless if they are available as a single drug or in combination, are currently: elexacaftor, ivacaftor, lumacaftor, tezacaftor.

Authority required

Cystic fibrosis

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be 2 years of age or older.

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

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

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

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

The authority application must be in writing and must include:

(1) a completed authority prescription; and

(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and

(3) details of the pathology report substantiating the patient being homozygous for the F508del mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and

(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

Authority required

Cystic fibrosis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be 2 years of age or older.

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

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

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

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.
The authority application must be in writing and must include:
(1) a completed authority prescription; and
(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and
(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

lumacaftor 100 mg + ivacaftor 125 mg granules, 56 sachets

11841F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡1	5	..	17860.28	Orkambi [VR]

lumacaftor 150 mg + ivacaftor 188 mg granules, 56 sachets

11848N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡1	5	..	17860.28	Orkambi [VR]

▪ RAVULIZUMAB

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

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note WARNING: Ravulizumab increases the risk of meningococcal infections (septicaemia and/or meningitis).
Please consult the approved PI for information about vaccination against meningococcal infection.

Note Special Pricing Arrangements apply.

Authority required

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Grandfather (transition from non-PBS-subsidised treatment)

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 March 2022, **AND**
- Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with ravulizumab, **AND**
- Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with ravulizumab, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with ravulizumab, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of condition, the details of which must be kept with the patient's record, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with ravulizumab; OR
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with ravulizumab; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with ravulizumab; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with ravulizumab; OR
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with ravulizumab; OR
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m^2, where causes other than PNH have been excluded prior to commencing treatment with ravulizumab; OR
- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with ravulizumab, **AND**
- The treatment must not be in combination with eculizumab.

Treatment criteria:

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

Population criteria:

- Patient must be aged 18 years or over.

At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested.

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

(i) Haemoglobin (g/L)

(ii) Platelets ($x10^9$/L)

(iii) White Cell Count ($x10^9$/L)

(iv) Reticulocytes ($x10^9$/L)

(v) Neutrophils ($x10^9$/L)

(vi) Granulocyte clone size (%)

(vii) Lactate Dehydrogenase (LDH) and the upper limit of normal (ULN) for the reporting laboratory

(viii) Multiple of LDH , ULN

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'First Continuing Treatment' criteria.

Note This grandfather restriction will cease to operate from 5 years after the date specified in the clinical criteria.

Authority required

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: First Continuing Treatment

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug for this condition under an 'Initial' or 'Grandfather' treatment criteria, **AND**
- The treatment must not be in combination with eculizumab.

Treatment criteria:

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

Population criteria:

- Patient must be aged 18 years or over.

At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested.

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

(i) Haemoglobin (g/L)

(ii) Platelets ($x10^9$/L)

(iii) White Cell Count ($x10^9$/L)

(iv) Reticulocytes ($x10^9$/L)

(v) Neutrophils ($x10^9$/L)

(vi) Granulocyte clone size (%)

(vii) Lactate Dehydrogenase (LDH) and the upper limit of normal (ULN) for the reporting laboratory

(viii) Multiple of LDH , ULN

Authority required

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Subsequent Continuing Treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the 'First Continuing Treatment' or 'Return' criteria, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of condition, **AND**
- The treatment must not be in combination with eculizumab.

Treatment criteria:

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

Population criteria:

- Patient must be aged 18 years or over.

At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested.

ravulizumab 300 mg/3 mL injection, 3 mL vial

12895Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	..	6925.35	Ultomiris [XI]

ravulizumab 1.1 g/11 mL injection, 11 mL vial

12897T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	..	25265.54	Ultomiris [XI]

▪ SILTUXIMAB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note Special Pricing Arrangements apply.

