



Australian Government

**Department of Health
and Aged Care**



Schedule of Pharmaceutical Benefits

Summary of Changes

Effective 1 June 2023



Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 June 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 June 2023. The Schedule is updated on the first day of each month and is available on the internet at www.pbs.gov.au.

General Pharmaceutical Benefits

Additions

Addition – Item

13288J	APALUTAMIDE , apalutamide 60 mg tablet, 120 (<i>Erlyand</i>)
13277T	CANNABIDIOL , cannabidiol 100 mg/mL oral liquid, 100 mL (<i>Epidyolex</i>)
13278W	CEFALEXIN , cefalexin 250 mg/5 mL powder for oral liquid, 100 mL (<i>Keforal</i>)
13285F	CEFALEXIN , cefalexin 250 mg/5 mL powder for oral liquid, 100 mL (<i>Keforal</i>)
13284E	CICLOSPORIN , ciclosporin 0.09% eye drops, 60 x 0.25 mL unit doses (<i>Cequa</i>)
13280Y	DISOPYRAMIDE , disopyramide 100 mg capsule, 84 (<i>Rythmodan (Canada)</i>)
13281B	LAROTRECTINIB , larotrectinib 20 mg/mL oral liquid, 2 x 50 mL (<i>VITRAKVI</i>)
13289K	LAROTRECTINIB , larotrectinib 20 mg/mL oral liquid, 2 x 50 mL (<i>VITRAKVI</i>)
13290L	LENVATINIB , lenvatinib 4 mg capsule, 30 (<i>Lenvima</i>)
13283D	LENVATINIB , lenvatinib 10 mg capsule, 30 (<i>Lenvima</i>)
13279X	MINOXIDIL , minoxidil 10 mg tablet, 60 (<i>Minoxidil 10 mg (Roma Pharmaceuticals)</i>)
13282C	PHENOXYMETHYLPENICILLIN , phenoxymethylpenicillin 250 mg/5 mL powder for oral liquid, 100 mL (<i>Penopen</i>)
13291M	PHENOXYMETHYLPENICILLIN , phenoxymethylpenicillin 250 mg/5 mL powder for oral liquid, 100 mL (<i>Penopen</i>)

Addition – Brand

2751T	<i>Blooms Amlodipine, BG</i> – AMLODIPINE , amlodipine 5 mg tablet, 30
2752W	<i>Blooms Amlodipine, BG</i> – AMLODIPINE , amlodipine 10 mg tablet, 30
13179P	<i>Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo – Pro Pharmaceuticals), QY</i> – AMOXICILLIN + CLAVULANIC ACID , amoxicillin 875 mg + clavulanic acid 125 mg tablet, 20
13179P	<i>Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Micro Labs), QZ</i> – AMOXICILLIN + CLAVULANIC ACID , amoxicillin 875 mg + clavulanic acid 125 mg tablet, 20
13190F	<i>Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo – Pro Pharmaceuticals), QY</i> – AMOXICILLIN + CLAVULANIC ACID , amoxicillin 875 mg + clavulanic acid 125 mg tablet, 20
13190F	<i>Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Micro Labs), QZ</i> – AMOXICILLIN + CLAVULANIC ACID , amoxicillin 875 mg + clavulanic acid 125 mg tablet, 20
13194K	<i>Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo – Pro Pharmaceuticals), QY</i> – AMOXICILLIN + CLAVULANIC ACID , amoxicillin 875 mg + clavulanic acid 125 mg tablet, 20
13194K	<i>Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Micro Labs), QZ</i> – AMOXICILLIN + CLAVULANIC ACID , amoxicillin 875 mg + clavulanic acid 125 mg tablet, 20
12114N	<i>Ceftriaxone Viatrix, AL</i> – CEFTRIAZONE , ceftriaxone 1 g injection, 10 vials
1788D	<i>Ceftriaxone Viatrix, AL</i> – CEFTRIAZONE , ceftriaxone 1 g injection, 5 vials
11169W	<i>Ceftriaxone Viatrix, AL</i> – CEFTRIAZONE , ceftriaxone 2 g injection, 5 vials

12112L	<i>Ceftriaxone Viatris, AL</i> – CEFTRIAZONE , ceftriaxone 2 g injection, 10 vials
1357K	<i>Dosulepin Viatris, MQ</i> – DOSULEPIN (DOTHIEPIN) , dosulepin (dothiepin) hydrochloride 25 mg capsule, 50
9432K	<i>APO-Escitalopram, TX</i> – ESCITALOPRAM , escitalopram 10 mg tablet, 28
9433L	<i>APO-Escitalopram, TX</i> – ESCITALOPRAM , escitalopram 20 mg tablet, 28
8757X	<i>BTC Ezetimibe, BG</i> – EZETIMIBE , ezetimibe 10 mg tablet, 30
5262Y	<i>Fingolimod-Teva, TB</i> – FINGOLIMOD , fingolimod 500 microgram capsule, 28
8432T	<i>Fluticasone Salmeterol Ciphale 500/50, LR</i> – FLUTICASONE PROPIONATE + SALMETEROL , fluticasone propionate 500 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations
11107N	<i>FOSAPREPITANT-AFT, AE</i> – FOSAPREPITANT , fosaprepitant 150 mg injection, 1 vial
9302N	<i>Gliclazide Lupin MR, GQ</i> – GLICLAZIDE , gliclazide 60 mg modified release tablet, 60
2174K	<i>Levothox, AF</i> – LEVOTHYROXINE , levothyroxine sodium 50 microgram tablet, 200
9287T	<i>Levothox, AF</i> – LEVOTHYROXINE , levothyroxine sodium 75 microgram tablet, 200
2175L	<i>Levothox, AF</i> – LEVOTHYROXINE , levothyroxine sodium 100 microgram tablet, 200
12830G	<i>Levothox, AF</i> – LEVOTHYROXINE , levothyroxine sodium 125 microgram tablet, 200
2173J	<i>Levothox, AF</i> – LEVOTHYROXINE , levothyroxine sodium 200 microgram tablet, 200
2147B	<i>Olsetan, MQ</i> – OLMESARTAN , olmesartan medoxomil 20 mg tablet, 30
2148C	<i>Olsetan, MQ</i> – OLMESARTAN , olmesartan medoxomil 40 mg tablet, 30
8814X	<i>Parapane OSTEO, AF</i> – PARACETAMOL , paracetamol 665 mg modified release tablet, 96
2242B	<i>Blooms The Chemist Paroxetine, BG</i> – PAROXETINE , paroxetine 20 mg tablet, 30
11296M	<i>Tenofovir Disoproxil Emtricitabine Viatris 300/200, AL</i> – TENOFOVIR DISOPROXIL + EMTRICITABINE , tenofovir disoproxil maleate 300 mg + emtricitabine 200 mg tablet, 30
9009E	<i>Velabine, LI</i> – VINORELBINE , vinorelbine 20 mg capsule, 1
9010F	<i>Velabine, LI</i> – VINORELBINE , vinorelbine 30 mg capsule, 1

Addition – Equivalence Indicator

2923W	<i>Rythmodan, PB</i> – DISOPYRAMIDE , disopyramide 100 mg capsule, 100
11107N	<i>Emend IV, MK</i> – FOSAPREPITANT , fosaprepitant 150 mg injection, 1 vial
13030T	<i>Vitrakvi, BN</i> – LAROTRECTINIB , larotrectinib 20 mg/mL oral liquid, 100 mL
13035C	<i>Vitrakvi, BN</i> – LAROTRECTINIB , larotrectinib 20 mg/mL oral liquid, 100 mL
2174K	<i>Eltroxin, LT</i> – LEVOTHYROXINE , levothyroxine sodium 50 microgram tablet, 200
9287T	<i>Eltroxin, LT</i> – LEVOTHYROXINE , levothyroxine sodium 75 microgram tablet, 200
2175L	<i>Eltroxin, LT</i> – LEVOTHYROXINE , levothyroxine sodium 100 microgram tablet, 200
12830G	<i>Eltroxin, LT</i> – LEVOTHYROXINE , levothyroxine sodium 125 microgram tablet, 200
2173J	<i>Eltroxin, LT</i> – LEVOTHYROXINE , levothyroxine sodium 200 microgram tablet, 200
2313R	<i>Loniten, PF</i> – MINOXIDIL , minoxidil 10 mg tablet, 100
5029Q	<i>Phenoxymethylpenicillin-AFT, AE</i> – PHENOXYMETHYLPENICILLIN , phenoxymethylpenicillin 250 mg/5 mL powder for oral liquid, 100 mL
8977L	<i>Phenoxymethylpenicillin-AFT, AE</i> – PHENOXYMETHYLPENICILLIN , phenoxymethylpenicillin 250 mg/5 mL powder for oral liquid, 100 mL
9009E	<i>Navelbine, FB</i> – VINORELBINE , vinorelbine 20 mg capsule, 1
9010F	<i>Navelbine, FB</i> – VINORELBINE , vinorelbine 30 mg capsule, 1

Addition – Note

3095X	CEFALEXIN , cefalexin 250 mg/5 mL powder for oral liquid, 100 mL (<i>Cefalexin Sandoz, Ibilex 250, Keflex</i>)
3320R	CEFALEXIN , cefalexin 250 mg/5 mL powder for oral liquid, 100 mL (<i>Cefalexin Sandoz, Ibilex 250, Keflex</i>)
2923W	DISOPYRAMIDE , disopyramide 100 mg capsule, 100 (<i>Rythmodan</i>)
13030T	LAROTRECTINIB , larotrectinib 20 mg/mL oral liquid, 100 mL (<i>Vitrakvi</i>)

