



**Australian Government**

**Department of Health  
and Aged Care**



# Schedule of Pharmaceutical Benefits

Summary of Changes

**Effective 1 April 2023**



# Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 April 2023 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	\$7.82
	Dangerous drug fee	\$4.84
	Extemporaneously-prepared	\$9.86
	Allowable additional patient charge*	\$3.29
Additional Fees (for safety net prices):	Ready-prepared	\$1.31
	Extemporaneously-prepared	\$1.68
Patient Co-payments:	General	\$30.00
	Concessional	\$7.30
Safety Net Thresholds:	General	\$1563.50
	Concessional	\$262.80
Safety Net Card Issue Fee:		\$11.42

\* 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 2023. The Schedule is updated on the first day of each month and is available on the internet at [www.pbs.gov.au](http://www.pbs.gov.au).

## Prescriber Bag

### Deletions

#### Deletion – Brand

- 3479D *DBL Morphine Sulfate Pentahydrate, PF* – **MORPHINE**, morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules
- 3480E *DBL Morphine Sulfate Pentahydrate, PF* – **MORPHINE**, morphine sulfate pentahydrate 30 mg/mL injection, 5 x 1 mL ampoules

#### Deletion – Equivalence Indicator

- 3479D *MORPHINE SULFATE 15 mg/1 mL MEDSURGE, DZ* – **MORPHINE**, morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules
- 3480E *MORPHINE SULFATE 30 mg/1 mL MEDSURGE, DZ* – **MORPHINE**, morphine sulfate pentahydrate 30 mg/mL injection, 5 x 1 mL ampoules

## General Pharmaceutical Benefits

### Additions

#### Addition – Item

- 13247F **MESALAZINE**, mesalazine 1.2 g modified release tablet, 120 (*MESALZ*)
- 13233L **OXYCODONE**, oxycodone hydrochloride 5 mg tablet, 10 (*ENDONE, Oxycodone Viatris*)
- 13234M **OXYCODONE**, oxycodone hydrochloride 5 mg tablet, 10 (*ENDONE, Oxycodone Viatris*)
- 13241X **RUXOLITINIB**, ruxolitinib 5 mg tablet, 56 (*Jakavi*)
- 13235N **RUXOLITINIB**, ruxolitinib 10 mg tablet, 56 (*Jakavi*)

#### Addition – Brand

- 8625Y *Rilast TURBUHALER 200/6, ZA* – **BUDESONIDE + FORMOTEROL (EFORMOTEROL)**, budesonide 200 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations
- 10203B *Estro-Pess, AS* – **ESTRADIOL**, estradiol 10 microgram modified release pessary, 18
- 5262Y *AKM Fingolimod, RW* – **FINGOLIMOD**, fingolimod 500 microgram capsule, 28
- 5262Y *Fingolimod SUN, RA* – **FINGOLIMOD**, fingolimod 500 microgram capsule, 28
- 8565T *Recagon, OV* – **FOLLITROPIN BETA**, follitropin beta 300 units/0.36 mL injection, 0.36 mL cartridge
- 8566W *Recagon, OV* – **FOLLITROPIN BETA**, follitropin beta 600 units/0.72 mL injection, 0.72 mL cartridge
- 8871X *Recagon, OV* – **FOLLITROPIN BETA**, follitropin beta 900 units/1.08 mL injection, 1.08 mL cartridge
- 1976B *Icatibant Lupin, GQ* – **ICATIBANT**, icatibant 30 mg/3 mL injection, 3 mL syringe
- 12626M *Lacosam, AF* – **LACOSAMIDE**, lacosamide 50 mg tablet, 14
- 12634Y *Lacosam, AF* – **LACOSAMIDE**, lacosamide 100 mg tablet, 56
- 12627N *Lacosam, AF* – **LACOSAMIDE**, lacosamide 150 mg tablet, 56

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12658F	<i>Lacosam, AF</i> – <b>LACOSAMIDE</b> , lacosamide 200 mg tablet, 56
3440C	<i>Rubifen LA, AE</i> – <b>METHYLPHENIDATE</b> , methylphenidate hydrochloride 10 mg modified release capsule, 30
2276T	<i>Rubifen LA, AE</i> – <b>METHYLPHENIDATE</b> , methylphenidate hydrochloride 20 mg modified release capsule, 30
2280B	<i>Rubifen LA, AE</i> – <b>METHYLPHENIDATE</b> , methylphenidate hydrochloride 30 mg modified release capsule, 30
2283E	<i>Rubifen LA, AE</i> – <b>METHYLPHENIDATE</b> , methylphenidate hydrochloride 40 mg modified release capsule, 30
12116Q	<i>Rubifen LA, AE</i> – <b>METHYLPHENIDATE</b> , methylphenidate hydrochloride 60 mg modified release capsule, 30
9316H	<i>Nebivolol Lupin, GQ</i> – <b>NEBIVOLOL</b> , nebivolol 1.25 mg tablet, 28
9311C	<i>Nebivolol Lupin, GQ</i> – <b>NEBIVOLOL</b> , nebivolol 5 mg tablet, 28
9312D	<i>Nebivolol Lupin, GQ</i> – <b>NEBIVOLOL</b> , nebivolol 10 mg tablet, 28
2348N	<i>Pregabalin Lupin, HQ</i> – <b>PREGABALIN</b> , pregabalin 25 mg capsule, 56
2335X	<i>Pregabalin Lupin, HQ</i> – <b>PREGABALIN</b> , pregabalin 75 mg capsule, 56
2355Y	<i>Pregabalin Lupin, HQ</i> – <b>PREGABALIN</b> , pregabalin 150 mg capsule, 56
2363J	<i>Pregabalin Lupin, HQ</i> – <b>PREGABALIN</b> , pregabalin 300 mg capsule, 56
1952R	<i>Rasagiline Lupin, HQ</i> – <b>RASAGILINE</b> , rasagiline 1 mg tablet, 30
10784N	<i>Bactrim DS, XO</i> – <b>TRIMETHOPRIM + SULFAMETHOXAZOLE</b> , trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10
2951H	<i>Bactrim DS, XO</i> – <b>TRIMETHOPRIM + SULFAMETHOXAZOLE</b> , trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10
3390K	<i>Bactrim DS, XO</i> – <b>TRIMETHOPRIM + SULFAMETHOXAZOLE</b> , trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10
5469W	<i>VARENAPIX, TX</i> – <b>VARENICLINE</b> , varenicline 1 mg tablet, 56
9129L	<i>VARENAPIX, TX</i> – <b>VARENICLINE</b> , varenicline 1 mg tablet, 56

#### **Addition – Equivalence Indicator**

10203B	<i>Vagifem Low, NO</i> – <b>ESTRADIOL</b> , estradiol 10 microgram modified release pessary, 18
8565T	<i>Puregon 300 IU/0.36 mL, OQ</i> – <b>FOLLITROPIN BETA</b> , follitropin beta 300 units/0.36 mL injection, 0.36 mL cartridge
8566W	<i>Puregon 600 IU/0.72 mL, OQ</i> – <b>FOLLITROPIN BETA</b> , follitropin beta 600 units/0.72 mL injection, 0.72 mL cartridge
8871X	<i>Puregon 900 IU/1.08 mL, OQ</i> – <b>FOLLITROPIN BETA</b> , follitropin beta 900 units/1.08 mL injection, 1.08 mL cartridge
3440C	<i>Ritalin LA, NV</i> – <b>METHYLPHENIDATE</b> , methylphenidate hydrochloride 10 mg modified release capsule, 30
2276T	<i>Ritalin LA, NV</i> – <b>METHYLPHENIDATE</b> , methylphenidate hydrochloride 20 mg modified release capsule, 30
2280B	<i>Ritalin LA, NV</i> – <b>METHYLPHENIDATE</b> , methylphenidate hydrochloride 30 mg modified release capsule, 30
2283E	<i>Ritalin LA, NV</i> – <b>METHYLPHENIDATE</b> , methylphenidate hydrochloride 40 mg modified release capsule, 30
12116Q	<i>Ritalin LA, NV</i> – <b>METHYLPHENIDATE</b> , methylphenidate hydrochloride 60 mg modified release capsule, 30

#### **Addition – Note**

2997R	<b>CALCITONIN SALMON (SALCATONIN)</b> , calcitonin salmon (salcatonin) 100 units/mL injection, 5 x 1 mL ampoules ( <i>Miacalcic 100</i> )
8516F	<b>FLUTICASONE PROPIONATE</b> , fluticasone propionate 50 microgram/actuation inhalation, 120 actuations ( <i>Axotide Junior, Flixotide Junior</i> )
9353G	<b>MESALAZINE</b> , mesalazine 1.2 g modified release tablet, 60 ( <i>Mesalazine 1.2 TAKEDA, Mezavant</i> )
1629R	<b>METHYLDOPA</b> , methyldopa 250 mg tablet, 100 ( <i>Aldomet</i> )

#### **Addition – Restriction**

8516F	<b>FLUTICASONE PROPIONATE</b> , fluticasone propionate 50 microgram/actuation inhalation, 120 actuations ( <i>Axotide Junior, Flixotide Junior</i> )
1629R	<b>METHYLDOPA</b> , methyldopa 250 mg tablet, 100 ( <i>Aldomet</i> )

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12996B **NIRMATRELVIR (& RITONAVIR**, nirmatrelvir 150 mg tablet [4] (&) ritonavir 100 mg tablet [2], 5 x 6 (*Paxlovid*)

## Deletions

### Deletion – Item

8083K **APRACLONIDINE**, apraclonidine 0.5% eye drops, 10 mL (*Iopidine 0.5%*)

12838Q **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL cartridges (*Enbrel*)

12845C **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL cartridges (*Enbrel*)

12848F **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL cartridges (*Enbrel*)

12852K **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL cartridges (*Enbrel*)

12853L **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL cartridges (*Enbrel*)

12863B **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL cartridges (*Enbrel*)

12870J **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL cartridges (*Enbrel*)

12871K **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL cartridges (*Enbrel*)

12873M **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL cartridges (*Enbrel*)

12874N **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL cartridges (*Enbrel*)

12875P **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL cartridges (*Enbrel*)

12881Y **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL cartridges (*Enbrel*)

12882B **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL cartridges (*Enbrel*)

12893N **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL cartridges (*Enbrel*)

12894P **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL cartridges (*Enbrel*)

1413J **ETHOSUXIMIDE**, ethosuximide 250 mg capsule, 200 (*Zarontin*)

13127X **ETHOSUXIMIDE**, ethosuximide 250 mg capsule, 56 (*Ethosuximide Essential Generics*)

8805K **INTERFERON BETA-1A**, interferon beta-1a 6 million units (30 microgram)/0.5 mL injection, 4 x 0.5 mL syringes (*Avonex*)

13098J **OXYBUTYNIN**, oxybutynin hydrochloride 5 mg tablet, 100 (*Oxybutynin Chloride (Novitium)*)

13176L **OXYBUTYNIN**, oxybutynin hydrochloride 5 mg tablet, 84 (*Oxybutynin hydrochloride tablets (Niche Generics Limited)*)

12023T **OXYCODONE**, oxycodone hydrochloride 5 mg tablet, 20 (*Endone, Mayne Pharma Oxycodone IR, Oxycodone Mylan, Oxycodone Viatris, Oxyndone*)

12048D **OXYCODONE**, oxycodone hydrochloride 5 mg tablet, 20 (*Endone, Mayne Pharma Oxycodone IR, Oxycodone Mylan, Oxycodone Viatris, Oxyndone*)

8619P **TESTOSTERONE**, testosterone 5 mg/24 hours patch, 30 (*Androderm*)