Authority required

Idiopathic multicentric Castleman disease (iMCD)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a diagnosis of iMCD consistent with the latest international, evidence-based consensus diagnostic criteria for this condition with the relevant diagnostic findings documented in the patient's medical records, **AND**
- The condition must not be, to the prescriber's best knowledge, any of the following diseases that can mimic iMCD: (i) human herpes virus-8 infection, (ii) an Epstein-Barr virus-lymphoproliferative disorder, (iii) an acute/uncontrolled infection (e.g. cytomegalovirus, toxoplasmosis, human immunodeficiency virus, tuberculosis) leading to inflammation with adenopathy, (iv) an autoimmune/autoinflammatory disease, (v) a malignant/lymphoproliferative disorder.

Treatment criteria:

- Must be treated by a haematologist; OR
- Must be treated by a medical physician working under the supervision of a haematologist, **AND**
- Patient must be undergoing treatment through this treatment phase once only in a lifetime, where the full number of repeats are prescribed; OR
- Patient must be undergoing treatment through this treatment phase for up to the first 5 doses in a lifetime, where the full number of repeats was not prescribed with the first prescription.

Prescribe the most efficient combination of vials/strengths based on the patient's body weight to keep any amount of unused drug to a minimum.

Note The international, evidence-based consensus iMCD diagnostic criteria developed by an international working group of clinical experts lists various findings under 'Major' and 'Minor' diagnostic criteria that constitute a diagnosis of iMCD. At the time of writing, under these consensus criteria, diagnostic findings that meet: (i) both Major criteria and (ii) at least 2 of 11 Minor criteria including at least 1 laboratory abnormality and (iii) exclude various differential diagnoses, form a diagnosis of iMCD.
Details of these criteria are presented in Table 2 of the following literature article:
Fajgenbaum DC, Uldrick TS, Bagg A, Frank D et. al. International, evidence-based consensus diagnostic criteria for HHV-8-negative/idiopathic multicentric Castleman disease. **Blood** 2017; 129(12): 1646-1657.
Where updates to these diagnostic criteria have occurred since the publication, refer to the latest version.
Do not contact the PBS-administrator to discuss whether an individual patient meets these consensus criteria.

Authority required

Idiopathic multicentric Castleman disease (iMCD)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Treatment criteria:

- Must be treated by a haematologist; OR
- Must be treated by a medical physician working under the supervision of a haematologist.

Prescribe the most efficient combination of vials/strengths based on the patient's body weight to keep any amount of unused drug to a minimum.

siltuximab 100 mg injection, 1 vial

12930M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	4	..	*1606.34	Sylvant [EY]

siltuximab 400 mg injection, 1 vial

12934R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	4	..	*6281.98	Sylvant [EY]

▪ TEZACAFTOR + IVACAFTOR (&) IVACAFTOR

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 Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note For the purposes of this restriction, CFTR modulators, regardless if they are available as a single drug or in combination, are currently: elexacaftor, ivacaftor, lumacaftor, tezacaftor.

Authority required

Cystic fibrosis - one residual function (RF) mutation

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have at least one residual function (RF) mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor with ivacaftor, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities.

Population criteria:

- Patient must be 12 years of age or older.

For the purposes of this restriction, the list of mutations considered to be responsive to tezacaftor with ivacaftor is defined in the TGA approved product information.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

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

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

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

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

The authority application must be in writing and must include:

(1) a completed authority prescription; and

(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and

(3) details of the pathology report substantiating the patient having at least one RF mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient ; and

(4) CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

Authority required

Cystic fibrosis - one residual function (RF) mutation

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be 12 years of age or older.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

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

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

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

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

The authority application must be in writing and must include:

(1) a completed authority prescription; and

(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and

(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

tezacaftor 100 mg + ivacaftor 150 mg tablet [28] (&) ivacaftor 150 mg tablet [28], 56

11833T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	19997.78	Symdeko [VR]

▪ TEZACAFTOR + IVACAFTOR (&) IVACAFTOR

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 Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note For the purposes of this restriction, CFTR modulators, regardless if they are available as a single drug or in combination, are currently: elexacaftor, ivacaftor, lumacaftor, tezacaftor.