13035C	LAROTRECTINIB , larotrectinib 20 mg/mL oral liquid, 100 mL (<i>Vitrakvi</i>)
2313R	MINOXIDIL , minoxidil 10 mg tablet, 100 (<i>Loniten</i>)
5029Q	PHENOXYMETHYLPENICILLIN , phenoxymethylpenicillin 250 mg/5 mL powder for oral liquid, 100 mL (<i>Phenoxymethylpenicillin-AFT</i>)
8977L	PHENOXYMETHYLPENICILLIN , phenoxymethylpenicillin 250 mg/5 mL powder for oral liquid, 100 mL (<i>Phenoxymethylpenicillin-AFT</i>)

Deletions

Deletion – Brand

8595J	<i>Amisulpride 200 Winthrop, WA</i> – AMISULPRIDE , amisulpride 200 mg tablet, 60
1209P	<i>Ciprofloxacin GH, HQ</i> – CIPROFLOXACIN , ciprofloxacin 500 mg tablet, 14
2532G	<i>Donepezil-DRLA, RZ</i> – DONEPEZIL , donepezil hydrochloride 5 mg tablet, 28
8495D	<i>Donepezil-DRLA, RZ</i> – DONEPEZIL , donepezil hydrochloride 5 mg tablet, 28
2479L	<i>Donepezil-DRLA, RZ</i> – DONEPEZIL , donepezil hydrochloride 10 mg tablet, 28
8496E	<i>Donepezil-DRLA, RZ</i> – DONEPEZIL , donepezil hydrochloride 10 mg tablet, 28
1392G	<i>Triphasil 28, PF</i> – LEVONORGESTREL + ETHINYLESTRADIOL , 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> – LISINOPRIL , lisinopril 5 mg tablet, 30
2457H	<i>Lisinopril generichealth, GQ</i> – LISINOPRIL , lisinopril 10 mg tablet, 30
10804P	<i>Momasone, AS</i> – MOMETASONE , mometasone furoate 0.1% lotion, 30 mL
10805Q	<i>Momasone, AS</i> – MOMETASONE , mometasone furoate 0.1% lotion, 30 mL
10819K	<i>Momasone, AS</i> – MOMETASONE , mometasone furoate 0.1% lotion, 30 mL
10826T	<i>Momasone, AS</i> – MOMETASONE , mometasone furoate 0.1% lotion, 30 mL
8043H	<i>Momasone, AS</i> – MOMETASONE , mometasone furoate 0.1% lotion, 30 mL
8170B	<i>Olanzapine-DRLA, RZ</i> – OLANZAPINE , olanzapine 2.5 mg tablet, 28
8185T	<i>Olanzapine-DRLA, RZ</i> – OLANZAPINE , olanzapine 5 mg tablet, 28
8186W	<i>Olanzapine-DRLA, RZ</i> – OLANZAPINE , olanzapine 7.5 mg tablet, 28
8187X	<i>Olanzapine-DRLA, RZ</i> – OLANZAPINE , olanzapine 10 mg tablet, 28
5470X	<i>Ondansetron ODT GH, GQ</i> – ONDANSETRON , ondansetron 4 mg orally disintegrating tablet, 4
5472B	<i>Ondansetron ODT GH, GQ</i> – ONDANSETRON , ondansetron 4 mg orally disintegrating tablet, 10
5471Y	<i>Ondansetron ODT GH, GQ</i> – ONDANSETRON , ondansetron 8 mg orally disintegrating tablet, 4
5473C	<i>Ondansetron ODT GH, GQ</i> – ONDANSETRON , ondansetron 8 mg orally disintegrating tablet, 10
8829Q	<i>Pravastatin generichealth, GQ</i> – PRAVASTATIN , pravastatin sodium 80 mg tablet, 30
9240H	<i>Pravastatin generichealth, GQ</i> – PRAVASTATIN , pravastatin sodium 80 mg tablet, 30
2348N	<i>Pregabalin GH, GQ</i> – PREGABALIN , pregabalin 25 mg capsule, 56
1970Q	<i>Quinapril generichealth, GQ</i> – QUINAPRIL , quinapril 20 mg tablet, 30
1978D	<i>Zantac, AS</i> – RANITIDINE , ranitidine 150 mg tablet, 60
1977C	<i>Zantac, AS</i> – RANITIDINE , ranitidine 300 mg tablet, 30
1952R	<i>Rasazil, GQ</i> – RASAGILINE , rasagiline 1 mg tablet, 30
8356T	<i>Telmisartan GH, GQ</i> – TELMISARTAN , telmisartan 80 mg tablet, 28
8622T	<i>Telmisartan HCT GH 40/12.5, GQ</i> – TELMISARTAN + HYDROCHLOROTHIAZIDE , telmisartan 40 mg + hydrochlorothiazide 12.5 mg tablet, 28
8623W	<i>Telmisartan HCT GH 80/12.5, GQ</i> – TELMISARTAN + HYDROCHLOROTHIAZIDE , telmisartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28

Deletion – Equivalence Indicator

1392G	<i>Trifeme 28, FZ</i> – LEVONORGESTREL + ETHINYLESTRADIOL , 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
1978D	<i>APO-Ranitidine, TX</i> – RANITIDINE , ranitidine 150 mg tablet, 60
1977C	<i>APO-Ranitidine, TX</i> – RANITIDINE , ranitidine 300 mg tablet, 30

Deletion – Note

12467E	CANNABIDIOL , cannabidiol 100 mg/mL oral liquid, 100 mL (<i>Epidyolex</i>)
10076H	NICOTINE , nicotine 25 mg/16 hours patch, 28 (<i>nicorette 16hr Invisipatch</i>)
5465P	NICOTINE , nicotine 21 mg/24 hours patch, 28 (<i>Nicabate P</i>)

Alterations

Alteration – Brand Name

From	
13179P	<i>Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg, DZ</i> – AMOXICILLIN + CLAVULANIC ACID , amoxicillin 875 mg + clavulanic acid 125 mg tablet, 20
To	
13179P	<i>Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo - Medsurge), DZ</i> – AMOXICILLIN + CLAVULANIC ACID , amoxicillin 875 mg + clavulanic acid 125 mg tablet, 20
From	
13190F	<i>Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg, DZ</i> – AMOXICILLIN + CLAVULANIC ACID , amoxicillin 875 mg + clavulanic acid 125 mg tablet, 20
To	
13190F	<i>Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo - Medsurge), DZ</i> – AMOXICILLIN + CLAVULANIC ACID , amoxicillin 875 mg + clavulanic acid 125 mg tablet, 20
From	
13194K	<i>Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg, DZ</i> – AMOXICILLIN + CLAVULANIC ACID , amoxicillin 875 mg + clavulanic acid 125 mg tablet, 20
To	
13194K	<i>Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo - Medsurge), DZ</i> – AMOXICILLIN + CLAVULANIC ACID , amoxicillin 875 mg + clavulanic acid 125 mg tablet, 20

Alteration – Authorised Prescriber

		From	To
8370M	NALTREXONE , naltrexone hydrochloride 50 mg tablet, 30 (<i>Naltrexone GH</i>)	M	M,N

Alteration – Note

12969N	LEVOTHYROXINE , levothyroxine sodium 50 microgram tablet, 2 x 100 (<i>LEVOXINE</i>)
2174K	LEVOTHYROXINE , levothyroxine sodium 50 microgram tablet, 200 (<i>Eltroxin, Eutroxsig, Levothox, Oroxine</i>)
12960D	LEVOTHYROXINE , levothyroxine sodium 75 microgram tablet, 2 x 100 (<i>LEVOXINE</i>)
9287T	LEVOTHYROXINE , levothyroxine sodium 75 microgram tablet, 200 (<i>Eltroxin, Eutroxsig, Levothox, Oroxine</i>)
12968M	LEVOTHYROXINE , levothyroxine sodium 100 microgram tablet, 2 x 100 (<i>LEVOXINE</i>)
2175L	LEVOTHYROXINE , levothyroxine sodium 100 microgram tablet, 200 (<i>Eltroxin, Eutroxsig, Levothox, Oroxine</i>)
12970P	LEVOTHYROXINE , levothyroxine sodium 200 microgram tablet, 2 x 100 (<i>LEVOXINE</i>)
2173J	LEVOTHYROXINE , levothyroxine sodium 200 microgram tablet, 200 (<i>Eltroxin, Eutroxsig, Levothox, Oroxine</i>)

Alteration – Restriction

12663L	CICLOSPORIN , ciclosporin 0.1% eye drops, 30 x 0.3 mL unit doses (<i>Ikervis</i>)
5573H	NICOTINE , nicotine 7 mg/24 hours patch, 28 (<i>Nicotinell Step 3</i>)
5572G	NICOTINE , nicotine 14 mg/24 hours patch, 28 (<i>Nicotinell Step 2</i>)
10076H	NICOTINE , nicotine 25 mg/16 hours patch, 28 (<i>nicorette 16hr Invisipatch</i>)
3414Q	NICOTINE , nicotine 21 mg/24 hours patch, 28 (<i>Nicotinell Step 1</i>)
5465P	NICOTINE , nicotine 21 mg/24 hours patch, 28 (<i>Nicabate P</i>)