### Deletion – Brand

8179L *Anastrol, TB* – **ANASTROZOLE**, anastrozole 1 mg tablet, 30

9092M *Strattera, LY* – **ATOMOXETINE**, atomoxetine 10 mg capsule, 28

9093N *Strattera, LY* – **ATOMOXETINE**, atomoxetine 18 mg capsule, 28

9094P *Strattera, LY* – **ATOMOXETINE**, atomoxetine 25 mg capsule, 28

9095Q *Strattera, LY* – **ATOMOXETINE**, atomoxetine 40 mg capsule, 28

9096R *Strattera, LY* – **ATOMOXETINE**, atomoxetine 60 mg capsule, 28

9289X *Strattera, LY* – **ATOMOXETINE**, atomoxetine 80 mg capsule, 28

9290Y *Strattera, LY* – **ATOMOXETINE**, atomoxetine 100 mg capsule, 28

2436F *Natrilix, SE* – **INDAPAMIDE**, indapamide hemihydrate 2.5 mg tablet, 90

8196J *Sporanox, JC* – **ITRACONAZOLE**, itraconazole 100 mg capsule, 60

1644M *DBL Morphine Sulfate Pentahydrate, PF* – **MORPHINE**, morphine sulfate pentahydrate 10 mg/mL injection, 5 x 1 mL ampoules

5168B *DBL Morphine Sulfate Pentahydrate, PF* – **MORPHINE**, morphine sulfate pentahydrate 10 mg/mL injection, 5 x 1 mL ampoules

1645N	<i>DBL Morphine Sulfate Pentahydrate, PF</i> – <b>MORPHINE</b> , morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules
5169C	<i>DBL Morphine Sulfate Pentahydrate, PF</i> – <b>MORPHINE</b> , morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules
1647Q	<i>DBL Morphine Sulfate Pentahydrate, PF</i> – <b>MORPHINE</b> , morphine sulfate pentahydrate 30 mg/mL injection, 5 x 1 mL ampoules
5170D	<i>DBL Morphine Sulfate Pentahydrate, PF</i> – <b>MORPHINE</b> , morphine sulfate pentahydrate 30 mg/mL injection, 5 x 1 mL ampoules
8456C	<i>Quetiapine-DRLA, RZ</i> – <b>QUETIAPINE</b> , quetiapine 25 mg tablet, 60
8457D	<i>Quetiapine-DRLA, RZ</i> – <b>QUETIAPINE</b> , quetiapine 100 mg tablet, 90
8458E	<i>Quetiapine-DRLA, RZ</i> – <b>QUETIAPINE</b> , quetiapine 200 mg tablet, 60
8580N	<i>Quetiapine-DRLA, RZ</i> – <b>QUETIAPINE</b> , quetiapine 300 mg tablet, 60

### Deletion – Equivalence Indicator

11703Y	<i>Zarontin, IX</i> – <b>ETHOSUXIMIDE</b> , ethosuximide 250 mg capsule, 100
1645N	<i>MORPHINE SULFATE 15 mg/1 mL MEDSURGE, DZ</i> – <b>MORPHINE</b> , morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules
5169C	<i>MORPHINE SULFATE 15 mg/1 mL MEDSURGE, DZ</i> – <b>MORPHINE</b> , morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules
1647Q	<i>MORPHINE SULFATE 30 mg/1 mL MEDSURGE, DZ</i> – <b>MORPHINE</b> , morphine sulfate pentahydrate 30 mg/mL injection, 5 x 1 mL ampoules
5170D	<i>MORPHINE SULFATE 30 mg/1 mL MEDSURGE, DZ</i> – <b>MORPHINE</b> , morphine sulfate pentahydrate 30 mg/mL injection, 5 x 1 mL ampoules
8039D	<i>Ditropan, SW</i> – <b>OXYBUTYNIN</b> , oxybutynin hydrochloride 5 mg tablet, 100

### Deletion – Note

11703Y	<b>ETHOSUXIMIDE</b> , ethosuximide 250 mg capsule, 100 ( <i>Zarontin</i> )
8039D	<b>OXYBUTYNIN</b> , oxybutynin hydrochloride 5 mg tablet, 100 ( <i>Ditropan</i> )

## Alterations

### Alteration – Item Description

<i>From</i>	
1426C	<b>INSULIN ISOPHANE HUMAN + INSULIN NEUTRAL HUMAN</b> , insulin neutral human 30 units/mL + insulin isophane human 70 units/mL injection, 1 x 10 mL vial ( <i>Humulin 30/70</i> )
<i>To</i>	
1426C	<b>INSULIN NEUTRAL HUMAN + INSULIN ISOPHANE HUMAN</b> , insulin neutral human 30 units/mL + insulin isophane human 70 units/mL injection, 10 mL vial ( <i>Humulin 30/70</i> )
<i>From</i>	
12255B	<b>INSULIN ISOPHANE HUMAN + INSULIN NEUTRAL HUMAN</b> , insulin isophane human 70 units/mL + insulin neutral human 30 units/mL injection, 5 x 3 mL pen devices ( <i>Mixtard 30/70 InnoLet</i> )
<i>To</i>	
12255B	<b>INSULIN NEUTRAL HUMAN + INSULIN ISOPHANE HUMAN</b> , insulin neutral human 30 units/mL + insulin isophane human 70 units/mL injection, 5 x 3 mL pen devices ( <i>Mixtard 30/70 InnoLet</i> )
<i>From</i>	
1763T	<b>INSULIN ISOPHANE HUMAN + INSULIN NEUTRAL HUMAN</b> , insulin isophane human 70 units/mL + insulin neutral human 30 units/mL injection, 5 x 3 mL cartridges ( <i>Humulin 30/70, Mixtard 30/70 Penfill 3 mL</i> )
<i>To</i>	
1763T	<b>INSULIN NEUTRAL HUMAN + INSULIN ISOPHANE HUMAN</b> , insulin neutral human 30 units/mL + insulin isophane human 70 units/mL injection, 5 x 3 mL cartridges ( <i>Humulin 30/70, Mixtard 30/70 Penfill 3 mL</i> )
<i>From</i>	
2062M	<b>INSULIN ISOPHANE HUMAN + INSULIN NEUTRAL HUMAN</b> , insulin neutral human 50 units/mL + insulin isophane human 50 units/mL injection, 5 x 3 mL cartridges ( <i>Mixtard 50/50 Penfill 3 mL</i> )
<i>To</i>	
2062M	<b>INSULIN NEUTRAL HUMAN + INSULIN ISOPHANE HUMAN</b> , insulin neutral human 50 units/mL + insulin isophane human 50 units/mL injection, 5 x 3 mL cartridges ( <i>Mixtard 50/50 Penfill 3 mL</i> )

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**Alteration – Brand Name**

From	
2622B	Endone, AF – <b>OXYCODONE</b> , oxycodone hydrochloride 5 mg tablet, 20
To	
2622B	ENDONE, AF – <b>OXYCODONE</b> , oxycodone hydrochloride 5 mg tablet, 20
From	
5195K	Endone, AF – <b>OXYCODONE</b> , oxycodone hydrochloride 5 mg tablet, 20
To	
5195K	ENDONE, AF – <b>OXYCODONE</b> , oxycodone hydrochloride 5 mg tablet, 20

**Alteration – Note**

11273H	<b>BUDESONIDE + FORMOTEROL (EFORMOTEROL)</b> , budesonide 200 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations ( <i>BiResp Spiromax, DuoResp Spiromax</i> )
12041R	<b>BUDESONIDE + FORMOTEROL (EFORMOTEROL)</b> , budesonide 200 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations ( <i>Symbicort Turbuhaler 200/6</i> )
8625Y	<b>BUDESONIDE + FORMOTEROL (EFORMOTEROL)</b> , budesonide 200 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations ( <i>Rilast TURBUHALER 200/6, Symbicort Turbuhaler 200/6</i> )
10732W	<b>ITRACONAZOLE</b> , itraconazole 50 mg capsule, 60 ( <i>Lozanoc</i> )
8196J	<b>ITRACONAZOLE</b> , itraconazole 100 mg capsule, 60 ( <i>APO-Itraconazole, ITRANOX, Itracap</i> )
11971C	<b>SAPROPTERIN</b> , sapropterin dihydrochloride 500 mg powder for oral liquid, 30 sachets ( <i>Kuvan</i> )
11983Q	<b>SAPROPTERIN</b> , sapropterin dihydrochloride 500 mg powder for oral liquid, 30 sachets ( <i>Kuvan</i> )
12570N	<b>SAPROPTERIN</b> , sapropterin dihydrochloride 500 mg powder for oral liquid, 30 sachets ( <i>Kuvan</i> )
11676M	<b>SAPROPTERIN</b> , sapropterin dihydrochloride 100 mg soluble tablet, 30 ( <i>Kuvan</i> )
11691H	<b>SAPROPTERIN</b> , sapropterin dihydrochloride 100 mg soluble tablet, 30 ( <i>Kuvan</i> )
12579C	<b>SAPROPTERIN</b> , sapropterin dihydrochloride 100 mg soluble tablet, 30 ( <i>Kuvan</i> )
5469W	<b>VARENICLINE</b> , varenicline 1 mg tablet, 56 ( <i>Champix, VARENAPIX</i> )
9129L	<b>VARENICLINE</b> , varenicline 1 mg tablet, 56 ( <i>Champix, VARENAPIX</i> )
12947K	<b>VARENICLINE</b> , varenicline 1 mg tablet, 56 ( <i>APO-Varenicline (Canada)</i> )
12978C	<b>VARENICLINE</b> , varenicline 1 mg tablet, 56 ( <i>APO-Varenicline (Canada)</i> )

**Alteration – Restriction**

2997R	<b>CALCITONIN SALMON (SALCATONIN)</b> , calcitonin salmon (salcatonin) 100 units/mL injection, 5 x 1 mL ampoules ( <i>Miacalcic 100</i> )
11971C	<b>SAPROPTERIN</b> , sapropterin dihydrochloride 500 mg powder for oral liquid, 30 sachets ( <i>Kuvan</i> )
11983Q	<b>SAPROPTERIN</b> , sapropterin dihydrochloride 500 mg powder for oral liquid, 30 sachets ( <i>Kuvan</i> )
12570N	<b>SAPROPTERIN</b> , sapropterin dihydrochloride 500 mg powder for oral liquid, 30 sachets ( <i>Kuvan</i> )
11676M	<b>SAPROPTERIN</b> , sapropterin dihydrochloride 100 mg soluble tablet, 30 ( <i>Kuvan</i> )
11691H	<b>SAPROPTERIN</b> , sapropterin dihydrochloride 100 mg soluble tablet, 30 ( <i>Kuvan</i> )
12579C	<b>SAPROPTERIN</b> , sapropterin dihydrochloride 100 mg soluble tablet, 30 ( <i>Kuvan</i> )

**Alteration – Restriction Level**

		From	To
2997R	<b>CALCITONIN SALMON (SALCATONIN)</b> , calcitonin salmon (salcatonin) 100 units/mL injection, 5 x 1 mL ampoules ( <i>Miacalcic 100</i> )	restricted	authority-required
8516F	<b>FLUTICASONE PROPIONATE</b> , fluticasone propionate 50 microgram/actuation inhalation, 120 actuations ( <i>Axotide Junior, Flixotide Junior</i> )	unrestricted	authority-required
1629R	<b>METHYLDOPA</b> , methyldopa 250 mg tablet, 100 ( <i>Aldomet</i> )	unrestricted	authority-required

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## Alteration – Maximum Quantity

		From	To
11676M	<b>SAPROPTERIN</b> , sapropterin dihydrochloride 100 mg soluble tablet, 30 ( <i>Kuvan</i> )	3	1

## Supply Only

When a product is deleted from the Schedule it may be available under 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](http://www.pbs.gov.au)