Authority required

Cystic fibrosis - homozygous for the F508del mutation

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities.

Population criteria:

- Patient must be 12 years of age or older.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

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

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

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

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

The authority application must be in writing and must include:

(1) a completed authority prescription; and

(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and

(3) details of the pathology report substantiating the patient being homozygous for the F508del mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and

(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

Authority required

Cystic fibrosis - homozygous for the F508del mutation

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**

- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be 12 years of age or older.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

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

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

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

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

The authority application must be in writing and must include:

(1) a completed authority prescription; and

(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and

(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

tezacaftor 100 mg + ivacaftor 150 mg tablet [28] (&) ivacaftor 150 mg tablet [28], 56

11834W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	19997.78	Symdeko [VR]

Highly Specialised Drugs Program (Public Hospital)

▪ AZACITIDINE

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Acute Myeloid Leukaemia

Clinical criteria:

- The treatment must be used in combination with venetoclax (refer to Product Information for timing of azacitidine and venetoclax doses).

azacitidine 100 mg injection, 1 vial

12771E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
14	2	..	*1345.96	[a] Azacitidine Accord [OC]	[a] AZACITIDINE DR.REDDY'S [RI]
				[a] Azacitidine Juno [JO]	[a] Azacitidine MSN [JU]
				[a] Azacitidine-Teva [TB]	[a] Azadine [RZ]

▪ ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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 For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor and elexacaftor/ tezacaftor/ ivacaftor.

Note Special Pricing Arrangements apply.

Authority required

Cystic fibrosis

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have at least one F508del mutation in the cystic fibrosis transmembrane conductance (CFTR) gene, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, prior to initiating treatment with this drug.

Population criteria:

- Patient must be 12 years of age or older.

The patient must be registered in the Australian Cystic Fibrosis Database Registry.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Cystic Fibrosis elexacaftor, tezacaftor with ivacaftor Authority Application Supporting Information Form; and

(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and

(4) details of the name of the molecular testing for the patient having at least one F508del mutation including: (i) name of the pathology report provider (ii) date of pathology report (iii) unique identifying number/code that links the pathology result to the individual patient.

Authority required

Cystic fibrosis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be 12 years of age or older.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Cystic Fibrosis elexacaftor, tezacaftor with ivacaftor Authority Application Supporting Information Form; and

(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

elexacaftor 100 mg + tezacaftor 50 mg + ivacaftor 75 mg tablet [56] (&) ivacaftor 150 mg tablet [28], 84

12936W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	21375.00	Trikafta [VR]

▪ IVACAFTOR

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

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Cystic fibrosis

Treatment Phase: Initial treatment - New patients

Clinical criteria:

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

Population criteria:

- Patient must be aged 12 months or older.

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

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

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

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

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

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

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

The authority application must be in writing and must include:

(1) a completed authority prescription; and

(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and

(3) details of the pathology report substantiating G551D mutation or other gating (class III) mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and

(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and

(5) sweat chloride result.

Authority required

Cystic fibrosis

Treatment Phase: Continuing treatment

Clinical criteria:

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

Population criteria:

- Patient must be aged 12 months or older.

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

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

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

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

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

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

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

The authority application must be in writing and must include:

(1) a completed authority prescription; and

(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and

(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

ivacaftor 50 mg granules, 56 sachets

11105L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	21375.00	Kalydeco [VR]

ivacaftor 75 mg granules, 56 sachets

11098D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	21375.00	Kalydeco [VR]

ivacaftor 150 mg tablet, 56

10170G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	21375.00	Kalydeco [VR]

▪ LUMACAFTOR + IVACAFTOR

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 Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs

Reply Paid 9826
HOBART TAS 7001

Note For the purposes of this restriction, CFTR modulators, regardless if they are available as a single drug or in combination, are currently: elexacaftor, ivacaftor, lumacaftor, tezacaftor.