Alteration – Manufacturer Code

		<i>From</i>	<i>To</i>
10046R	<i>Lumigan PF – BIMATOPROST</i> , bimatoprost 0.03% eye drops, 30 x 0.4 mL unit doses	AG	VE
10053D	<i>Lumigan PF – BIMATOPROST</i> , bimatoprost 0.03% eye drops, 30 x 0.4 mL unit doses	AG	VE
5551E	<i>Lumigan – BIMATOPROST</i> , bimatoprost 0.03% eye drops, 3 mL	AG	VE
8620Q	<i>Lumigan – BIMATOPROST</i> , bimatoprost 0.03% eye drops, 3 mL	AG	VE
10107Y	<i>GANfort PF 0.3/5 – BIMATOPROST + TIMOLOL</i> , bimatoprost 0.03% + timolol 0.5% eye drops, 30 x 0.4 mL unit doses	AG	VE
10108B	<i>GANfort PF 0.3/5 – BIMATOPROST + TIMOLOL</i> , bimatoprost 0.03% + timolol 0.5% eye drops, 30 x 0.4 mL unit doses	AG	VE
5558M	<i>Ganfort 0.3/5 – BIMATOPROST + TIMOLOL</i> , bimatoprost 0.03% + timolol 0.5% eye drops, 3 mL	AG	VE
9464D	<i>Ganfort 0.3/5 – BIMATOPROST + TIMOLOL</i> , bimatoprost 0.03% + timolol 0.5% eye drops, 3 mL	AG	VE
5298W	<i>Alphagan P 1.5 – BRIMONIDINE</i> , brimonidine tartrate 0.15% eye drops, 5 mL	AG	VE
5563T	<i>Alphagan P 1.5 – BRIMONIDINE</i> , brimonidine tartrate 0.15% eye drops, 5 mL	AG	VE
5534G	<i>Alphagan – BRIMONIDINE</i> , brimonidine tartrate 0.2% eye drops, 5 mL	AG	VE
5534G	<i>Enidin – BRIMONIDINE</i> , brimonidine tartrate 0.2% eye drops, 5 mL	PE	VB
8351M	<i>Alphagan – BRIMONIDINE</i> , brimonidine tartrate 0.2% eye drops, 5 mL	AG	VE
8351M	<i>Enidin – BRIMONIDINE</i> , brimonidine tartrate 0.2% eye drops, 5 mL	PE	VB
5535H	<i>Combigan – BRIMONIDINE + TIMOLOL</i> , brimonidine tartrate 0.2% + timolol 0.5% eye drops, 5 mL	AG	VE
8826M	<i>Combigan – BRIMONIDINE + TIMOLOL</i> , brimonidine tartrate 0.2% + timolol 0.5% eye drops, 5 mL	AG	VE
2338C	<i>Cellufresh – CARMELLOSE SODIUM</i> , carmellose sodium 0.5% eye drops, 30 x 0.4 mL unit doses	AG	VE
5506T	<i>Cellufresh – CARMELLOSE SODIUM</i> , carmellose sodium 0.5% eye drops, 30 x 0.4 mL unit doses	AG	VE
5507W	<i>Refresh Tears Plus – CARMELLOSE SODIUM</i> , carmellose sodium 0.5% eye drops, 15 mL	AG	VE
8548X	<i>Refresh Tears Plus – CARMELLOSE SODIUM</i> , carmellose sodium 0.5% eye drops, 15 mL	AG	VE
9211T	<i>Refresh Tears Plus – CARMELLOSE SODIUM</i> , carmellose sodium 0.5% eye drops, 15 mL	AG	VE
2324H	<i>Celluvisc – CARMELLOSE SODIUM</i> , carmellose sodium 1% eye drops, 30 x 0.4 mL unit doses	AG	VE
5505R	<i>Celluvisc – CARMELLOSE SODIUM</i> , carmellose sodium 1% eye drops, 30 x 0.4 mL unit doses	AG	VE
5508X	<i>Refresh Liquigel – CARMELLOSE SODIUM</i> , carmellose sodium 1% eye drops, 15 mL	AG	VE
8593G	<i>Refresh Liquigel – CARMELLOSE SODIUM</i> , carmellose sodium 1% eye drops, 15 mL	AG	VE
9212W	<i>Refresh Liquigel – CARMELLOSE SODIUM</i> , carmellose sodium 1% eye drops, 15 mL	AG	VE
5556K	<i>Optive – CARMELLOSE SODIUM + GLYCEROL</i> , carmellose sodium 0.5% + glycerol 0.9% eye drops, 15 mL	AG	VE
9355J	<i>Optive – CARMELLOSE SODIUM + GLYCEROL</i> , carmellose sodium 0.5% + glycerol 0.9% eye drops, 15 mL	AG	VE
9356K	<i>Optive – CARMELLOSE SODIUM + GLYCEROL</i> , carmellose sodium 0.5% + glycerol 0.9% eye drops, 15 mL	AG	VE
10943Y	<i>Ozurdex – DEXAMETHASONE</i> , dexamethasone 700 microgram implant, 1	AG	VE
11317P	<i>Ozurdex – DEXAMETHASONE</i> , dexamethasone 700 microgram implant, 1	AG	VE
11469P	<i>Ozurdex – DEXAMETHASONE</i> , dexamethasone 700 microgram implant, 1	AG	VE
13142Q	<i>Ozurdex – DEXAMETHASONE</i> , dexamethasone 700 microgram implant, 1	AG	VE
13168C	<i>Ozurdex – DEXAMETHASONE</i> , dexamethasone 700 microgram implant, 1	AG	VE

5437E	<i>Fenpatch 12</i> – FENTANYL , fentanyl 12 microgram/hour patch, 5	ZP	RW
5438F	<i>Fenpatch 25</i> – FENTANYL , fentanyl 25 microgram/hour patch, 5	ZP	RW
5439G	<i>Fenpatch 50</i> – FENTANYL , fentanyl 50 microgram/hour patch, 5	ZP	RW
5440H	<i>Fenpatch 75</i> – FENTANYL , fentanyl 75 microgram/hour patch, 5	ZP	RW
5441J	<i>Fenpatch 100</i> – FENTANYL , fentanyl 100 microgram/hour patch, 5	ZP	RW
1204J	<i>FML Liquifilm</i> – FLUOROMETHOLONE , fluorometholone 0.1% eye drops, 5 mL	AG	VE
5513E	<i>FML Liquifilm</i> – FLUOROMETHOLONE , fluorometholone 0.1% eye drops, 5 mL	AG	VE
1441W	<i>Genoptic</i> – GENTAMICIN , gentamicin 0.3% eye drops, 5 mL	AG	VE
5566Y	<i>Genoptic</i> – GENTAMICIN , gentamicin 0.3% eye drops, 5 mL	AG	VE
8374R	<i>Lunava 10</i> – LEFLUNOMIDE , leflunomide 10 mg tablet, 30	ZP	RW
8375T	<i>Lunava 20</i> – LEFLUNOMIDE , leflunomide 20 mg tablet, 30	ZP	RW
5567B	<i>Ocuflox</i> – OFLOXACIN , ofloxacin 0.3% eye drops, 5 mL	AG	VE
8383F	<i>Ocuflox</i> – OFLOXACIN , ofloxacin 0.3% eye drops, 5 mL	AG	VE
11683X	<i>Ozmep</i> – OMEPRAZOLE , omeprazole 20 mg enteric tablet, 30	ZP	RW
12272X	<i>Ozmep</i> – OMEPRAZOLE , omeprazole 20 mg enteric tablet, 30	ZP	RW
8331L	<i>Ozmep</i> – OMEPRAZOLE , omeprazole 20 mg enteric tablet, 30	ZP	RW
8333N	<i>Ozmep</i> – OMEPRAZOLE , omeprazole 20 mg enteric tablet, 30	ZP	RW
1750D	<i>Refresh Night Time</i> – PARAFFIN , paraffin 1 g/g eye ointment, 2 x 3.5 g	AG	VE
5522P	<i>Refresh Night Time</i> – PARAFFIN , paraffin 1 g/g eye ointment, 2 x 3.5 g	AG	VE
9218E	<i>Refresh Night Time</i> – PARAFFIN , paraffin 1 g/g eye ointment, 2 x 3.5 g	AG	VE
11908R	<i>Prednefrin Forte</i> – PREDNISOLONE ACETATE + PHENYLEPHRINE , prednisolone acetate 1% + phenylephrine hydrochloride 0.12% eye drops, 10 mL	AG	VE
3112T	<i>Prednefrin Forte</i> – PREDNISOLONE ACETATE + PHENYLEPHRINE , prednisolone acetate 1% + phenylephrine hydrochloride 0.12% eye drops, 10 mL	AG	VE
5568C	<i>Prednefrin Forte</i> – PREDNISOLONE ACETATE + PHENYLEPHRINE , prednisolone acetate 1% + phenylephrine hydrochloride 0.12% eye drops, 10 mL	AG	VE
8868R	<i>Elaxine SR 37.5</i> – VENLAFAXINE , venlafaxine 37.5 mg modified release capsule, 28	ZP	RW
8301X	<i>Elaxine SR 75</i> – VENLAFAXINE , venlafaxine 75 mg modified release capsule, 28	ZP	RW
8302Y	<i>Elaxine SR 150</i> – VENLAFAXINE , venlafaxine 150 mg modified release capsule, 28	ZP	RW

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

Supply Only Commencing 1 June 2023

1567L **LABETALOL**, labetalol hydrochloride 200 mg tablet, 100 (*Trandate*)

Advance Notices

1 July 2023

Deletion – Brand

9012H *Alendronate plus D3-DRLA, RZ* – **ALENDRONATE + COLECALCIFEROL**, alendronate 70 mg + colecalciferol 70 microgram (2800 units) tablet, 4

9183H *Alendronate plus D3-DRLA, RZ* – **ALENDRONATE + COLECALCIFEROL**, alendronate 70 mg + colecalciferol 140 microgram (5600 units) tablet, 4

2688L *Azathioprine GH, GQ* – **AZATHIOPRINE**, azathioprine 25 mg tablet, 100

11692J *Esomeprazole Sandoz, SZ* – **ESOMEPRAZOLE**, esomeprazole 20 mg enteric tablet, 30