2390T	<b>AMPICILLIN</b> , ampicillin 500 mg injection, 5 vials ( <i>Austrapen</i> )
3313J	<b>AMPICILLIN</b> , ampicillin 500 mg injection, 5 vials ( <i>Austrapen</i> )
9299K	<b>HYDROMORPHONE</b> , hydromorphone hydrochloride 4 mg modified release tablet, 14 ( <i>Jurnista</i> )
9406C	<b>HYDROMORPHONE</b> , hydromorphone hydrochloride 8 mg modified release tablet, 14 ( <i>Jurnista</i> )
9407D	<b>HYDROMORPHONE</b> , hydromorphone hydrochloride 16 mg modified release tablet, 14 ( <i>Jurnista</i> )
9408E	<b>HYDROMORPHONE</b> , hydromorphone hydrochloride 32 mg modified release tablet, 14 ( <i>Jurnista</i> )
9409F	<b>HYDROMORPHONE</b> , hydromorphone hydrochloride 64 mg modified release tablet, 14 ( <i>Jurnista</i> )
11705C	<b>INSULIN ASPART</b> , insulin aspart 100 units/mL fast acting injection, 1 x 10 mL vial ( <i>Fiasp</i> )
11706D	<b>INSULIN ASPART</b> , insulin aspart 100 units/mL fast acting injection, 5 x 3 mL pen devices ( <i>Fiasp FlexTouch</i> )
11618L	<b>NICOTINE</b> , nicotine 2 mg chewing gum, 216 ( <i>Nicotinell</i> )
11612E	<b>NICOTINE</b> , nicotine 4 mg chewing gum, 216 ( <i>Nicotinell</i> )
11617K	<b>NICOTINE</b> , nicotine 2 mg lozenge, 216 ( <i>Nicotinell</i> )
11619M	<b>NICOTINE</b> , nicotine 4 mg lozenge, 216 ( <i>Nicotinell</i> )

## Advance Notices

1 May 2023

### Deletion – Brand

8750M	<i>Symbicort Turbuhaler 400/12, AP</i> – <b>BUDESONIDE + FORMOTEROL (EFORMOTEROL)</b> , budesonide 400 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 12 microgram/actuation powder for inhalation, 2 x 60 actuations
8797B	<i>TRIDOPA, TD</i> – <b>LEVODOPA + CARBIDOPA + ENTACAPONE</b> , levodopa 50 mg + carbidopa 12.5 mg + entacapone 200 mg tablet, 100
8798C	<i>TRIDOPA, TD</i> – <b>LEVODOPA + CARBIDOPA + ENTACAPONE</b> , levodopa 100 mg + carbidopa 25 mg + entacapone 200 mg tablet, 100
8799D	<i>TRIDOPA, TD</i> – <b>LEVODOPA + CARBIDOPA + ENTACAPONE</b> , levodopa 150 mg + carbidopa 37.5 mg + entacapone 200 mg tablet, 100
9292C	<i>TRIDOPA, TD</i> – <b>LEVODOPA + CARBIDOPA + ENTACAPONE</b> , levodopa 200 mg + carbidopa 50 mg + entacapone 200 mg tablet, 100
9344T	<i>TRIDOPA, TD</i> – <b>LEVODOPA + CARBIDOPA + ENTACAPONE</b> , levodopa 75 mg + carbidopa 18.75 mg + entacapone 200 mg tablet, 100
9345W	<i>TRIDOPA, TD</i> – <b>LEVODOPA + CARBIDOPA + ENTACAPONE</b> , levodopa 125 mg + carbidopa 31.25 mg + entacapone 200 mg tablet, 100
2775C	<i>Brevinor-1, PF</i> – <b>NORETHISTERONE + ETHINYLESTRADIOL</b> , norethisterone 1 mg + ethinylestradiol 35 microgram tablet [21] (& inert substance tablet [7], 4 x 28
5191F	<i>Oxycodone BNM, BZ</i> – <b>OXYCODONE</b> , oxycodone hydrochloride 5 mg capsule, 20
8464L	<i>Oxycodone BNM, BZ</i> – <b>OXYCODONE</b> , oxycodone hydrochloride 5 mg capsule, 20
8502L	<i>Oxycodone BNM, BZ</i> – <b>OXYCODONE</b> , oxycodone hydrochloride 20 mg capsule, 20

1 June 2023

### Deletion – Brand

1209P	<i>Ciprofloxacin GH, HQ</i> – <b>CIPROFLOXACIN</b> , ciprofloxacin 500 mg tablet, 14
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1567L	<i>Trandate, AS</i> – <b>LABELALOL</b> , labetalol hydrochloride 200 mg tablet, 100
1392G	<i>Triphasil 28, PF</i> – <b>LEVONORGESTREL + ETHINYLESTRADIOL</b> , levonorgestrel 50 microgram + ethinylestradiol 30 microgram tablet [6] (&) levonorgestrel 75 microgram + ethinylestradiol 40 microgram tablet [5] (&) levonorgestrel 125 microgram + ethinylestradiol 30 microgram tablet [10] (&) inert substance tablet [7], 4 x 28
2456G	<i>Lisinopril generichealth, GQ</i> – <b>LISINOPRIL</b> , lisinopril 5 mg tablet, 30
2457H	<i>Lisinopril generichealth, GQ</i> – <b>LISINOPRIL</b> , lisinopril 10 mg tablet, 30
10804P	<i>Momasone, AS</i> – <b>MOMETASONE</b> , mometasone furoate 0.1% lotion, 30 mL
10805Q	<i>Momasone, AS</i> – <b>MOMETASONE</b> , mometasone furoate 0.1% lotion, 30 mL
10819K	<i>Momasone, AS</i> – <b>MOMETASONE</b> , mometasone furoate 0.1% lotion, 30 mL
10826T	<i>Momasone, AS</i> – <b>MOMETASONE</b> , mometasone furoate 0.1% lotion, 30 mL
8043H	<i>Momasone, AS</i> – <b>MOMETASONE</b> , mometasone furoate 0.1% lotion, 30 mL
5470X	<i>Ondansetron ODT GH, GQ</i> – <b>ONDANSETRON</b> , ondansetron 4 mg orally disintegrating tablet, 4
5471Y	<i>Ondansetron ODT GH, GQ</i> – <b>ONDANSETRON</b> , ondansetron 8 mg orally disintegrating tablet, 4
5472B	<i>Ondansetron ODT GH, GQ</i> – <b>ONDANSETRON</b> , ondansetron 4 mg orally disintegrating tablet, 10
5473C	<i>Ondansetron ODT GH, GQ</i> – <b>ONDANSETRON</b> , ondansetron 8 mg orally disintegrating tablet, 10
8829Q	<i>Pravastatin generichealth, GQ</i> – <b>PRAVASTATIN</b> , pravastatin sodium 80 mg tablet, 30
9240H	<i>Pravastatin generichealth, GQ</i> – <b>PRAVASTATIN</b> , pravastatin sodium 80 mg tablet, 30
2348N	<i>Pregabalin GH, GQ</i> – <b>PREGABALIN</b> , pregabalin 25 mg capsule, 56
1970Q	<i>Quinapril generichealth, GQ</i> – <b>QUINAPRIL</b> , quinapril 20 mg tablet, 30
8356T	<i>Telmisartan GH, GQ</i> – <b>TELMISARTAN</b> , telmisartan 80 mg tablet, 28
8622T	<i>Telmisartan HCT GH 40/12.5, GQ</i> – <b>TELMISARTAN + HYDROCHLOROTHIAZIDE</b> , telmisartan 40 mg + hydrochlorothiazide 12.5 mg tablet, 28
8623W	<i>Telmisartan HCT GH 80/12.5, GQ</i> – <b>TELMISARTAN + HYDROCHLOROTHIAZIDE</b> , telmisartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28

### 1 July 2023

#### Deletion – Brand

12031F	<i>Oxycodone BNM, BZ</i> – <b>OXYCODONE</b> , oxycodone hydrochloride 10 mg capsule, 20
12074L	<i>Oxycodone BNM, BZ</i> – <b>OXYCODONE</b> , oxycodone hydrochloride 10 mg capsule, 20
5197M	<i>Oxycodone BNM, BZ</i> – <b>OXYCODONE</b> , oxycodone hydrochloride 10 mg capsule, 20
8501K	<i>Oxycodone BNM, BZ</i> – <b>OXYCODONE</b> , oxycodone hydrochloride 10 mg capsule, 20

### 1 December 2023

#### Deletion – Brand

2418G	<i>Amitriptyline Alphapharm 25, MQ</i> – <b>AMITRIPTYLINE</b> , amitriptyline hydrochloride 25 mg tablet, 50
1358L	<i>Dosulepin Mylan, MQ</i> – <b>DOSULEPIN (DOTHIEPIN)</b> , dosulepin (dothiepin) hydrochloride 75 mg tablet, 30
1500Y	<i>Hydrocortisone Mylan 20, MQ</i> – <b>HYDROCORTISONE</b> , hydrocortisone 20 mg tablet, 60

## Palliative Care

### Deletions

#### Deletion – Brand

12499W	<i>DBL Morphine Sulfate Pentahydrate, PF</i> – <b>MORPHINE</b> , morphine sulfate pentahydrate 10 mg/mL injection, 5 x 1 mL ampoules
12548K	<i>DBL Morphine Sulfate Pentahydrate, PF</i> – <b>MORPHINE</b> , morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules
12503C	<i>DBL Morphine Sulfate Pentahydrate, PF</i> – <b>MORPHINE</b> , morphine sulfate pentahydrate 30 mg/mL injection, 5 x 1 mL ampoules

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### **Deletion – Equivalence Indicator**

- 12548K **MORPHINE SULFATE 15 mg/1 mL MEDSURGE, DZ – MORPHINE**, morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules
- 12503C **MORPHINE SULFATE 30 mg/1 mL MEDSURGE, DZ – MORPHINE**, morphine sulfate pentahydrate 30 mg/mL injection, 5 x 1 mL ampoules

### **Supply Only**

When a product is deleted from the Schedule it may be available under 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](http://www.pbs.gov.au)

- 12496Q **HYDROMORPHONE**, hydromorphone hydrochloride 4 mg modified release tablet, 14 (*Jurnista*)
- 12482Y **HYDROMORPHONE**, hydromorphone hydrochloride 8 mg modified release tablet, 14 (*Jurnista*)
- 12473L **HYDROMORPHONE**, hydromorphone hydrochloride 16 mg modified release tablet, 14 (*Jurnista*)
- 12543E **HYDROMORPHONE**, hydromorphone hydrochloride 32 mg modified release tablet, 14 (*Jurnista*)
- 12535R **HYDROMORPHONE**, hydromorphone hydrochloride 64 mg modified release tablet, 14 (*Jurnista*)

## **Highly Specialised Drugs Program (Private Hospital)**

### **Additions**

#### **Addition – Item**

- 13242Y **MEPOLIZUMAB**, mepolizumab 100 mg/mL injection, 1 mL pen device (*Nucala*)
- 13239T **RUXOLITINIB**, ruxolitinib 5 mg tablet, 56 (*Jakavi*)
- 13244C **RUXOLITINIB**, ruxolitinib 5 mg tablet, 56 (*Jakavi*)
- 13231J **RUXOLITINIB**, ruxolitinib 10 mg tablet, 56 (*Jakavi*)
- 13236P **RUXOLITINIB**, ruxolitinib 10 mg tablet, 56 (*Jakavi*)

### **Deletions**

#### **Deletion – Item**

- 12862Y **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL cartridges (*Enbrel*)
- 12693C **TOCILIZUMAB**, tocilizumab 80 mg/4 mL injection, 4 mL vial (*RoActemra*)
- 12727W **TOCILIZUMAB**, tocilizumab 80 mg/4 mL injection, 4 x 4 mL vials (*RoActemra*)
- 12726T **TOCILIZUMAB**, tocilizumab 200 mg/10 mL injection, 10 mL vial (*RoActemra*)
- 12747X **TOCILIZUMAB**, tocilizumab 200 mg/10 mL injection, 4 x 10 mL vials (*RoActemra*)
- 12705Q **TOCILIZUMAB**, tocilizumab 400 mg/20 mL injection, 4 x 20 mL vials (*RoActemra*)
- 12728X **TOCILIZUMAB**, tocilizumab 400 mg/20 mL injection, 20 mL vial (*RoActemra*)