Authority required

Cystic fibrosis

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be aged between 6 and 11 years inclusive.

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

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

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

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

The authority application must be in writing and must include:

(1) a completed authority prescription; and

(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and

(3) details of the pathology report substantiating the patient being homozygous for the F508del mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and

(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

Authority required

Cystic fibrosis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be aged between 6 and 11 years inclusive.

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

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

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

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

The authority application must be in writing and must include:

(1) a completed authority prescription; and

(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and

(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

lumacaftor 100 mg + ivacaftor 125 mg tablet, 112

11465K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	17812.50	Orkambi [VR]

▪ LUMACAFTOR + IVACAFTOR

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note For the purposes of this restriction, CFTR modulators, regardless if they are available as a single drug or in combination, are currently: elexacaftor, ivacaftor, lumacaftor, tezacaftor.

Authority required

Cystic fibrosis

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be 12 years of age or older.

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

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

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

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

The authority application must be in writing and must include:

(1) a completed authority prescription; and

(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and

(3) details of the pathology report substantiating the patient being homozygous for the F508del mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and

(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

Authority required

Cystic fibrosis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be 12 years of age or older.

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

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

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

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

The authority application must be in writing and must include:

(1) a completed authority prescription; and

(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and

(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

lumacaftor 200 mg + ivacaftor 125 mg tablet, 112

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
11466L	1	5	..	17812.50	Orkambi [VR]

▪ LUMACAFTOR + IVACAFTOR

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 Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note For the purposes of this restriction, CFTR modulators, regardless if they are available as a single drug or in combination, are currently: elexacaftor, ivacaftor, lumacaftor, tezacaftor.

Authority required

Cystic fibrosis

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be 2 years of age or older.

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

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

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

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

The authority application must be in writing and must include:

(1) a completed authority prescription; and

(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and

(3) details of the pathology report substantiating the patient being homozygous for the F508del mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and

(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

Authority required

Cystic fibrosis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be 2 years of age or older.

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

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

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

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.
The authority application must be in writing and must include:
(1) a completed authority prescription; and
(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and
(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

lumacaftor 100 mg + ivacaftor 125 mg granules, 56 sachets

11866M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡1	5	..	17812.50	Orkambi [VR]

lumacaftor 150 mg + ivacaftor 188 mg granules, 56 sachets

11851R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡1	5	..	17812.50	Orkambi [VR]

▪ RAVULIZUMAB

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

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note WARNING: Ravulizumab increases the risk of meningococcal infections (septicaemia and/or meningitis).
Please consult the approved PI for information about vaccination against meningococcal infection.

Note Special Pricing Arrangements apply.

Authority required

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Grandfather (transition from non-PBS-subsidised treatment)

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 March 2022, **AND**
- Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with ravulizumab, **AND**
- Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with ravulizumab, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with ravulizumab, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of condition, the details of which must be kept with the patient's record, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with ravulizumab; OR
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with ravulizumab; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with ravulizumab; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with ravulizumab; OR
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with ravulizumab; OR
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m^2, where causes other than PNH have been excluded prior to commencing treatment with ravulizumab; OR
- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with ravulizumab, **AND**
- The treatment must not be in combination with eculizumab.

Treatment criteria:

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

Population criteria:

- Patient must be aged 18 years or over.

At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested.

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

(i) Haemoglobin (g/L)

(ii) Platelets ($x10^9$/L)

(iii) White Cell Count ($x10^9$/L)

(iv) Reticulocytes ($x10^9$/L)

(v) Neutrophils ($x10^9$/L)

(vi) Granulocyte clone size (%)

(vii) Lactate Dehydrogenase (LDH) and the upper limit of normal (ULN) for the reporting laboratory

(viii) Multiple of LDH , ULN

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'First Continuing Treatment' criteria.

Note This grandfather restriction will cease to operate from 5 years after the date specified in the clinical criteria.