11692J	<i>Esomeprazole SZ, HX</i> – ESOMEPRAZOLE , esomeprazole 20 mg enteric tablet, 30
12283L	<i>Esomeprazole Sandoz, SZ</i> – ESOMEPRAZOLE , esomeprazole 40 mg enteric tablet, 30
12283L	<i>Esomeprazole SZ, HX</i> – ESOMEPRAZOLE , esomeprazole 40 mg enteric tablet, 30
12287Q	<i>Esomeprazole Sandoz, SZ</i> – ESOMEPRAZOLE , esomeprazole 20 mg enteric tablet, 30
12287Q	<i>Esomeprazole SZ, HX</i> – ESOMEPRAZOLE , esomeprazole 20 mg enteric tablet, 30
3401B	<i>Esomeprazole Sandoz, SZ</i> – ESOMEPRAZOLE , esomeprazole 40 mg enteric tablet, 30
3401B	<i>Esomeprazole SZ, HX</i> – ESOMEPRAZOLE , esomeprazole 40 mg enteric tablet, 30
8600P	<i>Esomeprazole Sandoz, SZ</i> – ESOMEPRAZOLE , esomeprazole 20 mg enteric tablet, 30
8600P	<i>Esomeprazole SZ, HX</i> – ESOMEPRAZOLE , esomeprazole 20 mg enteric tablet, 30
8601Q	<i>Esomeprazole Sandoz, SZ</i> – ESOMEPRAZOLE , esomeprazole 40 mg enteric tablet, 30
8601Q	<i>Esomeprazole SZ, HX</i> – ESOMEPRAZOLE , esomeprazole 40 mg enteric tablet, 30
8886Q	<i>Esomeprazole Sandoz, SZ</i> – ESOMEPRAZOLE , esomeprazole 20 mg enteric tablet, 30
8886Q	<i>Esomeprazole SZ, HX</i> – ESOMEPRAZOLE , esomeprazole 20 mg enteric tablet, 30
2848X	<i>Lamotrigine Sandoz, SZ</i> – LAMOTRIGINE , lamotrigine 25 mg tablet, 56
2849Y	<i>Lamotrigine Sandoz, SZ</i> – LAMOTRIGINE , lamotrigine 50 mg tablet, 56
2850B	<i>Lamotrigine Sandoz, SZ</i> – LAMOTRIGINE , lamotrigine 100 mg tablet, 56
2851C	<i>Lamotrigine Sandoz, SZ</i> – LAMOTRIGINE , lamotrigine 200 mg tablet, 56
8607B	<i>Sandoz Metformin, HX</i> – METFORMIN , metformin hydrochloride 1 g tablet, 90
8855C	<i>Mirtazapine Sandoz ODT 15, SZ</i> – MIRTAZAPINE , mirtazapine 15 mg orally disintegrating tablet, 30
8856D	<i>Mirtazapine Sandoz ODT 30, SZ</i> – MIRTAZAPINE , mirtazapine 30 mg orally disintegrating tablet, 30
8857E	<i>Mirtazapine Sandoz ODT 45, SZ</i> – MIRTAZAPINE , mirtazapine 45 mg orally disintegrating tablet, 30
12031F	<i>Oxycodone BNM, BZ</i> – OXYCODONE , oxycodone hydrochloride 10 mg capsule, 20
12074L	<i>Oxycodone BNM, BZ</i> – OXYCODONE , oxycodone hydrochloride 10 mg capsule, 20
5197M	<i>Oxycodone BNM, BZ</i> – OXYCODONE , oxycodone hydrochloride 10 mg capsule, 20
8501K	<i>Oxycodone BNM, BZ</i> – OXYCODONE , oxycodone hydrochloride 10 mg capsule, 20
8829Q	<i>Pravastatin Sandoz, SZ</i> – PRAVASTATIN , pravastatin sodium 80 mg tablet, 30
9240H	<i>Pravastatin Sandoz, SZ</i> – PRAVASTATIN , pravastatin sodium 80 mg tablet, 30
10551H	<i>Rizatriptan-AU, DZ</i> – RIZATRIPTAN , rizatriptan 10 mg orally disintegrating tablet, 2
8355R	<i>Telmisartan GH, GQ</i> – TELMISARTAN , telmisartan 40 mg tablet, 28

1 August 2023

Deletion – Brand

1358L	<i>Dosulepin Mylan, MQ</i> – DOSULEPIN (DOTHIEPIN) , dosulepin (dothiepin) hydrochloride 75 mg tablet, 30
11264W	<i>Iressa, AP</i> – GEFITINIB , gefitinib 250 mg tablet, 30
8769M	<i>Iressa, AP</i> – GEFITINIB , gefitinib 250 mg tablet, 30
1500Y	<i>Hydrocortisone Mylan 20, MQ</i> – HYDROCORTISONE , hydrocortisone 20 mg tablet, 60
13030T	<i>Vitrakvi, BN</i> – LAROTRECTINIB , larotrectinib 20 mg/mL oral liquid, 100 mL
13035C	<i>Vitrakvi, BN</i> – LAROTRECTINIB , larotrectinib 20 mg/mL oral liquid, 100 mL

1 December 2023

Deletion – Brand

2418G	<i>Amitriptyline Alphapharm 25, MQ</i> – AMITRIPTYLINE , amitriptyline hydrochloride 25 mg tablet, 50
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Palliative Care

Additions

Addition – Brand

5343F	<i>Parapane OSTEO, AF</i> – PARACETAMOL , paracetamol 665 mg modified release tablet, 96
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Alterations

Alteration – Manufacturer Code

		<i>From</i>	<i>To</i>
12530L	<i>Fenpatch 12 – FENTANYL</i> , fentanyl 12 microgram/hour patch, 5	ZP	RW
12521B	<i>Fenpatch 25 – FENTANYL</i> , fentanyl 25 microgram/hour patch, 5	ZP	RW
12513N	<i>Fenpatch 50 – FENTANYL</i> , fentanyl 50 microgram/hour patch, 5	ZP	RW
12517T	<i>Fenpatch 75 – FENTANYL</i> , fentanyl 75 microgram/hour patch, 5	ZP	RW
12480W	<i>Fenpatch 100 – FENTANYL</i> , fentanyl 100 microgram/hour patch, 5	ZP	RW

Highly Specialised Drugs Program (Private Hospital)

Additions

Addition – Brand

12201E	<i>Ambrisentan Viatris, AL – AMBRISENTAN</i> , ambrisentan 5 mg tablet, 30
9648T	<i>Ambrisentan Viatris, AL – AMBRISENTAN</i> , ambrisentan 5 mg tablet, 30
11036W	<i>Lenalidomide Viatris, AF – LENALIDOMIDE</i> , lenalidomide 5 mg capsule, 21
12038N	<i>Lenalidomide Viatris, AF – LENALIDOMIDE</i> , lenalidomide 5 mg capsule, 21
12071H	<i>Lenalidomide Viatris, AF – LENALIDOMIDE</i> , lenalidomide 5 mg capsule, 21
12984J	<i>Lenalidomide Viatris, AF – LENALIDOMIDE</i> , lenalidomide 5 mg capsule, 21
2798G	<i>Lenalidomide Viatris, AF – LENALIDOMIDE</i> , lenalidomide 5 mg capsule, 21
9642L	<i>Lenalidomide Viatris, AF – LENALIDOMIDE</i> , lenalidomide 5 mg capsule, 21
11063G	<i>Lenalidomide Viatris, AF – LENALIDOMIDE</i> , lenalidomide 10 mg capsule, 21
12050F	<i>Lenalidomide Viatris, AF – LENALIDOMIDE</i> , lenalidomide 10 mg capsule, 21
12060R	<i>Lenalidomide Viatris, AF – LENALIDOMIDE</i> , lenalidomide 10 mg capsule, 21
12980E	<i>Lenalidomide Viatris, AF – LENALIDOMIDE</i> , lenalidomide 10 mg capsule, 21
2796E	<i>Lenalidomide Viatris, AF – LENALIDOMIDE</i> , lenalidomide 10 mg capsule, 21
9643M	<i>Lenalidomide Viatris, AF – LENALIDOMIDE</i> , lenalidomide 10 mg capsule, 21
11042E	<i>Lenalidomide Viatris, AF – LENALIDOMIDE</i> , lenalidomide 15 mg capsule, 21
12011E	<i>Lenalidomide Viatris, AF – LENALIDOMIDE</i> , lenalidomide 15 mg capsule, 21
12020P	<i>Lenalidomide Viatris, AF – LENALIDOMIDE</i> , lenalidomide 15 mg capsule, 21
12986L	<i>Lenalidomide Viatris, AF – LENALIDOMIDE</i> , lenalidomide 15 mg capsule, 21
9644N	<i>Lenalidomide Viatris, AF – LENALIDOMIDE</i> , lenalidomide 15 mg capsule, 21
11055W	<i>Lenalidomide Viatris, AF – LENALIDOMIDE</i> , lenalidomide 25 mg capsule, 21
12037M	<i>Lenalidomide Viatris, AF – LENALIDOMIDE</i> , lenalidomide 25 mg capsule, 21
12068E	<i>Lenalidomide Viatris, AF – LENALIDOMIDE</i> , lenalidomide 25 mg capsule, 21
12993W	<i>Lenalidomide Viatris, AF – LENALIDOMIDE</i> , lenalidomide 25 mg capsule, 21
9645P	<i>Lenalidomide Viatris, AF – LENALIDOMIDE</i> , lenalidomide 25 mg capsule, 21