#### **Deletion – Brand**

- 10111E **EPOPROSTENOL SUN, RA – EPOPROSTENOL**, epoprostenol 500 microgram injection, 1 vial
- 10129D **EPOPROSTENOL SUN, RA – EPOPROSTENOL**, epoprostenol 1.5 mg injection, 1 vial

#### **Deletion – Equivalence Indicator**

- 1419Q *Actemra, RO – TOCILIZUMAB*, tocilizumab 80 mg/4 mL injection, 4 mL vial
- 1423X *Actemra, RO – TOCILIZUMAB*, tocilizumab 200 mg/10 mL injection, 10 mL vial
- 1464C *Actemra, RO – TOCILIZUMAB*, tocilizumab 400 mg/20 mL injection, 20 mL vial

#### **Deletion – Note**

- 11036W **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 (*Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid*)



9645P	<b>LENALIDOMIDE</b> , lenalidomide 25 mg capsule, 21 ( <i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid</i> )
1419Q	<b>TOCILIZUMAB</b> , tocilizumab 80 mg/4 mL injection, 4 mL vial ( <i>Actemra</i> )
1423X	<b>TOCILIZUMAB</b> , tocilizumab 200 mg/10 mL injection, 10 mL vial ( <i>Actemra</i> )
1464C	<b>TOCILIZUMAB</b> , tocilizumab 400 mg/20 mL injection, 20 mL vial ( <i>Actemra</i> )
6371H	<b>ZOLEDRONIC ACID</b> , zoledronic acid 4 mg/5 mL injection, 5 mL vial ( <i>APO-Zoledronic Acid, DEZTRON, Zoledronate-DRLA 4, Zoledronic Acid Accord, Zometa</i> )

## Highly Specialised Drugs Program (Public Hospital)

### Additions

#### Addition – Item

13237Q	<b>MEPOLIZUMAB</b> , mepolizumab 100 mg/mL injection, 1 mL pen device ( <i>Nucala</i> )
13238R	<b>RUXOLITINIB</b> , ruxolitinib 5 mg tablet, 56 ( <i>Jakavi</i> )
13243B	<b>RUXOLITINIB</b> , ruxolitinib 5 mg tablet, 56 ( <i>Jakavi</i> )
13232K	<b>RUXOLITINIB</b> , ruxolitinib 10 mg tablet, 56 ( <i>Jakavi</i> )
13245D	<b>RUXOLITINIB</b> , ruxolitinib 10 mg tablet, 56 ( <i>Jakavi</i> )

### Deletions

#### Deletion – Item

12880X	<b>ETANERCEPT</b> , etanercept 50 mg/mL injection, 4 x 1 mL cartridges ( <i>Enbrel</i> )
12713D	<b>TOCILIZUMAB</b> , tocilizumab 80 mg/4 mL injection, 4 mL vial ( <i>RoActemra</i> )
12714E	<b>TOCILIZUMAB</b> , tocilizumab 80 mg/4 mL injection, 4 x 4 mL vials ( <i>RoActemra</i> )
12692B	<b>TOCILIZUMAB</b> , tocilizumab 200 mg/10 mL injection, 4 x 10 mL vials ( <i>RoActemra</i> )
12706R	<b>TOCILIZUMAB</b> , tocilizumab 200 mg/10 mL injection, 10 mL vial ( <i>RoActemra</i> )
12694D	<b>TOCILIZUMAB</b> , tocilizumab 400 mg/20 mL injection, 20 mL vial ( <i>RoActemra</i> )
12707T	<b>TOCILIZUMAB</b> , tocilizumab 400 mg/20 mL injection, 4 x 20 mL vials ( <i>RoActemra</i> )

#### Deletion – Brand

10130E	<i>EPOPROSTENOL SUN, RA</i> – <b>EPOPROSTENOL</b> , epoprostenol 500 microgram injection, 1 vial
10117L	<i>EPOPROSTENOL SUN, RA</i> – <b>EPOPROSTENOL</b> , epoprostenol 1.5 mg injection, 1 vial

#### Deletion – Equivalence Indicator

1476Q	<i>Actemra, RO</i> – <b>TOCILIZUMAB</b> , tocilizumab 80 mg/4 mL injection, 4 mL vial
1481Y	<i>Actemra, RO</i> – <b>TOCILIZUMAB</b> , tocilizumab 200 mg/10 mL injection, 10 mL vial
1482B	<i>Actemra, RO</i> – <b>TOCILIZUMAB</b> , tocilizumab 400 mg/20 mL injection, 20 mL vial

#### Deletion – Note

11029L	<b>LENALIDOMIDE</b> , lenalidomide 5 mg capsule, 21 ( <i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid</i> )
11967W	<b>LENALIDOMIDE</b> , lenalidomide 5 mg capsule, 28 ( <i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid</i> )
12034J	<b>LENALIDOMIDE</b> , lenalidomide 5 mg capsule, 21 ( <i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid</i> )
12035K	<b>LENALIDOMIDE</b> , lenalidomide 5 mg capsule, 14 ( <i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid</i> )
12039P	<b>LENALIDOMIDE</b> , lenalidomide 5 mg capsule, 21 ( <i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid</i> )
12985K	<b>LENALIDOMIDE</b> , lenalidomide 5 mg capsule, 21 ( <i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid</i> )
2799H	<b>LENALIDOMIDE</b> , lenalidomide 5 mg capsule, 21 ( <i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid</i> )

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5783J	<b>LENALIDOMIDE</b> , lenalidomide 5 mg capsule, 21 ( <i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid</i> )
11064H	<b>LENALIDOMIDE</b> , lenalidomide 10 mg capsule, 21 ( <i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid</i> )
11968X	<b>LENALIDOMIDE</b> , lenalidomide 10 mg capsule, 28 ( <i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid</i> )
12057N	<b>LENALIDOMIDE</b> , lenalidomide 10 mg capsule, 21 ( <i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid</i> )
12061T	<b>LENALIDOMIDE</b> , lenalidomide 10 mg capsule, 21 ( <i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid</i> )
12070G	<b>LENALIDOMIDE</b> , lenalidomide 10 mg capsule, 14 ( <i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid</i> )
12988N	<b>LENALIDOMIDE</b> , lenalidomide 10 mg capsule, 21 ( <i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid</i> )
2802L	<b>LENALIDOMIDE</b> , lenalidomide 10 mg capsule, 21 ( <i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid</i> )
5784K	<b>LENALIDOMIDE</b> , lenalidomide 10 mg capsule, 21 ( <i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid</i> )
11062F	<b>LENALIDOMIDE</b> , lenalidomide 15 mg capsule, 21 ( <i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid</i> )
11964Q	<b>LENALIDOMIDE</b> , lenalidomide 15 mg capsule, 28 ( <i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid</i> )
12012F	<b>LENALIDOMIDE</b> , lenalidomide 15 mg capsule, 14 ( <i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid</i> )
12026Y	<b>LENALIDOMIDE</b> , lenalidomide 15 mg capsule, 21 ( <i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid</i> )
12062W	<b>LENALIDOMIDE</b> , lenalidomide 15 mg capsule, 21 ( <i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid</i> )
12991R	<b>LENALIDOMIDE</b> , lenalidomide 15 mg capsule, 21 ( <i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid</i> )
5785L	<b>LENALIDOMIDE</b> , lenalidomide 15 mg capsule, 21 ( <i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid</i> )
11041D	<b>LENALIDOMIDE</b> , lenalidomide 25 mg capsule, 21 ( <i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid</i> )
12019N	<b>LENALIDOMIDE</b> , lenalidomide 25 mg capsule, 14 ( <i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid</i> )
12036L	<b>LENALIDOMIDE</b> , lenalidomide 25 mg capsule, 21 ( <i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid</i> )
12059Q	<b>LENALIDOMIDE</b> , lenalidomide 25 mg capsule, 21 ( <i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid</i> )
12979D	<b>LENALIDOMIDE</b> , lenalidomide 25 mg capsule, 21 ( <i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid</i> )
5786M	<b>LENALIDOMIDE</b> , lenalidomide 25 mg capsule, 21 ( <i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid</i> )
1476Q	<b>TOCILIZUMAB</b> , tocilizumab 80 mg/4 mL injection, 4 mL vial ( <i>Actemra</i> )
1481Y	<b>TOCILIZUMAB</b> , tocilizumab 200 mg/10 mL injection, 10 mL vial ( <i>Actemra</i> )
1482B	<b>TOCILIZUMAB</b> , tocilizumab 400 mg/20 mL injection, 20 mL vial ( <i>Actemra</i> )
9653C	<b>ZOLEDRONIC ACID</b> , zoledronic acid 4 mg/5 mL injection, 5 mL vial ( <i>APO-Zoledronic Acid, DEZTRON, Zoledronate-DRLA 4, Zoledronic Acid Accord, Zometa</i> )

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## Highly Specialised Drugs Program (Community Access)

### Additions

#### Addition – Note

10356C **ABACAVIR**, abacavir 20 mg/mL oral liquid, 240 mL (*Ziagen*)

### Alterations

#### Alteration – Restriction

10356C **ABACAVIR**, abacavir 20 mg/mL oral liquid, 240 mL (*Ziagen*)

#### Alteration – Restriction Level

	<i>From</i>	<i>To</i>
10356C <b>ABACAVIR</b> , abacavir 20 mg/mL oral liquid, 240 mL ( <i>Ziagen</i> )	streamlined	authority-required

## IVF Program

### Additions

#### Addition – Brand

6335K *Recagon, OV* – **FOLLITROPIN BETA**, follitropin beta 300 units/0.36 mL injection, 0.36 mL cartridge  
6336L *Recagon, OV* – **FOLLITROPIN BETA**, follitropin beta 600 units/0.72 mL injection, 0.72 mL cartridge  
6464F *Recagon, OV* – **FOLLITROPIN BETA**, follitropin beta 900 units/1.08 mL injection, 1.08 mL cartridge  
9584K *Ganirelix Theramex, TT* – **GANIRELIX**, ganirelix 250 microgram/0.5 mL injection, 5 x 0.5 mL syringes

#### Addition – Equivalence Indicator

6335K *Puregon 300 IU/0.36 mL, OQ* – **FOLLITROPIN BETA**, follitropin beta 300 units/0.36 mL injection, 0.36 mL cartridge  
6336L *Puregon 600 IU/0.72 mL, OQ* – **FOLLITROPIN BETA**, follitropin beta 600 units/0.72 mL injection, 0.72 mL cartridge  
6464F *Puregon 900 IU/1.08 mL, OQ* – **FOLLITROPIN BETA**, follitropin beta 900 units/1.08 mL injection, 1.08 mL cartridge

## Repatriation Pharmaceutical Benefits

### Deletions

#### Deletion – Item

4290T **VARDENAFIL**, vardenafil 10 mg tablet, 4 (*Levitra*)  
4302K **VARDENAFIL**, vardenafil 20 mg tablet, 4 (*Levitra*)

# General Pharmaceutical Benefits

## ■ BUDESONIDE + FORMOTEROL (EFORMOTEROL)

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

**Note** Patient must be aged 12 years or over.

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD) or for allergen-induced or exercise-induced bronchoconstriction in the absence of asthma.

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

### Authority required (STREAMLINED)

**10464**

Mild asthma

#### Clinical criteria:

- Patient must have asthma and require an anti-inflammatory reliever therapy, **AND**
- Patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA).  
Device (inhaler) technique should be reviewed at each clinical visit and before initiating treatment with this medicine.