Authority required

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: First Continuing Treatment

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug for this condition under an 'Initial' or 'Grandfather' treatment criteria, **AND**
- The treatment must not be in combination with eculizumab.

Treatment criteria:

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

Population criteria:

- Patient must be aged 18 years or over.

At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested.

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

(i) Haemoglobin (g/L)

(ii) Platelets ($x10^9$/L)

(iii) White Cell Count ($x10^9$/L)

(iv) Reticulocytes ($x10^9$/L)

(v) Neutrophils ($x10^9$/L)

(vi) Granulocyte clone size (%)

(vii) Lactate Dehydrogenase (LDH) and the upper limit of normal (ULN) for the reporting laboratory

(viii) Multiple of LDH , ULN

Authority required

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Subsequent Continuing Treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the 'First Continuing Treatment' or 'Return' criteria, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of condition, **AND**
- The treatment must not be in combination with eculizumab.

Treatment criteria:

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

Population criteria:

- Patient must be aged 18 years or over.

At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested.

ravulizumab 300 mg/3 mL injection, 3 mL vial

12884D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	..	6877.57	Ultomiris [XI]

ravulizumab 1.1 g/11 mL injection, 11 mL vial

12883C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	..	25217.76	Ultomiris [XI]

▪ SILTUXIMAB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note Special Pricing Arrangements apply.

Authority required

Idiopathic multicentric Castleman disease (iMCD)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a diagnosis of iMCD consistent with the latest international, evidence-based consensus diagnostic criteria for this condition with the relevant diagnostic findings documented in the patient's medical records, **AND**
- The condition must not be, to the prescriber's best knowledge, any of the following diseases that can mimic iMCD: (i) human herpes virus-8 infection, (ii) an Epstein-Barr virus-lymphoproliferative disorder, (iii) an acute/uncontrolled infection (e.g. cytomegalovirus, toxoplasmosis, human immunodeficiency virus, tuberculosis) leading to inflammation with adenopathy, (iv) an autoimmune/autoinflammatory disease, (v) a malignant/lymphoproliferative disorder.

Treatment criteria:

- Must be treated by a haematologist; OR
- Must be treated by a medical physician working under the supervision of a haematologist, **AND**
- Patient must be undergoing treatment through this treatment phase once only in a lifetime, where the full number of repeats are prescribed; OR
- Patient must be undergoing treatment through this treatment phase for up to the first 5 doses in a lifetime, where the full number of repeats was not prescribed with the first prescription.

Prescribe the most efficient combination of vials/strengths based on the patient's body weight to keep any amount of unused drug to a minimum.

Note The international, evidence-based consensus iMCD diagnostic criteria developed by an international working group of clinical experts lists various findings under 'Major' and 'Minor' diagnostic criteria that constitute a diagnosis of iMCD. At the time of writing, under these consensus criteria, diagnostic findings that meet: (i) both Major criteria and (ii) at least 2 of 11 Minor criteria including at least 1 laboratory abnormality and (iii) exclude various differential diagnoses, form a diagnosis of iMCD.
Details of these criteria are presented in Table 2 of the following literature article:
Fajgenbaum DC, Uldrick TS, Bagg A, Frank D et. al. International, evidence-based consensus diagnostic criteria for HHV-8-negative/idiopathic multicentric Castleman disease. **Blood** 2017; 129(12): 1646-1657.
Where updates to these diagnostic criteria have occurred since the publication, refer to the latest version.
Do not contact the PBS-administrator to discuss whether an individual patient meets these consensus criteria.

Authority required

Idiopathic multicentric Castleman disease (iMCD)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Treatment criteria:

- Must be treated by a haematologist; OR
- Must be treated by a medical physician working under the supervision of a haematologist.