Deletions

Deletion – Brand

12784W	<i>AZACITIDINE DR.REDDY'S, RI – AZACITIDINE</i> , azacitidine 100 mg injection, 1 vial
12784W	<i>Azadine, RZ – AZACITIDINE</i> , azacitidine 100 mg injection, 1 vial
13033Y	<i>AZACITIDINE DR.REDDY'S, RI – AZACITIDINE</i> , azacitidine 100 mg injection, 1 vial
13033Y	<i>Azadine, RZ – AZACITIDINE</i> , azacitidine 100 mg injection, 1 vial
13038F	<i>AZACITIDINE DR.REDDY'S, RI – AZACITIDINE</i> , azacitidine 100 mg injection, 1 vial
13038F	<i>Azadine, RZ – AZACITIDINE</i> , azacitidine 100 mg injection, 1 vial
13039G	<i>AZACITIDINE DR.REDDY'S, RI – AZACITIDINE</i> , azacitidine 100 mg injection, 1 vial
13039G	<i>Azadine, RZ – AZACITIDINE</i> , azacitidine 100 mg injection, 1 vial

9644N	LENALIDOMIDE , lenalidomide 15 mg capsule, 21 (<i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, Lenalidomide-Teva, Revlimid</i>)
11055W	LENALIDOMIDE , lenalidomide 25 mg capsule, 21 (<i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, Lenalidomide-Teva, Revlimid</i>)
12018M	LENALIDOMIDE , lenalidomide 25 mg capsule, 14 (<i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid</i>)
12037M	LENALIDOMIDE , lenalidomide 25 mg capsule, 21 (<i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, Lenalidomide-Teva, Revlimid</i>)
12068E	LENALIDOMIDE , lenalidomide 25 mg capsule, 21 (<i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, Lenalidomide-Teva, Revlimid</i>)
12993W	LENALIDOMIDE , lenalidomide 25 mg capsule, 21 (<i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, Lenalidomide-Teva, Revlimid</i>)
9645P	LENALIDOMIDE , lenalidomide 25 mg capsule, 21 (<i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, Lenalidomide-Teva, Revlimid</i>)
13099K	SELINEXOR , selinexor 20 mg tablet, 16 (<i>Xpovio</i>)
13103P	SELINEXOR , selinexor 20 mg tablet, 20 (<i>Xpovio</i>)
13105R	SELINEXOR , selinexor 20 mg tablet, 32 (<i>Xpovio</i>)

Alteration – Caution

13099K	SELINEXOR , selinexor 20 mg tablet, 16 (<i>Xpovio</i>)
13103P	SELINEXOR , selinexor 20 mg tablet, 20 (<i>Xpovio</i>)
13105R	SELINEXOR , selinexor 20 mg tablet, 32 (<i>Xpovio</i>)

Alteration – Restriction

13099K	SELINEXOR , selinexor 20 mg tablet, 16 (<i>Xpovio</i>)
13103P	SELINEXOR , selinexor 20 mg tablet, 20 (<i>Xpovio</i>)
13105R	SELINEXOR , selinexor 20 mg tablet, 32 (<i>Xpovio</i>)

Highly Specialised Drugs Program (Public Hospital)

Additions

Addition – Brand

12212R	<i>Ambrisentan Viatris, AL</i> – AMBRISENTAN , ambrisentan 5 mg tablet, 30
5607D	<i>Ambrisentan Viatris, AL</i> – AMBRISENTAN , ambrisentan 5 mg tablet, 30
11029L	<i>Lenalidomide Viatris, AF</i> – LENALIDOMIDE , lenalidomide 5 mg capsule, 21
12034J	<i>Lenalidomide Viatris, AF</i> – LENALIDOMIDE , lenalidomide 5 mg capsule, 21
12039P	<i>Lenalidomide Viatris, AF</i> – LENALIDOMIDE , lenalidomide 5 mg capsule, 21
12985K	<i>Lenalidomide Viatris, AF</i> – LENALIDOMIDE , lenalidomide 5 mg capsule, 21
2799H	<i>Lenalidomide Viatris, AF</i> – LENALIDOMIDE , lenalidomide 5 mg capsule, 21
5783J	<i>Lenalidomide Viatris, AF</i> – LENALIDOMIDE , lenalidomide 5 mg capsule, 21
11064H	<i>Lenalidomide Viatris, AF</i> – LENALIDOMIDE , lenalidomide 10 mg capsule, 21
12057N	<i>Lenalidomide Viatris, AF</i> – LENALIDOMIDE , lenalidomide 10 mg capsule, 21
12061T	<i>Lenalidomide Viatris, AF</i> – LENALIDOMIDE , lenalidomide 10 mg capsule, 21
12988N	<i>Lenalidomide Viatris, AF</i> – LENALIDOMIDE , lenalidomide 10 mg capsule, 21
2802L	<i>Lenalidomide Viatris, AF</i> – LENALIDOMIDE , lenalidomide 10 mg capsule, 21
5784K	<i>Lenalidomide Viatris, AF</i> – LENALIDOMIDE , lenalidomide 10 mg capsule, 21
11062F	<i>Lenalidomide Viatris, AF</i> – LENALIDOMIDE , lenalidomide 15 mg capsule, 21
12026Y	<i>Lenalidomide Viatris, AF</i> – LENALIDOMIDE , lenalidomide 15 mg capsule, 21
12062W	<i>Lenalidomide Viatris, AF</i> – LENALIDOMIDE , lenalidomide 15 mg capsule, 21
12991R	<i>Lenalidomide Viatris, AF</i> – LENALIDOMIDE , lenalidomide 15 mg capsule, 21

5785L	<i>Lenalidomide Viatris, AF</i> – LENALIDOMIDE , lenalidomide 15 mg capsule, 21
11041D	<i>Lenalidomide Viatris, AF</i> – LENALIDOMIDE , lenalidomide 25 mg capsule, 21
12036L	<i>Lenalidomide Viatris, AF</i> – LENALIDOMIDE , lenalidomide 25 mg capsule, 21
12059Q	<i>Lenalidomide Viatris, AF</i> – LENALIDOMIDE , lenalidomide 25 mg capsule, 21
12979D	<i>Lenalidomide Viatris, AF</i> – LENALIDOMIDE , lenalidomide 25 mg capsule, 21
5786M	<i>Lenalidomide Viatris, AF</i> – LENALIDOMIDE , lenalidomide 25 mg capsule, 21

Deletions

Deletion – Brand

12771E	<i>AZACITIDINE DR.REDDY'S, RI</i> – AZACITIDINE , azacitidine 100 mg injection, 1 vial
12771E	<i>Azadine, RZ</i> – AZACITIDINE , azacitidine 100 mg injection, 1 vial
13028Q	<i>AZACITIDINE DR.REDDY'S, RI</i> – AZACITIDINE , azacitidine 100 mg injection, 1 vial
13028Q	<i>Azadine, RZ</i> – AZACITIDINE , azacitidine 100 mg injection, 1 vial
13036D	<i>AZACITIDINE DR.REDDY'S, RI</i> – AZACITIDINE , azacitidine 100 mg injection, 1 vial
13036D	<i>Azadine, RZ</i> – AZACITIDINE , azacitidine 100 mg injection, 1 vial
13042K	<i>AZACITIDINE DR.REDDY'S, RI</i> – AZACITIDINE , azacitidine 100 mg injection, 1 vial
13042K	<i>Azadine, RZ</i> – AZACITIDINE , azacitidine 100 mg injection, 1 vial
13044M	<i>AZACITIDINE DR.REDDY'S, RI</i> – AZACITIDINE , azacitidine 100 mg injection, 1 vial
13044M	<i>Azadine, RZ</i> – AZACITIDINE , azacitidine 100 mg injection, 1 vial
9597D	<i>AZACITIDINE DR.REDDY'S, RI</i> – AZACITIDINE , azacitidine 100 mg injection, 1 vial
9597D	<i>Azadine, RZ</i> – AZACITIDINE , azacitidine 100 mg injection, 1 vial
9598E	<i>AZACITIDINE DR.REDDY'S, RI</i> – AZACITIDINE , azacitidine 100 mg injection, 1 vial
9598E	<i>Azadine, RZ</i> – AZACITIDINE , azacitidine 100 mg injection, 1 vial

Alterations

Alteration – Note

11029L	LENALIDOMIDE , lenalidomide 5 mg capsule, 21 (<i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, Lenalidomide-Teva, Revlimid</i>)
11967W	LENALIDOMIDE , lenalidomide 5 mg capsule, 28 (<i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid</i>)
12034J	LENALIDOMIDE , lenalidomide 5 mg capsule, 21 (<i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, Lenalidomide-Teva, Revlimid</i>)
12035K	LENALIDOMIDE , lenalidomide 5 mg capsule, 14 (<i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid</i>)
12039P	LENALIDOMIDE , lenalidomide 5 mg capsule, 21 (<i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, Lenalidomide-Teva, Revlimid</i>)
12985K	LENALIDOMIDE , lenalidomide 5 mg capsule, 21 (<i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, Lenalidomide-Teva, Revlimid</i>)
2799H	LENALIDOMIDE , lenalidomide 5 mg capsule, 21 (<i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, Lenalidomide-Teva, Revlimid</i>)
5783J	LENALIDOMIDE , lenalidomide 5 mg capsule, 21 (<i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, Lenalidomide-Teva, Revlimid</i>)
11064H	LENALIDOMIDE , lenalidomide 10 mg capsule, 21 (<i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, Lenalidomide-Teva, Revlimid</i>)
11968X	LENALIDOMIDE , lenalidomide 10 mg capsule, 28 (<i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid</i>)
12057N	LENALIDOMIDE , lenalidomide 10 mg capsule, 21 (<i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, Lenalidomide-Teva, Revlimid</i>)
12061T	LENALIDOMIDE , lenalidomide 10 mg capsule, 21 (<i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, Lenalidomide-Teva, Revlimid</i>)