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

12041R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	2	..	36.15	30.00	<sup>a</sup> Symbicort Turbuhaler 200/6 [AP]

## ■ BUDESONIDE + FORMOTEROL (EFORMOTEROL)

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

**Note** Patient must be aged 18 years or older.

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

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

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

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

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

### Authority required (STREAMLINED)

**7970**

Asthma

#### Clinical criteria:

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

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

11273H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	36.15	30.00	<sup>a</sup> BiResp Spiromax [TB]	<sup>a</sup> DuoResp Spiromax [EV]

## ■ BUDESONIDE + FORMOTEROL (EFORMOTEROL)

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

**Note** Patient must be aged 12 years or over.

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

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

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

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

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

**Authority required (STREAMLINED)**

**7970**

Asthma

**Clinical criteria:**

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

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

8625Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	‡1	5	..	36.15	30.00	<sup>a</sup> Rilast TURBUHALER 200/6 [ZA]	<sup>a</sup> Symbicort Turbuhaler 200/6 [AP]

▪ **CALCITONIN SALMON (SALCATONIN)**

**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](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**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**

Symptomatic Paget disease of bone

**Clinical criteria:**

- The treatment must be for a patient who cannot tolerate bisphosphonates due to kidney disease.

**Authority required**

Hypercalcaemia

**Clinical criteria:**

- The treatment must be initiated in a hospital, **AND**
- The treatment must be for a patient who cannot tolerate bisphosphonates due to kidney disease.

**calcitonin salmon (salcatonin) 100 units/mL injection, 5 x 1 mL ampoules**

2997R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	3	5	..	*127.07	30.00	Miacalcic 100 [EU]

▪ **FLUTICASONE PROPIONATE**

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

**Authority required**

Asthma

**Population criteria:**

- Patient must be less than 6.00 years of age.

**Treatment criteria:**

- Must be treated by a respiratory physician; OR
- Must be treated by a paediatrician; OR
- Must be treated by a health practitioner who is continuing treatment that was initiated by one of the specialists above.

**fluticasone propionate 50 microgram/actuation inhalation, 120 actuations**

8516F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	5	..	19.55	20.86	<sup>a</sup> Axotide Junior [GC]
			<sup>B</sup> 4.00	23.55	20.86	<sup>a</sup> Flixotide Junior [GK]

▪ **ITRACONAZOLE**

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

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

**Note** Not for use in superficial mycoses

**Note Shared Care Model:**

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

**Authority required (STREAMLINED)**

**6022**

Systemic aspergillosis

**Authority required (STREAMLINED)**

**6005**

Systemic sporotrichosis

**Authority required (STREAMLINED)**

**6057**

Systemic histoplasmosis

**Authority required (STREAMLINED)**

**5988**

Disseminated pulmonary histoplasmosis infection

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

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

**Authority required (STREAMLINED)**

**6037**

Chronic pulmonary histoplasmosis infection

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

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

**Authority required (STREAMLINED)**

**6016**

Oropharyngeal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed.

**Authority required (STREAMLINED)**

**6035**

Oesophageal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed.

**itraconazole 100 mg capsule, 60**

8196J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	116.90	30.00	<sup>a</sup> APO-Itraconazole [TX]	<sup>a</sup> Itracap [AF]
						<sup>a</sup> ITRANOX [RW]	

**itraconazole 50 mg capsule, 60**

10732W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	116.90	30.00	Lozanoc [YN]

▪ **MESALAZINE**

**Note** Not for the treatment of Crohn disease

**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 form pack size mesalazine 1.2 g modified release tablet, 60 and mesalazine 1.2 g modified release tablet, 120 are equivalent for the purposes of substitution.

**Restricted benefit**

Ulcerative colitis

**mesalazine 1.2 g modified release tablet, 120**

13247F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	172.26	30.00	<sup>a</sup> MESALZ [RA]

**mesalazine 1.2 g modified release tablet, 60**

9353G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*172.26	30.00	<sup>a</sup> Mesalazine 1.2 TAKEDA [NQ]	<sup>a</sup> Mezavant [TK]

## ■ METHYLDOPA

**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](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.


### Authority required

Hypertension

### Population criteria:

- Patient must be pregnant.

## methyldopa 250 mg tablet, 100

1629R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	20.94	22.25	Aldomet [AS]

## ■ NIRMATRELVIR (&) RITONAVIR

**Caution** Nirmatrelvir with ritonavir has significant drug-drug interactions. Please refer to the TGA approved Paxlovid Product Information. Prescribers and dispensers should carefully review a patient's concomitant medications including over-the-counter medications, herbal supplements, and recreational drugs.

**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)

**13759**

SARS-CoV-2 infection

### Clinical criteria:

- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset; OR
- The treatment must be initiated as soon as possible after a diagnosis is confirmed where asymptomatic.

### Population criteria:

- Patient must be at least 70 years of age.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

### Authority required (STREAMLINED)

**13821**

SARS-CoV-2 infection

### Clinical criteria:

- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- Patient must satisfy at least one of the following criteria: (i) be moderately to severely immunocompromised with risk of progression to severe COVID-19 disease due to the immunocompromised status, (ii) has experienced past COVID-19 infection resulting in hospitalisation, **AND**
- The treatment must be initiated within 5 days of symptom onset.

### Population criteria:

- Patient must be at least 18 years of age.

For the purpose of administering this restriction, 'moderately to severely immunocompromised' patients are those with:

1. Any primary or acquired immunodeficiency including:

a. Haematologic neoplasms: leukaemias, lymphomas, myelodysplastic syndromes, multiple myeloma and other plasma cell disorders,

b. Post-transplant: solid organ (on immunosuppressive therapy), haematopoietic stem cell transplant (within 24 months),

c. Immunocompromised due to primary or acquired (HIV/AIDS) immunodeficiency; OR

2. Any significantly immunocompromising condition(s) where, in the last 3 months the patient has received:

a. Chemotherapy or whole body radiotherapy,

b. High-dose corticosteroids (at least 20 mg of prednisone per day, or equivalent) for at least 14 days in a month, or pulse corticosteroid therapy,

c. Biological agents and other treatments that deplete or inhibit B cell or T cell function (abatacept, anti-CD20 antibodies, BTK inhibitors, JAK inhibitors, sphingosine 1-phosphate receptor modulators, anti-CD52 antibodies, anti-complement antibodies, anti-thymocyte globulin),

d. Selected conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs) including mycophenolate, methotrexate, leflunomide, azathioprine, 6-mercaptopurine (at least 1.5mg/kg/day), alkylating agents (e.g. cyclophosphamide, chlorambucil), and systemic calcineurin inhibitors (e.g. cyclosporin, tacrolimus); OR

3. Any significantly immunocompromising condition(s) where, in the last 12 months the patient has received an anti-CD20 monoclonal antibody treatment, but criterion 2c above is not met; OR

- 
4. Others with very high-risk conditions including Down Syndrome, cerebral palsy, congenital heart disease, thalassemia, sickle cell disease and other haemoglobinopathies; OR
5. People with disability with multiple comorbidities and/or frailty.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

**Authority required (STREAMLINED)**

**13748**

SARS-CoV-2 infection

**Clinical criteria:**

- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset.

**Population criteria:**

- Patient must be each of: (i) identify as Aboriginal or Torres Strait Islander, (ii) at least 30 years of age, (iii) at high risk. For the purpose of administering this restriction, high risk is defined as the presence of at least one of the following conditions:

1. The patient is in residential aged care
2. The patient has disability with multiple comorbidities and/or frailty
3. Neurological conditions, including stroke and dementia and demyelinating conditions
4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease
5. Heart failure, coronary artery disease, cardiomyopathies
6. Obesity (BMI greater than 30 kg/m<sup>2</sup>)
7. Diabetes type I or II, requiring medication for glycaemic control
8. Renal impairment (eGFR less than 60mL/min)
9. Cirrhosis
10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above
11. Past COVID-19 infection episode resulting in hospitalisation.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

**Note** The Modified Monash Model categorises an area according to geographical remoteness and town size. Details can be found at: <https://www.health.gov.au/health-topics/rural-health-workforce/classifications/mmm>

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**Authority required (STREAMLINED)**

**13765**

SARS-CoV-2 infection

**Clinical criteria:**

- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset.

**Population criteria:**

- Patient must be both: (i) at least 50 years of age, (ii) at high risk. For the purpose of administering this restriction, high risk is defined as either a past COVID-19 infection episode resulting in hospitalisation, or the presence of at least two of the following conditions:
1. The patient is in residential aged care,
  2. The patient has disability with multiple comorbidities and/or frailty,
  3. Neurological conditions, including stroke and dementia and demyelinating conditions,

4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease,
5. Heart failure, coronary artery disease, cardiomyopathies,
6. Obesity (BMI greater than 30 kg/m<sup>2</sup>),
7. Diabetes type I or II, requiring medication for glycaemic control,
8. Renal impairment (eGFR less than 60mL/min),
9. Cirrhosis, or
10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

**Note** The Modified Monash Model categorises an area according to geographical remoteness and town size. Details can be found at: <https://www.health.gov.au/health-topics/rural-health-workforce/classifications/mmm>

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

**13893**

SARS-CoV-2 infection

#### **Clinical criteria:**

- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset.

#### **Population criteria:**

- Patient must be at least 60 years old, but not older than 70 years, **AND**
- Patient must be at high risk of requiring hospitalisation for COVID-19 infection.

For the purpose of administering this restriction, high risk is defined as the presence of at least one of the following conditions:

1. The patient is in residential aged care
2. The patient has disability with multiple comorbidities and/or frailty
3. Neurological conditions, including stroke and dementia and demyelinating conditions
4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease
5. Heart failure, coronary artery disease, cardiomyopathies
6. Obesity (BMI greater than 30 kg/m<sup>2</sup>)
7. Diabetes type I or II, requiring medication for glycaemic control
8. Renal impairment (eGFR less than 60mL/min)
9. Cirrhosis
10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above
11. Past COVID-19 infection episode resulting in hospitalisation.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.


Access to this drug through this restriction is permitted irrespective of vaccination status.

Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

#### **nirmatrelvir 150 mg tablet [4] (&) ritonavir 100 mg tablet [2], 5 x 6**

12996B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	1113.99	30.00	Paxlovid [HD]

#### **▪ OXYCODONE**

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.


#### **Restricted benefit**

Severe pain

**Clinical criteria:**

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**oxycodone hydrochloride 5 mg tablet, 10**

13234M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	18.64	19.95	<sup>a</sup> ENDONE [AF]	<sup>a</sup> Oxycodone Viatris [MQ]

▪ **OXYCODONE**

**Caution** The risk of drug dependence is high.

**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**

Severe pain

**Clinical criteria:**

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**oxycodone hydrochloride 5 mg tablet, 10**

13233L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	18.64	19.95	<sup>a</sup> ENDONE [AF]	<sup>a</sup> Oxycodone Viatris [MQ]

▪ **RUXOLITINIB**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**13906**

Moderate to severe chronic graft versus host disease (cGVHD)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have received prior systemic steroid treatment for this condition, **AND**
- Patient must be one of the following: (i) refractory to steroid treatment, (ii) dependent on steroid treatment, (iii) intolerant to steroid treatment, **AND**
- The treatment must be the sole PBS-subsidised treatment for this condition with the exception of: (i) corticosteroids, (ii) calcineurin inhibitors.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR
- Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types, **AND**

• Patient must be undergoing treatment with this drug following allogeneic haematopoietic stem cell transplantation.

The severity of cGVHD is defined by the **National Institutes of Health (NIH)** criteria (Jagasia et al., 2015):

(a) Moderate cGVHD: at least one organ (not lung) with a score of 2, 3 or more organs involved with a score of 1 in each organ, or lung score of 1

(b) Severe cGVHD: at least 1 organ with a score of 3, or lung score of 2 or 3

Steroid-refractory disease is defined as:

(a) a lack of response or disease progression after administration of a minimum prednisone dose of 1 mg/kg/day for at least 1 week (or equivalent); or

(b) disease persistence without improvement despite continued treatment with prednisone at greater than 0.5 mg/kg/day or 1 mg/kg/every other day for at least 4 weeks (or equivalent).

Steroid-dependent disease is defined as an increased prednisone dose to greater than 0.25 mg/kg/day after two unsuccessful attempts to taper the dose (or equivalent).

Steroid intolerance is defined as a patient developing an intolerance of a severity necessitating treatment withdrawal.

Details of prior steroid use should be documented in the patient's medical records.