Prescribe the most efficient combination of vials/strengths based on the patient's body weight to keep any amount of unused drug to a minimum.

siltuximab 100 mg injection, 1 vial

12916T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	4	..	*1558.56	Sylvant [EY]

siltuximab 400 mg injection, 1 vial

12922D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	4	..	*6234.20	Sylvant [EY]

▪ TEZACAFTOR + IVACAFTOR (&) IVACAFTOR

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 Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note For the purposes of this restriction, CFTR modulators, regardless if they are available as a single drug or in combination, are currently: elexacaftor, ivacaftor, lumacaftor, tezacaftor.

Authority required

Cystic fibrosis - homozygous for the F508del mutation

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities.

Population criteria:

- Patient must be 12 years of age or older.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

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

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

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

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

The authority application must be in writing and must include:

(1) a completed authority prescription; and

(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and

(3) details of the pathology report substantiating the patient being homozygous for the F508del mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and

(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

Authority required

Cystic fibrosis - homozygous for the F508del mutation

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be 12 years of age or older.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

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

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

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

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

The authority application must be in writing and must include:

(1) a completed authority prescription; and

(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and

(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

tezacaftor 100 mg + ivacaftor 150 mg tablet [28] (&) ivacaftor 150 mg tablet [28], 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
11854X	1	5	..	19950.00	Symdeko [VR]

▪ TEZACAFTOR + IVACAFTOR (&) IVACAFTOR

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 Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note For the purposes of this restriction, CFTR modulators, regardless if they are available as a single drug or in combination, are currently: elexacaftor, ivacaftor, lumacaftor, tezacaftor.

Authority required

Cystic fibrosis - one residual function (RF) mutation

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have at least one residual function (RF) mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor with ivacaftor, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities.

Population criteria:

- Patient must be 12 years of age or older.

For the purposes of this restriction, the list of mutations considered to be responsive to tezacaftor with ivacaftor is defined in the TGA approved product information.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

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

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

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

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

The authority application must be in writing and must include:

(1) a completed authority prescription; and

(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and

(3) details of the pathology report substantiating the patient having at least one RF mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient ; and

(4) CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

Authority required

Cystic fibrosis - one residual function (RF) mutation

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**

- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be 12 years of age or older.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

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

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

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

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

The authority application must be in writing and must include:

(1) a completed authority prescription; and

(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and

(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

tezacaftor 100 mg + ivacaftor 150 mg tablet [28] (&) ivacaftor 150 mg tablet [28], 56

11863J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	19950.00	Symdeko [VR]

Highly Specialised Drugs Program (Community Access)

▪ CABOTEGRAVIR

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)
12619
HIV infection
Clinical criteria:

- Patient must be virologically suppressed on a stable antiretroviral regimen for at least 6 months, **AND**
- The treatment must be in combination with rilpivirine tablets, **AND**
- Patient must intend to proceed to treatment with intramuscular administration of cabotegravir and rilpivirine.

cabotegravir 30 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12939B NP	1	..	..	665.34	42.50	Vocabria [VI]

▪ CABOTEGRAVIR (&) RILPIVIRINE

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.
Note It is recommended that patients have previously received 4 weeks of PBS-subsidised initial oral lead-in treatment with cabotegravir and rilpivirine.

Authority required (STREAMLINED)
12636
HIV infection
Clinical criteria:

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

cabotegravir 600 mg/3 mL modified release injection [3 mL vial] (&) rilpivirine 900 mg/3 mL modified release injection [3 mL vial], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12937X NP	1	5	..	2827.78	42.50	Cabenuva [VI]

Growth Hormone Program

▪ SOMATROPIN

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

Authority required

Severe growth hormone deficiency

Treatment Phase: Initial treatment of late onset growth hormone deficiency

Treatment criteria:

- Must be treated by an endocrinologist.