12070G	LENALIDOMIDE , lenalidomide 10 mg capsule, 14 (<i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid</i>)
12988N	LENALIDOMIDE , lenalidomide 10 mg capsule, 21 (<i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, Lenalidomide-Teva, Revlimid</i>)
2802L	LENALIDOMIDE , lenalidomide 10 mg capsule, 21 (<i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, Lenalidomide-Teva, Revlimid</i>)
5784K	LENALIDOMIDE , lenalidomide 10 mg capsule, 21 (<i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, Lenalidomide-Teva, Revlimid</i>)
11062F	LENALIDOMIDE , lenalidomide 15 mg capsule, 21 (<i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, Lenalidomide-Teva, Revlimid</i>)
11964Q	LENALIDOMIDE , lenalidomide 15 mg capsule, 28 (<i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid</i>)
12012F	LENALIDOMIDE , lenalidomide 15 mg capsule, 14 (<i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid</i>)
12026Y	LENALIDOMIDE , lenalidomide 15 mg capsule, 21 (<i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, Lenalidomide-Teva, Revlimid</i>)
12062W	LENALIDOMIDE , lenalidomide 15 mg capsule, 21 (<i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, Lenalidomide-Teva, Revlimid</i>)
12991R	LENALIDOMIDE , lenalidomide 15 mg capsule, 21 (<i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, Lenalidomide-Teva, Revlimid</i>)
5785L	LENALIDOMIDE , lenalidomide 15 mg capsule, 21 (<i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, Lenalidomide-Teva, Revlimid</i>)
11041D	LENALIDOMIDE , lenalidomide 25 mg capsule, 21 (<i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, Lenalidomide-Teva, Revlimid</i>)
12019N	LENALIDOMIDE , lenalidomide 25 mg capsule, 14 (<i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid</i>)
12036L	LENALIDOMIDE , lenalidomide 25 mg capsule, 21 (<i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, Lenalidomide-Teva, Revlimid</i>)
12059Q	LENALIDOMIDE , lenalidomide 25 mg capsule, 21 (<i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, Lenalidomide-Teva, Revlimid</i>)
12979D	LENALIDOMIDE , lenalidomide 25 mg capsule, 21 (<i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, Lenalidomide-Teva, Revlimid</i>)
5786M	LENALIDOMIDE , lenalidomide 25 mg capsule, 21 (<i>Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, Lenalidomide-Teva, Revlimid</i>)
13085Q	SELINEXOR , selinexor 20 mg tablet, 16 (<i>Xpovio</i>)
13086R	SELINEXOR , selinexor 20 mg tablet, 20 (<i>Xpovio</i>)
13104Q	SELINEXOR , selinexor 20 mg tablet, 32 (<i>Xpovio</i>)

Alteration – Caution

13085Q	SELINEXOR , selinexor 20 mg tablet, 16 (<i>Xpovio</i>)
13086R	SELINEXOR , selinexor 20 mg tablet, 20 (<i>Xpovio</i>)
13104Q	SELINEXOR , selinexor 20 mg tablet, 32 (<i>Xpovio</i>)

Alteration – Restriction

13085Q	SELINEXOR , selinexor 20 mg tablet, 16 (<i>Xpovio</i>)
13086R	SELINEXOR , selinexor 20 mg tablet, 20 (<i>Xpovio</i>)
13104Q	SELINEXOR , selinexor 20 mg tablet, 32 (<i>Xpovio</i>)

Highly Specialised Drugs Program (Community Access)

Additions

Addition – Brand

11149T	<i>Tenofovir Disoproxil Emtricitabine Viatris 300/200, AL</i> – TENOFOVIR DISOPROXIL + EMTRICITABINE , tenofovir disoproxil maleate 300 mg + emtricitabine 200 mg tablet, 30
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Botulinum Toxin Program

Alterations

Alteration – Manufacturer Code

		<i>From</i>	<i>To</i>
10993N	<i>Botox</i> – BOTULINUM TOXIN TYPE A , botulinum toxin type A 100 units injection, 1 vial	AG	VE
10997T	<i>Botox</i> – BOTULINUM TOXIN TYPE A , botulinum toxin type A 100 units injection, 1 vial	AG	VE
10998W	<i>Botox</i> – BOTULINUM TOXIN TYPE A , botulinum toxin type A 100 units injection, 1 vial	AG	VE
10999X	<i>Botox</i> – BOTULINUM TOXIN TYPE A , botulinum toxin type A 100 units injection, 1 vial	AG	VE
11000Y	<i>Botox</i> – BOTULINUM TOXIN TYPE A , botulinum toxin type A 100 units injection, 1 vial	AG	VE
11004E	<i>Botox</i> – BOTULINUM TOXIN TYPE A , botulinum toxin type A 100 units injection, 1 vial	AG	VE
11016T	<i>Botox</i> – BOTULINUM TOXIN TYPE A , botulinum toxin type A 100 units injection, 1 vial	AG	VE
11023E	<i>Botox</i> – BOTULINUM TOXIN TYPE A , botulinum toxin type A 100 units injection, 1 vial	AG	VE
11751L	<i>Botox</i> – BOTULINUM TOXIN TYPE A , botulinum toxin type A 100 units injection, 1 vial	AG	VE
12017L	<i>Botox</i> – BOTULINUM TOXIN TYPE A , botulinum toxin type A 100 units injection, 1 vial	AG	VE

Repatriation Pharmaceutical Benefits

Alterations

Alteration – Manufacturer Code

		<i>From</i>	<i>To</i>
4042R	<i>Aquacare H.P.</i> – UREA , urea 10% cream, 100 g	AG	VE

Advance Notices

1 July 2023

Deletion – Brand

2194L	<i>Alendronate plus D3-DRLA, RZ</i> – ALENDRONATE + COLECALCIFEROL , alendronate 70 mg + colecalciferol 70 microgram (2800 units) tablet, 4
2224C	<i>Alendronate plus D3-DRLA, RZ</i> – ALENDRONATE + COLECALCIFEROL , alendronate 70 mg + colecalciferol 140 microgram (5600 units) tablet, 4

General Pharmaceutical Benefits

■ APALUTAMIDE

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

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

Note 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

Metastatic castration sensitive carcinoma of the prostate

Clinical criteria:

- The treatment must be/have been initiated within 6 months of treatment initiation with androgen deprivation therapy, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.

Treatment criteria:

- Patient must be undergoing concurrent androgen deprivation therapy.

apalutamide 60 mg tablet, 120

13288J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3714.58	30.00	Erlyand [JC]

■ CANNABIDIOL

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

Note Requests for increased quantities may be sought based on daily doses not exceeding 20 mg/kg/day (in line with the Product Information) for up to 4 weeks per dispensing.

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

Note Special Pricing Arrangements apply.

Authority required

Seizures of the Lennox-Gastaut syndrome

Clinical criteria:

- Patient must have a diagnosis of Lennox-Gastaut syndrome confirmed by an electroencephalogram (EEG) that showed a pattern of slow (less than 3.0 hertz) spike-and-wave discharges with generalised paroxysmal fast activity (sleep recording should be obtained where it is possible), **AND**
- Patient must have (as an initiating patient)/have had (as a continuing patient) more than one type of generalised seizures, **AND**
- Patient must have had at least two drop seizures (atonic, tonic or tonic-clonic) per week that are not adequately controlled with at least two other anti-epileptic drugs prior to initiating treatment with this medicine, **AND**
- The treatment must be as adjunctive therapy to at least two other anti-epileptic drugs.

Treatment criteria:

- Must be treated by a neurologist if treatment is being initiated; OR
- Must be treated by a neurologist if treatment is being continued or re-initiated; OR
- Must be treated by a paediatrician in consultation with a neurologist if treatment is being continued; OR
- Must be treated by a general practitioner in consultation with a neurologist if treatment is being continued.

Tonic seizures must have been recorded on video-EEG or have been clearly observed and reported by a witness.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

cannabidiol 100 mg/mL oral liquid, 100 mL

13277T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1533.99	30.00	Epidyolex [EU]

■ CEFALEXIN

Note Pharmaceutical Benefits that have the form cefalexin 250 mg/5 mL powder for oral liquid, 100 mL are equivalent for the purpose of substitution in case of a shortage.

cefalexin 250 mg/5 mL powder for oral liquid, 100 mL

13278W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	±1	..	..	#35.49	30.00	^a Keforal [QY]

cefalexin 250 mg/5 mL powder for oral liquid, 100 mL

13285F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	1	..	#35.49	30.00	^a Keforal [QY]

cefalexin 250 mg/5 mL powder for oral liquid, 100 mL

3095X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±1	1	..	#18.07	19.75	^a Cefalexin Sandoz [SZ]	^a Ibilex 250 [AF]
			^b 6.01	#24.08	19.75	^a Keflex [AS]	

cefalexin 250 mg/5 mL powder for oral liquid, 100 mL

3320R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	±1	..	..	#18.07	19.75	^a Cefalexin Sandoz [SZ]	^a Ibilex 250 [AF]
			^b 6.01	#24.08	19.75	^a Keflex [AS]	

■ CICLOSPORIN

Caution It is recommended that the potential for immunosuppression with long term use of this drug be clinically reviewed after at least 24 months of treatment, if not already reviewed.

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

Authority required

Chronic severe dry eye disease with keratitis

Treatment Phase: Initial treatment for up to the first 180 days of treatment

Clinical criteria:

- Patient must have a corneal fluorescein staining (CFS) grade of 4 at treatment initiation, using at least one of: (i) the Oxford scale, (ii) the modified Oxford scale, (iii) an equivalent scale to the Oxford scale as determined by the prescriber, **AND**
- Patient must have an ocular surface disease index (OSDI) score of at least 23 at treatment initiation, **AND**
- The condition must be inadequately controlled by monotherapy with a preservative free artificial tears substitute, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Patient must be undergoing simultaneous treatment with a preservative free artificial tears substitute, **AND**
- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; OR
- Must be treated by an optometrist in accordance with Optometry Board of Australia guidelines, **AND**
- Patient must not be undergoing treatment with this drug under this treatment phase beyond day 180 of treatment.