A patient must demonstrate a response 24 weeks after initiating treatment with ruxolitinib to be eligible for continuing treatment.

Response is defined as attaining a complete or partial response as defined by the **National Institutes of Health (NIH)** criteria (Lee et al., 2015). Note that response is relative to the assessment of organ function affected by cGVHD prior to commencing initial treatment with ruxolitinib.

(a) complete response is defined as complete resolution of all signs and symptoms of cGVHD in all evaluable organs without initiation or addition of new systemic therapy.

(b) partial response is defined as an improvement in at least one organ (e.g. improvement of 1 or more points on a 4-to-7-point scale, or an improvement of 2 or more points on a 10-to-12-point scale) without progression in other organs or sites, initiation or addition of new systemic therapies.

The assessment of response must be documented in the patient's medical records.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

**Authority required (STREAMLINED)**

**13867**

Moderate to severe chronic graft versus host disease (cGVHD)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received initial PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have responding disease at 24 weeks compared with baseline, demonstrated by either a: (i) partial response, (ii) complete response, **AND**
- The treatment must be the sole PBS-subsidised treatment for this condition with the exception of: (i) corticosteroids, (ii) calcineurin inhibitors.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR
- Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types.

Response is defined as attaining a complete or partial response as defined by the **National Institutes of Health (NIH)** criteria (Lee et al., 2015). Note that response is relative to the assessment of organ function affected by cGVHD prior to commencing initial treatment with ruxolitinib.

(a) complete response is defined as complete resolution of all signs and symptoms of cGVHD in all evaluable organs without initiation or addition of new systemic therapy.

(b) partial response is defined as an improvement in at least one organ (e.g. improvement of 1 or more points on a 4-to-7-point scale, or an improvement of 2 or more points on a 10-to-12-point scale) without progression in other organs or sites, initiation or addition of new systemic therapies.

The assessment of response must be documented in the patient's medical records.

Tapering the dose of corticosteroids should be considered in patients with responding disease. Following successful tapering of corticosteroids, tapering the dose of ruxolitinib can be initiated.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

**Authority required (STREAMLINED)**

**13866**

Moderate to severe chronic graft versus host disease (cGVHD)

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

**Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 April 2023, **AND**
- Patient must have received systemic steroid treatment prior to initiation of this drug for this condition, **AND**
- Patient must be one of the following: (i) refractory to steroid treatment, (ii) dependent on steroid treatment, (iii) intolerant to steroid treatment, **AND**
- Patient must have responding disease at 24 weeks compared with baseline, demonstrated by either a: (i) partial response, (ii) complete response.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR
- Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types, **AND**
- Patient must be undergoing treatment with this drug following allogeneic haematopoietic stem cell transplantation.

Steroid-refractory disease is defined as:

(a) a lack of response or disease progression after administration of a minimum prednisone dose of 1 mg/kg/day for at least 1 week (or equivalent); or

(b) disease persistence without improvement despite continued treatment with prednisone at greater than 0.5 mg/kg/day or 1 mg/kg/every other day for at least 4 weeks (or equivalent).

Steroid-dependent disease is defined as an increased prednisone dose to greater than 0.25 mg/kg/day after two unsuccessful attempts to taper the dose (or equivalent).

Steroid intolerance is defined as a patient developing an intolerance of a severity necessitating treatment withdrawal.

Details of prior steroid use should be documented in the patient's medical records.

Response is defined as attaining a complete or partial response as defined by the **National Institutes of Health (NIH)** criteria (Lee et al., 2015). Note that response is relative to the assessment of organ function affected by cGVHD prior to commencing initial treatment with ruxolitinib.

(a) complete response is defined as complete resolution of all signs and symptoms of cGVHD in all evaluable organs without initiation or addition of new systemic therapy.

(b) partial response is defined as an improvement in at least one organ (e.g. improvement of 1 or more points on a 4-to-7-point scale, or an improvement of 2 or more points on a 10-to-12-point scale) without progression in other organs or sites, initiation or addition of new systemic therapies.

The assessment of response must be documented in the patient's medical records.

Tapering the dose of corticosteroids should be considered in patients with responding disease. Following successful tapering of corticosteroids, tapering the dose of ruxolitinib can be initiated.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

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

**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.

#### ruxolitinib 5 mg tablet, 56

13241X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	2509.21	30.00	Jakavi [NV]

#### ruxolitinib 10 mg tablet, 56

13235N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4911.28	30.00	Jakavi [NV]

### ■ SAPROPTERIN

**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](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Special Pricing Arrangements apply.

#### Authority required

Hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)

Treatment Phase: Initial treatment - responsiveness testing

#### **Treatment criteria:**

- Must be treated by a metabolic physician.

#### **Clinical criteria:**

- Patient must be untreated with this drug; OR
- Patient must have completed prior responsiveness testing on only 1 occasion - this occurred when the patient was less than 1 month of age, but this benefit is for a second attempt at responsiveness testing in a patient aged at least 1 month old, **AND**
- Patient must have a baseline blood phenylalanine level above 360 micromole per L and be less than one month of age; OR
- Patient must have a baseline blood phenylalanine level above 600 micromole per L and be more than one month of age, **AND**
- The treatment must be for the purpose of initial responsiveness testing for a period of 24 hours in a patient less than one month of age; OR
- The treatment must be for the purpose of initial responsiveness testing for a period of 7 days in a patient aged more than one month.

Dietary phenylalanine intake must be maintained at a constant level.

Patients or their parent/guardian should be assessed for their ability to comply with the sapropterin protocol and PKU diet prior to conducting initial responsiveness testing.

#### sapropterin dihydrochloride 100 mg soluble tablet, 30

11676M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	874.46	30.00	Kuvan [IO]

#### sapropterin dihydrochloride 500 mg powder for oral liquid, 30 sachets

11971C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	4246.28	30.00	Kuvan [IO]

### ■ SAPROPTERIN

**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](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Special Pricing Arrangements apply.

#### Authority required

Hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)

Treatment Phase: First continuing treatment

#### **Treatment criteria:**

- Must be treated by a metabolic physician; OR
- Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment under the Initial treatment - responsiveness testing restriction with this drug for this condition, **AND**
- Patient must have demonstrated a response to treatment with this drug of greater than or equal to a 30% reduction in phenylalanine levels from baseline during initial responsiveness testing.

Blood phenylalanine levels must be based on measurements taken during stable periods of the condition.

Dietary phenylalanine intake must be maintained at a constant level.

#### Authority required

Hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)

Treatment Phase: Subsequent continuing


**Treatment criteria:**

- Must be treated by a metabolic physician; OR
- Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician.


**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 be undergoing regular phenylalanine testing and assessment of adherence to dietary modifications.

**sapropterin dihydrochloride 100 mg soluble tablet, 30**

11691H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	6	5	..	*5063.24	30.00	Kuvan [IO]

**sapropterin dihydrochloride 500 mg powder for oral liquid, 30 sachets**

11983Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4246.28	30.00	Kuvan [IO]

▪ **SAPROPTERIN**

**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](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Request an appropriate maximum quantity based on testing response to treatment for 7 days, with the number of packs being a whole number, based on dosing no greater than 20 mg/kg per day. Combinations of the sachets and tablets are permitted to reduce high tablet burden.

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Maternal hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)

Treatment Phase: Initial treatment - responsiveness testing

**Clinical criteria:**

- The treatment must be for the purpose of ascertaining the patient's response to treatment over a period of 7 days, with the intent to then use the drug to control phenylalanine levels under the treatment phase: First continuing treatment, Indication: Hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU), **AND**
- Patient must have a baseline blood phenylalanine level above 250 micromol/L prior to commencing treatment with this drug despite best efforts to rely on dietary modifications to control phenylalanine levels.

**Treatment criteria:**

- Must be treated by a metabolic physician, **AND**
- Patient must be undergoing treatment with this drug for the first time, **AND**
- Patient must not be undergoing treatment with this drug under this Treatment phase, more than once per lifetime following completion of this authority application, **AND**
- Patient must not be undergoing simultaneous treatment with this drug under another PBS-listing (apply under either listing type, but not both simultaneously).

**Population criteria:**

- Patient must be one of: (i) planning conception, (ii) pregnant.

**sapropterin dihydrochloride 100 mg soluble tablet, 30**

12579C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	874.46	30.00	Kuvan [IO]

**sapropterin dihydrochloride 500 mg powder for oral liquid, 30 sachets**

12570N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	4246.28	30.00	Kuvan [IO]

▪ **VARENICLINE**

**Note** Pharmaceutical Benefits that have the brand APO-varenicline (Canada) may be substituted for Pharmaceutical Benefits that have the brands Champix or VARENAPIX in the case of a shortage.

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

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

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

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

**Authority required (STREAMLINED)**

**6885**

Nicotine dependence

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

**Clinical criteria:**

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

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

**Treatment criteria:**

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

**varenicline 1 mg tablet, 56**

12978C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	100.75	30.00	<sup>a</sup> APO-Varenicline (Canada) [XT]

**varenicline 1 mg tablet, 56**

5469W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	77.62	30.00	<sup>a</sup> Champix [PF]	<sup>a</sup> VARENAPIX [TX]

▪ **VARENICLINE**

**Note** Pharmaceutical Benefits that have the brand APO-varenicline (Canada) may be substituted for Pharmaceutical Benefits that have the brands Champix or VARENAPIX in the case of a shortage.

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

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

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

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

**Authority required (STREAMLINED)**

**7483**

Nicotine dependence

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

**Clinical criteria:**

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

**Treatment criteria:**

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

**varenicline 1 mg tablet, 56**

12947K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*193.22	30.00	<sup>a</sup> APO-Varenicline (Canada) [XT]

**varenicline 1 mg tablet, 56**

9129L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	..	..	*144.64	30.00	<sup>a</sup> Champix [PF]	<sup>a</sup> VARENAPIX [TX]

# Highly Specialised Drugs Program (Private Hospital)

## ▪ MEPOLIZUMAB

**Note** The length of a break in therapy is measured from the date that the relevant PBS-subsidised medicine listed for this PBS indication is ceased during the most recent treatment cycle, until the date of the subsequent application for treatment under a new treatment cycle.

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

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

**Note** Special Pricing Arrangements apply.

### **Authority required**

Chronic rhinosinusitis with nasal polyps (CRSwNP)

Treatment Phase: Initial treatment

### **Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) ear nose and throat specialist (ENT), (v) general physician experienced in the management of patients with CRSwNP.

### **Clinical criteria:**

- Patient must have a diagnosis of CRSwNP confirmed by at least one of: (i) nasal endoscopy, (ii) computed tomography (CT) scan, with the results documented in the patient's medical records; OR
- Patient must have a diagnosis of CRSwNP from at least two physicians of the above mentioned prescriber types, **AND**
- Patient must have undergone surgery for the removal of nasal polyps; OR
- Patient must have the written advice from at least two physicians of the above mentioned prescriber types demonstrating inappropriateness for surgery, **AND**
- Patient must have, despite optimised nasal polyp therapy, at least two of: (i) bilateral endoscopic nasal polyp score of at least 5 (out of a maximum score of 8, with a minimum score of 2 in each nasal cavity), (ii) nasal obstruction visual analogue scale (VAS) score greater than 5 (out of a maximum score of 10), (iii) overall symptom VAS score greater than 7 (out of a maximum score of 10), **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have had a 12 month break in PBS-subsidised treatment with a biological medicine for this condition, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps, (ii) uncontrolled severe allergic asthma, (iii) uncontrolled severe asthma, **AND**
- Patient must have failed to achieve adequate control with optimised nasal polyp therapy which has been documented, **AND**
- Patient must have blood eosinophil count greater than or equal to 300 cells per microlitre in the last 12 months.

### **Population criteria:**

- Patient must be at least 18 years of age.

Optimised nasal polyp therapy includes:

- (a) adherence to intranasal corticosteroid therapy for at least 2 months, unless contraindicated or not tolerated
- (b) if required, nasal irrigation with saline

Where the patient has a contraindication or intolerance to intranasal corticosteroid therapy, document the reasons for the contraindication or intolerance in the patient's medical file.