Clinical criteria:

- Patient must have onset of growth hormone deficiency secondary to organic hypothalamic or pituitary disease diagnosed at chronological age of 18 years or older; OR
- Patient must have onset of growth hormone deficiency diagnosed after skeletal maturity (bone age greater than or equal to 15.5 years in males or 13.5 years in females) and before chronological age of 18 years, **AND**
- Patient must have a diagnostic insulin tolerance test with maximum serum growth hormone (GH) less than 2.5 micrograms per litre; OR
- Patient must have a diagnostic arginine infusion test with maximum serum GH less than 0.4 micrograms per litre; OR
- Patient must have a diagnostic glucagon provocation test with maximum serum GH less than 3 micrograms per litre.

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Severe Growth Hormone Deficiency supporting information form; AND
3. Results of the growth hormone stimulation testing, including the date of testing, the type of test performed, the peak growth hormone concentration, and laboratory reference range for age/gender.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe growth hormone deficiency

Treatment Phase: Continuing treatment in a person with a mature skeleton or aged 18 years or older

Treatment criteria:

- Must be treated by an endocrinologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy with this drug for this condition under an initial treatment restriction applying to a documented childhood onset growth hormone deficiency due to a congenital, genetic or structural cause in a patient with a mature skeleton, or, in a patient with Prader-Willi syndrome and chronological age of 18 years or older; OR
- Patient must have previously received PBS-subsidised therapy with this drug for this condition under an initial treatment restriction applying to late onset of growth hormone deficiency secondary to organic hypothalamic or pituitary disease in a patient with chronological age of 18 years or older; OR
- Patient must have previously received PBS-subsidised therapy with this drug for this condition under an initial treatment restriction applying to late onset of growth hormone deficiency diagnosed after skeletal maturity (bone age greater than or equal to 15.5 years in males or 13.5 years in females) and before chronological age of 18 years.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Severe growth hormone deficiency

Treatment Phase: Initial treatment of childhood onset growth hormone deficiency in a patient who has received PBS-subsidised treatment as a child

Treatment criteria:

- Must be treated by an endocrinologist.

Clinical criteria:

- Patient must have a documented childhood onset growth hormone deficiency due to a congenital, genetic or structural cause, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition as a child.

Population criteria:

- Patient must have a mature skeleton; OR
- Patient must have a diagnosis of Prader-Willi syndrome and be aged 18 years or older.

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Severe Growth Hormone Deficiency supporting information form.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe growth hormone deficiency

Treatment Phase: Initial treatment of childhood onset growth hormone deficiency in a patient who has received non-PBS subsidised treatment as a child

Treatment criteria:

- Must be treated by an endocrinologist.

Clinical criteria:

- Patient must have a documented childhood onset growth hormone deficiency due to a congenital, genetic or structural cause, **AND**
- Patient must have previously received non-PBS subsidised treatment with this drug for this condition as a child, **AND**
- Patient must have current or historical evidence of an insulin tolerance test with maximum serum growth hormone (GH) less than 2.5 micrograms per litre; OR
- Patient must have current or historical evidence of an arginine infusion test with maximum serum GH less than 0.4 micrograms per litre; OR
- Patient must have current or historical evidence of a glucagon provocation test with maximum serum GH less than 3 micrograms per litre.

Population criteria:

- Patient must have a mature skeleton; OR
- Patient must have a diagnosis of Prader-Willi syndrome and be aged 18 years or older.

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Severe Growth Hormone Deficiency supporting information form; AND
3. Results of the growth hormone stimulation testing, including the date of testing, the type of test performed, the peak growth hormone concentration, and laboratory reference range for age/gender.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

---

somatropin 12 mg injection [1 chamber] (&) inert substance diluent [1 mL chamber], 1 dual chamber pen device

11495B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	510.59	42.50	Genotropin GoQuick [PF]

somatropin 5 mg injection [1 chamber] (&) inert substance diluent [1 mL chamber], 1 dual chamber pen device

11493X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	217.29	42.50	Genotropin GoQuick [PF]

somatropin 10 mg/2 mL injection, 2 mL cartridge

11650E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	426.80	42.50	NutropinAq [IS]

somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge

11895C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	217.29	42.50	Norditropin FlexPro [NO]