Population criteria:

- Patient must be at least 18 years of age.

Prescribing instruction:

State in the first authority application for this drug, for the purpose of having a baseline measurement to assess response to treatment under the Continuing treatment listing, each of: (i) the qualifying corneal fluorescein staining grade (a numerical value no less than 4), (ii) the qualifying ocular surface disease index score (a numerical value no less than 23).

Note The Oxford scale, modified Oxford scale and Ocular Surface Disease Index (OSDI) were relied upon in the submission supporting initial PBS listing.

The Oxford scale uses a chart system consisting of a series of panels, labelled A to E in order of increasing severity. In each chart, staining is represented by dots. To grade staining, comparisons are made between the panels and the appearance of staining on the exposed interpalpebral conjunctiva and cornea of the patient. The details of the chart are presented in Figure 1 and, in a simplified form in Figure 4 (where the criteria, dot count and log columns are not displayed), in the following literature article: Bron A, Evans V, Smith, J. Grading of corneal and conjunctival staining in the context of other dry eye tests. *Cornea*. 2003;22(7):640-650.

The modified Oxford scale is as above, but with the first grade depiction (Grade 0), termed 'Grade 0.5'.

A list of equivalent scales to the Oxford scale is not provided. Prescribers should be satisfied that a scale other than the Oxford scale, if used, is equivalent to the Oxford scale.

The Ocular Surface Disease Index (OSDI) is a 12-item questionnaire created by the Outcomes Research Group at Allergan Inc, Irvine, CA, USA, to assess dry eye symptoms and the effects on vision-related function.

The questionnaire has 3 subscales: ocular symptoms, vision-related function, and environmental triggers. Patients rate their responses on a 0 to 4 scale with 0 corresponding to 'none of the time' and 4 corresponding to 'all of the time'. A final score is calculated which ranges from 0 to 100 with scores 0 to 12 representing normal, 13 to 22 representing mild dry eye

disease, 23 to 32 representing moderate dry eye disease, and greater than 33 representing severe dry eye disease.

The OSDI questionnaire asks the following:

Presence of ocular symptoms - Have you experienced any of the following during the last week?

1. Eyes that are sensitive to light
2. Eyes that feel gritty
3. Painful or sore eyes
4. Blurred vision
5. Poor vision

Impact on daily activities - Have you had problems with your eyes limited you in performing any of the following during the last week?

1. Reading
2. Driving at night
3. Working with a computer or bank machine (ATM)
4. Watching TV

Environmental factors - Have your eyes felt uncomfortable in any of the following situations during the last week?

1. Windy conditions
2. Places or areas with low humidity (very dry)
3. Areas that are airconditioned

Rate responses on a scale of 0 to 4; 0 = none of the time, 1 = some of the time, 2 = half of the time, 3 = most of the time, and 4 = all of the time.

Further information on this index is in the following literature article: Walt J, Rowe M, Stern K. Evaluating the functional impact of dry eye: the Ocular Surface Disease Index. Drug Information Journal. 1997;31:1436

The 'Dry Eye OSDI 'Questionnaire' app developed by Allergan Inc is available to download for iPhone.

Note If the maximum number of repeats stated in this listing is not requested in this application, further supplies can be obtained through this treatment phase listing to continue treatment for up to the first 180 days of treatment, but the OSDI score and CFS grade need not be re-stated. Alternatively, treatment may be continued under the 'Continuing treatment' phase listing, provided the patient meets all eligibility criteria specified in that treatment phase listing.

Authority required

Chronic severe dry eye disease with keratitis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must have improved to an extent that corneal fluorescein staining, using the same scale used at the time of the first authority application, shows an improvement (reduction) by at least 3 grades from baseline (the grade stated in the first authority application) - the improvement need only be demonstrated by staining once only with the first Continuing treatment authority application, **AND**
- The condition must have improved to an extent that the patient's ocular surface disease index score at the time of this authority application, has improved (reduced) by at least 30% compared to the value stated in the first authority application (i.e. baseline), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; OR
- Must be treated by an optometrist in accordance with Optometry Board of Australia guidelines.

Prescribing instructions:

State in the first continuing treatment authority application for this drug:

(i) an improved corneal fluorescein staining grade (a numerical value that has improved by 3 grades from that provided in the first Initial 1 treatment authority application).

State in all continuing treatment authority applications:

(ii) the ocular surface disease index score at the time of this authority application (a numerical value that is at least 30% lower than that stated in the first Initial 1 treatment authority application).

ciclosporin 0.09% eye drops, 60 x 0.25 mL unit doses

13284E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	82.03	30.00	Cequa [RA]

ciclosporin 0.1% eye drops, 30 x 0.3 mL unit doses

12663L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	82.03	30.00	Ikervis [CS]

■ DISOPYRAMIDE

Note Pharmaceutical benefits that have the form disopyramide 100 mg capsule in a pack size of 84 can be substituted for a pack size of 100 in the case of a shortage.

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.

disopyramide 100 mg capsule, 84

13280Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1.19	5	..	*85.85	30.00	^a Rythmodan (Canada) [OJ]

disopyramide 100 mg capsule, 100

2923W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	24.61	25.92	^a Rythmodan [PB]

■ LAROTRECTINIB

Note For a patient who has received non-PBS-subsidised supply of this drug, apply under an 'Initial treatment' phase listing provided that they meet all stated PBS eligibility criteria.

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

Note Pharmaceutical benefits that have the form larotrectinib 20 mg/mL oral liquid, 100 mL and pharmaceutical benefits that have the form larotrectinib 20 mg/mL oral liquid, 2 x 50 mL are equivalent for the purposes of substitution.

Note Special Pricing Arrangements apply.

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

Authority required

Solid tumours with confirmed neurotrophic tropomyosin receptor kinase (NTRK) gene fusion

Treatment Phase: Continuing treatment

Treatment criteria:

- Patient must be undergoing continuing PBS-subsidised treatment commenced through an 'Initial treatment' listing.

Clinical criteria:

- The treatment must cease to be a PBS benefit upon radiographic progression, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.

Where radiographic progression is observed, mark any remaining repeat prescriptions with the word 'cancelled'.

larotrectinib 20 mg/mL oral liquid, 100 mL

13035C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	4286.28	30.00	^a Vitrakvi [BN]

larotrectinib 20 mg/mL oral liquid, 2 x 50 mL

13289K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4286.28	30.00	^a VITRAKVI [BN]

■ LAROTRECTINIB

Note For a patient who has received non-PBS-subsidised supply of this drug, apply under an 'Initial treatment' phase listing provided that they meet all stated PBS eligibility criteria.

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

Note Pharmaceutical benefits that have the form larotrectinib 20 mg/mL oral liquid, 100 mL and pharmaceutical benefits that have the form larotrectinib 20 mg/mL oral liquid, 2 x 50 mL are equivalent for the purposes of substitution.

Note Special Pricing Arrangements apply.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Solid tumours (of any type) with confirmed neurotrophic tropomyosin receptor kinase (NTRK) gene fusion where treatment with this drug is/was initiated in a child

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be confirmed to be positive for a neurotrophic tropomyosin receptor kinase (NTRK) gene fusion prior to treatment initiation with this drug through a pathology report from an Approved Pathology Authority - provide the following evidence: (i) the date of the pathology report substantiating the positive NTRK gene fusion, (ii) the name of the pathology service provider, (iii) the unique identifying number/code linking the pathology test result to the patient; the recency of the pathology report may be of any date, **AND**
- The condition must be metastatic disease; OR
- The condition must be both: (i) locally advanced, (ii) unresectable; OR

- The condition must be both: (i) locally advanced, (ii) require disfiguring surgery/limb amputation to achieve complete surgical resection, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.

Treatment criteria:

- Patient must not be undergoing treatment through this Initial treatment phase listing where the patient has developed disease progression while receiving this drug for this condition.

Population criteria:

- Patient must be/have been under 18 years of age (i.e. prior to their 18th birthday) at treatment initiation with this drug. The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail, and must include:

(a) details of the pathology report substantiating the positive NTRK gene fusion. The recency of the pathology report may be of any date.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS upload or mail, it must include:

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

Authority required

Solid tumours (of certain specified types) with confirmed neurotrophic tropomyosin receptor kinase (NTRK) gene fusion

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be confirmed to be positive for a neurotrophic tropomyosin receptor kinase (NTRK) gene fusion prior to treatment initiation with this drug through a pathology report from an Approved Pathology Authority - provide the following evidence: (i) the date of the pathology report substantiating the positive NTRK gene fusion, (ii) the name of the pathology service provider, (iii) the unique identifying number/code linking the pathology test result to the patient; the recency of the pathology report may be of any date, **AND**
- The condition must be a mammary analogue secretory carcinoma of the salivary gland confirmed through a pathology report from an Approved Pathology Authority (of any date); OR
- The condition must be a secretory breast carcinoma confirmed through a pathology report from an Approved Pathology Authority (of any date), **AND**
- The condition must be metastatic disease; OR
- The condition must be both: (i) locally advanced, (ii) unresectable; OR
- The condition must be both: (i) locally advanced, (ii) require disfiguring surgery/limb amputation to achieve complete surgical resection, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.

Treatment criteria:

- Patient must not be undergoing treatment through this Initial treatment phase listing where the patient has developed disease progression while receiving this drug for this condition.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail, and must include:

(a) details of the pathology report substantiating the positive NTRK gene fusion. The recency of the pathology report may be of any date.