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

- (a) a completed authority prescription form,
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice),
- (c) details (date of commencement and duration of therapy) of prior optimised nasal polyp medicine treatment,
- (d) details (date and treatment) of nasal polyp surgery; or
- (e) if applicable, details of surgical exception including serious comorbid disease (e.g. cardiovascular, stroke) making the risk of surgery unacceptable,
- (f) the eosinophil count and date,
- (g) two of the following, measured within the past 12 months: (i) baseline bilateral endoscopic nasal polyp score, (ii) baseline nasal obstruction VAS score, (iii) baseline overall VAS score.

**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).

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Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://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](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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**Authority required**

Chronic rhinosinusitis with nasal polyps (CRSwNP)

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) ear nose and throat specialist (ENT), (v) general physician experienced in the management of patients with CRSwNP.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have both demonstrated and sustained an adequate response to this drug, defined as having at least one of: (i) an improvement in bilateral endoscopic nasal polyp score of at least 1.0 compared to the baseline level provided with the initial authority application, (ii) an improvement in nasal obstruction visual analogue scale (VAS) score of at least 3.0 compared to the baseline level provided with the initial authority application, (iii) an improvement in overall symptom VAS score of at least 2.5 compared to the baseline level provided with the initial authority application.

**Population criteria:**

- Patient must be at least 18 years of age.

**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](http://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).

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**Authority required**

Chronic rhinosinusitis with nasal polyps (CRSwNP)

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

**Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) ear nose and throat specialist (ENT), (v) general physician experienced in the management of patients with CRSwNP.

**Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 April 2023, **AND**
- Patient must have met all initial treatment PBS-eligibility criteria applying to a non-grandfathered patient prior to having commenced treatment with this drug, which are described below.

**Population criteria:**

- Patient must be at least 18 years of age.

Criteria for Grandfathered patients are that:

- (a) the diagnosis of CRSwNP was confirmed by at least one of: (i) nasal endoscopy, (ii) computed tomography (CT) scan; or from at least two physicians of the above mentioned prescriber types
- (b) the patient has undergone surgery for the removal of nasal polyps; or the patient has the written advice from at least two physicians of the above mentioned prescriber types demonstrating inappropriateness for surgery
- (c) the patient had, despite optimised nasal polyp therapy, at least two of: (i) bilateral endoscopic nasal polyp score of at least 5 (out of a maximum score of 8, with a minimum score of 2 in each nasal cavity), (ii) nasal obstruction visual analogue scale (VAS) score greater than 5 (out of a maximum score of 10), (iii) overall symptom VAS score greater than 7 (out of a maximum score of 10)
- (d) the treatment was/is not used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps, (ii) uncontrolled severe allergic asthma, (iii) uncontrolled severe asthma
- (e) the patient had failed to achieve adequate control with optimised nasal polyp therapy which has been documented
- (f) the patient had a blood eosinophil count greater than or equal to 300 cells per microlitre in the 12 months preceding treatment.

Optimised nasal polyp therapy includes:

- (a) adherence to intranasal corticosteroid therapy for at least 2 months, unless contraindicated or not tolerated
- (b) if required, nasal irrigation with saline

Where the patient has a contraindication or intolerance to intranasal corticosteroid therapy, document the reasons for the contraindication or intolerance in the patient's medical file.

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

- (a) a completed authority prescription form,
  - (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice),
  - (c) details (date of commencement and duration of therapy) of prior optimised nasal polyp medicine treatment,
  - (d) details (date and treatment) of nasal polyp surgery; or
-

- (e) if applicable, details of surgical exception including serious comorbid disease (e.g. cardiovascular, stroke) making the risk of surgery unacceptable,
- (f) the eosinophil count and date,
- (g) two of the following, measured within the 12 months prior to non-PBS-subsidised treatment: (i) baseline bilateral endoscopic nasal polyp score, (ii) baseline nasal obstruction VAS score, (iii) baseline overall VAS score.

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

**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](http://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](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### mepolizumab 100 mg/mL injection, 1 mL pen device

13242Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1603.92	Nucala [GK]

### ▪ RUXOLITINIB

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

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

**Note** Special Pricing Arrangements apply.

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

##### **13911**

Grade II to IV acute graft versus host disease (aGVHD)

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- Patient must have received prior systemic steroid treatment for this condition, **AND**
- Patient must be one of the following: (i) refractory to steroid treatment, (ii) dependent on steroid treatment, (iii) intolerant to steroid treatment.

#### **Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR
- Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types.

The severity of aGVHD is defined by the Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016).

Steroid-refractory disease is defined as:

(a) progression after at least 3 days of high-dose systemic corticosteroid (methylprednisolone 2 mg/kg/day [or equivalent prednisone dose 2.5 mg/kg/day]) with or without calcineurin inhibitors for the treatment of Grade II-IV aGVHD; or

(b) failure to achieve a partial response after 5 days at the time of initiation of high-dose systemic corticosteroid (methylprednisolone 2 mg/kg/day [or equivalent prednisone dose 2.5 mg/kg/day]) with or without calcineurin inhibitors for the treatment of Grade II-IV aGVHD.

Steroid-dependent disease is defined as failed corticosteroid taper involving either one of the following criteria:

(a) an increase in the corticosteroid dose to methylprednisolone of at least 2 mg/kg/day (or equivalent prednisone dose of at least 2.5 mg/kg/day); or

(b) failure to taper the methylprednisolone dose to less than 0.5 mg/kg/day (or equivalent prednisone dose less than 0.6 mg/kg/day) for a minimum of 7 days.

Steroid intolerance is defined as a patient developing an intolerance of a severity necessitating treatment withdrawal.

Details of prior steroid use should be documented in the patient's medical records.

A patient must demonstrate a response 14 days after initiating treatment with ruxolitinib to be eligible for continuing treatment.

Response is defined as attaining a complete or partial response as assessed by Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016). Note that response is relative to the assessment of organ function affected by aGVHD prior to commencing initial treatment with ruxolitinib.

(a) complete response is defined as a score of 0 for the aGVHD grade in all evaluable organs, indicating a complete resolution of all signs and symptoms of aGVHD, without the administration of any additional systemic therapies for any earlier progression, mixed response or non-response of aGVHD.

(b) partial response is defined as an improvement of one stage, in at least one of the evaluable organs involved with aGVHD signs or symptoms, without disease progression in other organs or sites and without the administration of additional systemic therapies for any earlier progression, mixed response, or non-response of aGVHD.

The assessment of response must be documented in the patient's medical records.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

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**ruxolitinib 5 mg tablet, 56**

13239T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	2422.82	Jakavi [NV]

**ruxolitinib 10 mg tablet, 56**

13236P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	4797.82	Jakavi [NV]

**▪ RUXOLITINIB**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)****13876**

Grade II to IV acute graft versus host disease (aGVHD)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have responding disease compared with baseline after 14 days of treatment demonstrated by either a: (i) partial response (ii) complete response.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR
- Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types.

Response is defined as attaining a complete or partial response as assessed by Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016). Note that response is relative to the assessment of organ function affected by aGVHD prior to commencing initial treatment with ruxolitinib.

(a) complete response is defined as a score of 0 for the aGVHD grade in all evaluable organs, indicating a complete resolution of all signs and symptoms of aGVHD, without the administration of any additional systemic therapies for any earlier progression, mixed response or non-response of aGVHD.

(b) partial response is defined as an improvement of one stage, in at least one of the evaluable organs involved with aGVHD signs or symptoms, without disease progression in other organs or sites and without the administration of additional systemic therapies for any earlier progression, mixed response, or non-response of aGVHD.

The assessment of response must be documented in the patient's medical records.

Tapering the dose of corticosteroids should be considered in patients with responding disease. Following successful tapering of corticosteroids, tapering the dose of ruxolitinib can be initiated.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

**Authority required (STREAMLINED)****13877**

Grade II to IV acute graft versus host disease (aGVHD)

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

**Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 April 2023, **AND**
- Patient must have received systemic steroid treatment prior to initiation of this drug for this condition, **AND**
- Patient must be one of the following: (i) refractory to steroid treatment, (ii) dependent on steroid treatment, (iii) intolerant to steroid treatment, **AND**
- Patient must have responding disease compared with baseline after 14 days of treatment demonstrated by either a: (i) partial response (ii) complete response.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR
- Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types.

Steroid-refractory disease is defined as:

(a) progression after at least 3 days of high-dose systemic corticosteroid (methylprednisolone 2 mg/kg/day [or equivalent prednisone dose 2.5 mg/kg/day]) with or without calcineurin inhibitors for the treatment of Grade II-IV aGVHD; or

(b) failure to achieve a partial response after 5 days at the time of initiation of high-dose systemic corticosteroid (methylprednisolone 2 mg/kg/day [or equivalent prednisone dose 2.5 mg/kg/day]) with or without calcineurin inhibitors for the treatment of Grade II-IV aGVHD.

Steroid-dependent disease is defined as failed corticosteroid taper involving either one of the following criteria:

(a) an increase in the corticosteroid dose to methylprednisolone of at least 2 mg/kg/day (or equivalent prednisone dose of at least 2.5 mg/kg/day); or

(b) failure to taper the methylprednisolone dose to less than 0.5 mg/kg/day (or equivalent prednisone dose less than 0.6 mg/kg/day) for a minimum of 7 days.

Steroid intolerance is defined as a patient developing an intolerance of a severity necessitating treatment withdrawal.

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Details of prior steroid use should be documented in the patient's medical records.

Response is defined as attaining a complete or partial response as assessed by Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016). Note that response is relative to the assessment of organ function affected by aGVHD prior to commencing initial treatment with ruxolitinib.

(a) complete response is defined as a score of 0 for the aGVHD grade in all evaluable organs, indicating a complete resolution of all signs and symptoms of aGVHD, without the administration of any additional systemic therapies for any earlier progression, mixed response or non-response of aGVHD.

(b) partial response is defined as an improvement of one stage, in at least one of the evaluable organs involved with aGVHD signs or symptoms, without disease progression in other organs or sites and without the administration of additional systemic therapies for any earlier progression, mixed response, or non-response of aGVHD.

The assessment of response must be documented in the patient's medical records.

Tapering the dose of corticosteroids should be considered in patients with responding disease. Following successful tapering of corticosteroids, tapering the dose of ruxolitinib can be initiated.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

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

**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.

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**ruxolitinib 5 mg tablet, 56**

13244C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	2422.82	Jakavi [NV]

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**ruxolitinib 10 mg tablet, 56**

13231J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	4797.82	Jakavi [NV]

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# Highly Specialised Drugs Program (Public Hospital)

## ▪ MEPOLIZUMAB

**Note** The length of a break in therapy is measured from the date that the relevant PBS-subsidised medicine listed for this PBS indication is ceased during the most recent treatment cycle, until the date of the subsequent application for treatment under a new treatment cycle.

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

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

**Note** Special Pricing Arrangements apply.

### **Authority required**

Chronic rhinosinusitis with nasal polyps (CRSwNP)

Treatment Phase: Initial treatment

### **Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) ear nose and throat specialist (ENT), (v) general physician experienced in the management of patients with CRSwNP.

### **Clinical criteria:**

- Patient must have a diagnosis of CRSwNP confirmed by at least one of: (i) nasal endoscopy, (ii) computed tomography (CT) scan, with the results documented in the patient's medical records; OR
- Patient must have a diagnosis of CRSwNP from at least two physicians of the above mentioned prescriber types, **AND**
- Patient must have undergone surgery for the removal of nasal polyps; OR
- Patient must have the written advice from at least two physicians of the above mentioned prescriber types demonstrating inappropriateness for surgery, **AND**
- Patient must have, despite optimised nasal polyp therapy, at least two of: (i) bilateral endoscopic nasal polyp score of at least 5 (out of a maximum score of 8, with a minimum score of 2 in each nasal cavity), (ii) nasal obstruction visual analogue scale (VAS) score greater than 5 (out of a maximum score of 10), (iii) overall symptom VAS score greater than 7 (out of a maximum score of 10), **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have had a 12 month break in PBS-subsidised treatment with a biological medicine for this condition, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps, (ii) uncontrolled severe allergic asthma, (iii) uncontrolled severe asthma, **AND**
- Patient must have failed to achieve adequate control with optimised nasal polyp therapy which has been documented, **AND**
- Patient must have blood eosinophil count greater than or equal to 300 cells per microlitre in the last 12 months.

### **Population criteria:**

- Patient must be at least 18 years of age.

Optimised nasal polyp therapy includes:

- (a) adherence to intranasal corticosteroid therapy for at least 2 months, unless contraindicated or not tolerated
- (b) if required, nasal irrigation with saline

Where the patient has a contraindication or intolerance to intranasal corticosteroid therapy, document the reasons for the contraindication or intolerance in the patient's medical file.

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

- (a) a completed authority prescription form,
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice),
- (c) details (date of commencement and duration of therapy) of prior optimised nasal polyp medicine treatment,
- (d) details (date and treatment) of nasal polyp surgery; or
- (e) if applicable, details of surgical exception including serious comorbid disease (e.g. cardiovascular, stroke) making the risk of surgery unacceptable,
- (f) the eosinophil count and date,
- (g) two of the following, measured within the past 12 months: (i) baseline bilateral endoscopic nasal polyp score, (ii) baseline nasal obstruction VAS score, (iii) baseline overall VAS score.

**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).

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Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://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](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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**Authority required**

Chronic rhinosinusitis with nasal polyps (CRSwNP)

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) ear nose and throat specialist (ENT), (v) general physician experienced in the management of patients with CRSwNP.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have both demonstrated and sustained an adequate response to this drug, defined as having at least one of: (i) an improvement in bilateral endoscopic nasal polyp score of at least 1.0 compared to the baseline level provided with the initial authority application, (ii) an improvement in nasal obstruction visual analogue scale (VAS) score of at least 3.0 compared to the baseline level provided with the initial authority application, (iii) an improvement in overall symptom VAS score of at least 2.5 compared to the baseline level provided with the initial authority application.

**Population criteria:**

- Patient must be at least 18 years of age.

**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](http://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).

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**Authority required**

Chronic rhinosinusitis with nasal polyps (CRSwNP)

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

**Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) ear nose and throat specialist (ENT), (v) general physician experienced in the management of patients with CRSwNP.

**Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 April 2023, **AND**
- Patient must have met all initial treatment PBS-eligibility criteria applying to a non-grandfathered patient prior to having commenced treatment with this drug, which are described below.

**Population criteria:**

- Patient must be at least 18 years of age.

Criteria for Grandfathered patients are that:

(a) the diagnosis of CRSwNP was confirmed by at least one of: (i) nasal endoscopy, (ii) computed tomography (CT) scan; or from at least two physicians of the above mentioned prescriber types

(b) the patient has undergone surgery for the removal of nasal polyps; or the patient has the written advice from at least two physicians of the above mentioned prescriber types demonstrating inappropriateness for surgery

(c) the patient had, despite optimised nasal polyp therapy, at least two of: (i) bilateral endoscopic nasal polyp score of at least 5 (out of a maximum score of 8, with a minimum score of 2 in each nasal cavity), (ii) nasal obstruction visual analogue scale (VAS) score greater than 5 (out of a maximum score of 10), (iii) overall symptom VAS score greater than 7 (out of a maximum score of 10)

(d) the treatment was/is not used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps, (ii) uncontrolled severe allergic asthma, (iii) uncontrolled severe asthma

(e) the patient had failed to achieve adequate control with optimised nasal polyp therapy which has been documented

(f) the patient had a blood eosinophil count greater than or equal to 300 cells per microlitre in the 12 months preceding treatment.

Optimised nasal polyp therapy includes:

(a) adherence to intranasal corticosteroid therapy for at least 2 months, unless contraindicated or not tolerated

(b) if required, nasal irrigation with saline

Where the patient has a contraindication or intolerance to intranasal corticosteroid therapy, document the reasons for the contraindication or intolerance in the patient's medical file.

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

(a) a completed authority prescription form,

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice),

(c) details (date of commencement and duration of therapy) of prior optimised nasal polyp medicine treatment,

(d) details (date and treatment) of nasal polyp surgery; or

- (e) if applicable, details of surgical exception including serious comorbid disease (e.g. cardiovascular, stroke) making the risk of surgery unacceptable,
- (f) the eosinophil count and date,
- (g) two of the following, measured within the 12 months prior to non-PBS-subsidised treatment: (i) baseline bilateral endoscopic nasal polyp score, (ii) baseline nasal obstruction VAS score, (iii) baseline overall VAS score.

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

**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](http://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](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### mepolizumab 100 mg/mL injection, 1 mL pen device

13237Q	Max. Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1556.10	Nucala [GK]

### ▪ RUXOLITINIB

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

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

**Note** Special Pricing Arrangements apply.

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

**13907**

Grade II to IV acute graft versus host disease (aGVHD)

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- Patient must have received prior systemic steroid treatment for this condition, **AND**
- Patient must be one of the following: (i) refractory to steroid treatment, (ii) dependent on steroid treatment, (iii) intolerant to steroid treatment.

#### **Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR
- Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types.

The severity of aGVHD is defined by the Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016).

Steroid-refractory disease is defined as:

(a) progression after at least 3 days of high-dose systemic corticosteroid (methylprednisolone 2 mg/kg/day [or equivalent prednisone dose 2.5 mg/kg/day]) with or without calcineurin inhibitors for the treatment of Grade II-IV aGVHD; or

(b) failure to achieve a partial response after 5 days at the time of initiation of high-dose systemic corticosteroid (methylprednisolone 2 mg/kg/day [or equivalent prednisone dose 2.5 mg/kg/day]) with or without calcineurin inhibitors for the treatment of Grade II-IV aGVHD.

Steroid-dependent disease is defined as failed corticosteroid taper involving either one of the following criteria:

(a) an increase in the corticosteroid dose to methylprednisolone of at least 2 mg/kg/day (or equivalent prednisone dose of at least 2.5 mg/kg/day); or

(b) failure to taper the methylprednisolone dose to less than 0.5 mg/kg/day (or equivalent prednisone dose less than 0.6 mg/kg/day) for a minimum of 7 days.

Steroid intolerance is defined as a patient developing an intolerance of a severity necessitating treatment withdrawal.

Details of prior steroid use should be documented in the patient's medical records.

A patient must demonstrate a response 14 days after initiating treatment with ruxolitinib to be eligible for continuing treatment.

Response is defined as attaining a complete or partial response as assessed by Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016). Note that response is relative to the assessment of organ function affected by aGVHD prior to commencing initial treatment with ruxolitinib.

(a) complete response is defined as a score of 0 for the aGVHD grade in all evaluable organs, indicating a complete resolution of all signs and symptoms of aGVHD, without the administration of any additional systemic therapies for any earlier progression, mixed response or non-response of aGVHD.

(b) partial response is defined as an improvement of one stage, in at least one of the evaluable organs involved with aGVHD signs or symptoms, without disease progression in other organs or sites and without the administration of additional systemic therapies for any earlier progression, mixed response, or non-response of aGVHD.

The assessment of response must be documented in the patient's medical records.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

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**ruxolitinib 5 mg tablet, 56**

13243B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	2375.00	Jakavi [NV]

**ruxolitinib 10 mg tablet, 56**

13232K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	4750.00	Jakavi [NV]

**▪ RUXOLITINIB**

**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.

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**Authority required (STREAMLINED)****13892**

Grade II to IV acute graft versus host disease (aGVHD)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have responding disease compared with baseline after 14 days of treatment demonstrated by either a: (i) partial response (ii) complete response.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR
- Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types.

Response is defined as attaining a complete or partial response as assessed by Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016). Note that response is relative to the assessment of organ function affected by aGVHD prior to commencing initial treatment with ruxolitinib.

(a) complete response is defined as a score of 0 for the aGVHD grade in all evaluable organs, indicating a complete resolution of all signs and symptoms of aGVHD, without the administration of any additional systemic therapies for any earlier progression, mixed response or non-response of aGVHD.

(b) partial response is defined as an improvement of one stage, in at least one of the evaluable organs involved with aGVHD signs or symptoms, without disease progression in other organs or sites and without the administration of additional systemic therapies for any earlier progression, mixed response, or non-response of aGVHD.

The assessment of response must be documented in the patient's medical records.

Tapering the dose of corticosteroids should be considered in patients with responding disease. Following successful tapering of corticosteroids, tapering the dose of ruxolitinib can be initiated.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

**Authority required (STREAMLINED)****13891**

Grade II to IV acute graft versus host disease (aGVHD)

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

**Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 April 2023, **AND**
- Patient must have received systemic steroid treatment prior to initiation of this drug for this condition, **AND**
- Patient must be one of the following: (i) refractory to steroid treatment, (ii) dependent on steroid treatment, (iii) intolerant to steroid treatment, **AND**
- Patient must have responding disease compared with baseline after 14 days of treatment demonstrated by either a: (i) partial response (ii) complete response.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR
- Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types.

Steroid-refractory disease is defined as:

(a) progression after at least 3 days of high-dose systemic corticosteroid (methylprednisolone 2 mg/kg/day [or equivalent prednisone dose 2.5 mg/kg/day]) with or without calcineurin inhibitors for the treatment of Grade II-IV aGVHD; or

(b) failure to achieve a partial response after 5 days at the time of initiation of high-dose systemic corticosteroid (methylprednisolone 2 mg/kg/day [or equivalent prednisone dose 2.5 mg/kg/day]) with or without calcineurin inhibitors for the treatment of Grade II-IV aGVHD.

Steroid-dependent disease is defined as failed corticosteroid taper involving either one of the following criteria:

(a) an increase in the corticosteroid dose to methylprednisolone of at least 2 mg/kg/day (or equivalent prednisone dose of at least 2.5 mg/kg/day); or

(b) failure to taper the methylprednisolone dose to less than 0.5 mg/kg/day (or equivalent prednisone dose less than 0.6 mg/kg/day) for a minimum of 7 days.

Steroid intolerance is defined as a patient developing an intolerance of a severity necessitating treatment withdrawal.

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Details of prior steroid use should be documented in the patient's medical records.

Response is defined as attaining a complete or partial response as assessed by Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016). Note that response is relative to the assessment of organ function affected by aGVHD prior to commencing initial treatment with ruxolitinib.

(a) complete response is defined as a score of 0 for the aGVHD grade in all evaluable organs, indicating a complete resolution of all signs and symptoms of aGVHD, without the administration of any additional systemic therapies for any earlier progression, mixed response or non-response of aGVHD.

(b) partial response is defined as an improvement of one stage, in at least one of the evaluable organs involved with aGVHD signs or symptoms, without disease progression in other organs or sites and without the administration of additional systemic therapies for any earlier progression, mixed response, or non-response of aGVHD.

The assessment of response must be documented in the patient's medical records.

Tapering the dose of corticosteroids should be considered in patients with responding disease. Following successful tapering of corticosteroids, tapering the dose of ruxolitinib can be initiated.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

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

**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.

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#### **ruxolitinib 5 mg tablet, 56**

13238R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	2375.00	Jakavi [NV]

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#### **ruxolitinib 10 mg tablet, 56**

13245D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	4750.00	Jakavi [NV]

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# Highly Specialised Drugs Program (Community Access)

## ▪ ABACAVIR

**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](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

### Authority required

Human immunodeficiency virus (HIV) infection

### **Population criteria:**

- Patient must be less than 13.00 years of age.

### **Clinical criteria:**

- Patient must be unable to take a solid dose form of this drug, **AND**
- The treatment must be in combination with other antiretroviral agents.

### **abacavir 20 mg/mL oral liquid, 240 mL**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10356C	8	5	..	*562.94	30.00	Ziagen [VI]