(b) details of the pathology report establishing the carcinoma type (salivary gland/secretory breast carcinoma) being treated, if different to the pathology report provided to substantiate the NTRK gene fusion.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS upload or mail, it must include:

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

larotrectinib 20 mg/mL oral liquid, 100 mL

13030T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	4286.28	30.00	^a Vitrakvi [BN]

larotrectinib 20 mg/mL oral liquid, 2 x 50 mL

13281B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	4286.28	30.00	^a VITRAKVI [BN]

▪ **LENVATINIB**

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)

14042

Advanced, metastatic or recurrent endometrial carcinoma

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have received prior treatment with platinum-based chemotherapy, **AND**
- The condition must be untreated with each of: (i) programmed cell death-1/ligand-1 (PD-1/PDL-1) inhibitor therapy, (ii) tyrosine kinase inhibitor therapy, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation.

Treatment criteria:

- Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR
- Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records.

Authority required (STREAMLINED)**14041**

Advanced, metastatic or recurrent endometrial carcinoma

Treatment Phase: Continuing treatment

Clinical criteria:

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

Treatment criteria:

- Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR
- Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records; OR
- Patient must be undergoing monotherapy with this drug after completing an equivalent of 24 cumulative months of pembrolizumab treatment, measured from the first administered dose.

Authority required (STREAMLINED)**14043**

Advanced, metastatic or recurrent endometrial carcinoma

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

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 June 2023, **AND**
- The treatment must be occurring in a patient where each of the following is true: (i) the patient had received prior treatment with platinum-based chemotherapy, (ii) the patient was untreated at treatment initiation with each of: (a) programmed cell death-1/ligand-1 (PD-1/PDL-1) inhibitor therapy, (b) tyrosine kinase inhibitor therapy, (iii) the patient's WHO performance status was no higher than 1 at treatment initiation, (iv) this drug is being prescribed in either: (a) a combination of pembrolizumab plus lenvatinib only, (b) as monotherapy where there was a contraindication/intolerance to the other drug in the combination - document the details in the patient's medical records, (c) as monotherapy after completing an equivalent of 24 cumulative months of pembrolizumab treatment, measured from the first administered dose, (v) disease progression has not occurred whilst on treatment.

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

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

lenvatinib 4 mg capsule, 30

13290L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*5143.24	30.00	Lenvima [EI]

lenvatinib 10 mg capsule, 30

13283D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*5161.28	30.00	Lenvima [EI]

■ LEVOTHYROXINE**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 Eltroxin and Levothox are not interchangeable with Oroxine, Eutroxsig or Levoxine on a dose to dose basis, and dose titration may be required.

Note Pharmaceutical benefits that have the form levothyroxine sodium 75 microgram tablet, 200 (Eutroxsig and Oroxine brands) and pharmaceutical benefits that have the form levothyroxine sodium 75 microgram tablet, 2 x 100 (Levoxine brand) are equivalent for the purposes of substitution.

levothyroxine sodium 75 microgram tablet, 2 x 100

12960D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	22.41	23.72	^a LEVOXINE [RA]

NP

■ LEVOTHYROXINE

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 Eltroxin and Levothox are not interchangeable with Oroxine, Eutroxsig or Levoxine on a dose to dose basis, and dose titration may be required.

Note Pharmaceutical benefits that have the form levothyroxine sodium 100 microgram tablet, 200 (Eutroxsig and Oroxine brands) and pharmaceutical benefits that have the form levothyroxine sodium 100 microgram tablet, 2 x 100 (Levoxine brand) are equivalent for the purposes of substitution.

levothyroxine sodium 100 microgram tablet, 2 x 100

12968M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	22.60	23.91	^a LEVOXINE [RA]

■ LEVOTHYROXINE

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 Eltroxin and Levothox are not interchangeable with Oroxine, Eutroxsig or Levoxine on a dose to dose basis, and dose titration may be required.

Note Pharmaceutical benefits that have the form levothyroxine sodium 50 microgram tablet, 200 (Eutroxsig and Oroxine brands) and pharmaceutical benefits that have the form levothyroxine sodium 50 microgram tablet, 2 x 100 (Levoxine brand) are equivalent for the purposes of substitution.

levothyroxine sodium 50 microgram tablet, 2 x 100

12969N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	22.24	23.55	^a LEVOXINE [RA]

■ LEVOTHYROXINE

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 Eltroxin and Levothox are not interchangeable with Oroxine, Eutroxsig or Levoxine on a dose to dose basis, and dose titration may be required.

Note Pharmaceutical benefits that have the form levothyroxine sodium 200 microgram tablet, 200 (Eutroxsig and Oroxine brands) and pharmaceutical benefits that have the form levothyroxine sodium 200 microgram tablet, 2 x 100 (Levoxine brand) are equivalent for the purposes of substitution.

levothyroxine sodium 200 microgram tablet, 2 x 100

12970P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	24.41	25.72	^a LEVOXINE [RA]

■ LEVOTHYROXINE

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 Eltroxin and Levothox are not interchangeable with Oroxine, Eutroxsig or Levoxine on a dose to dose basis, and dose titration may be required.

Note Pharmaceutical benefits that have the form levothyroxine sodium 200 microgram tablet, 200 (Eltroxin and Levothox brands) are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form levothyroxine sodium 200 microgram tablet, 200 (Eutroxsig and Oroxine brands) and pharmaceutical benefits that have the form levothyroxine sodium 200 microgram tablet, 2 x 100 (Levoxine brand) are equivalent for the purposes of substitution.

levothyroxine sodium 200 microgram tablet, 200

2173J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	24.41	25.72	^a Eutroxsig [LN]	
						^b Eltroxin [LT]	^b Levothox [AF]
			^B 1.31	25.72	25.72	^a Oroxine [AS]	

■ LEVOTHYROXINE

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 Eltroxin and Levothox are not interchangeable with Oroxine, Eutroxsig or Levoxine on a dose to dose basis, and dose titration may be required.

Note Pharmaceutical benefits that have the form levothyroxine sodium 50 microgram tablet, 200 (Eltroxin and Levothox brands) are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form levothyroxine sodium 50 microgram tablet, 200 (Eutroxsig and Oroxine brands) and pharmaceutical benefits that have the form levothyroxine sodium 50 microgram tablet, 2 x 100 (Levioxine brand) are equivalent for the purposes of substitution.

levothyroxine sodium 50 microgram tablet, 200

2174K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	22.24	23.55	^a Eutroxsig [LN]	
						^b Eltroxin [LT]	^b Levothox [AF]
			^B 1.31	23.55	23.55	^a Oroxine [AS]	

▪ LEVOTHYROXINE

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 Eltroxin and Levothox are not interchangeable with Oroxine, Eutroxsig or Levoxine on a dose to dose basis, and dose titration may be required.

Note Pharmaceutical benefits that have the form levothyroxine sodium 100 microgram tablet, 200 (Eltroxin and Levothox brands) are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form levothyroxine sodium 100 microgram tablet, 200 (Eutroxsig and Oroxine brands) and pharmaceutical benefits that have the form levothyroxine sodium 100 microgram tablet, 2 x 100 (Levioxine brand) are equivalent for the purposes of substitution.

levothyroxine sodium 100 microgram tablet, 200

2175L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	22.60	23.91	^a Eutroxsig [LN]	
						^b Eltroxin [LT]	^b Levothox [AF]
			^B 1.31	23.91	23.91	^a Oroxine [AS]	

▪ LEVOTHYROXINE

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 Eltroxin and Levothox are not interchangeable with Oroxine, Eutroxsig or Levoxine on a dose to dose basis, and dose titration may be required.

Note Pharmaceutical benefits that have the form levothyroxine sodium 75 microgram tablet, 200 (Eltroxin and Levothox brands) are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form levothyroxine sodium 75 microgram tablet, 200 (Eutroxsig and Oroxine brands) and pharmaceutical benefits that have the form levothyroxine sodium 75 microgram tablet, 2 x 100 (Levioxine brand) are equivalent for the purposes of substitution.

levothyroxine sodium 75 microgram tablet, 200

9287T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	22.41	23.72	^a Eutroxsig [LN]	
						^b Eltroxin [LT]	^b Levothox [AF]
			^B 1.32	23.73	23.72	^a Oroxine [AS]	

▪ MINOXIDIL

Note Pharmaceutical benefits that have the form minoxidil 10 mg tablet in a pack size of 60 can be substituted for a pack size of 100 in the case of a shortage.

Note Continuing Therapy Only:

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

Restricted benefit

Severe refractory hypertension

Clinical criteria:

- The treatment must be initiated by a consultant physician.

minoxidil 10 mg tablet, 60

13279X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1.67	5	..	*124.75	30.00	^a Minoxidil 10 mg (Roma Pharmaceuticals) [OJ]

minoxidil 10 mg tablet, 100

2313R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	43.06	30.00	^a Loniten [PF]

■ NICOTINE

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

Nicotine dependence

Clinical criteria:

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must not be a PBS-benefit with other non-nicotine drugs that are PBS indicated for smoking cessation, **AND**
- Patient must have indicated they are ready to cease smoking, **AND**
- Patient must not receive more than 2 x 12-week PBS-subsidised treatment courses per 12 month period.

Treatment criteria:

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

nicotine 25 mg/16 hours patch, 28

10076H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	50.02	30.00	nicorette 16hr Invisipatch [JT]

nicotine 14 mg/24 hours patch, 28

5572G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	50.02	30.00	Nicotinell Step 2 [ON]

nicotine 21 mg/24 hours patch, 28

3414Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	50.02	30.00	Nicotinell Step 1 [ON]

nicotine 21 mg/24 hours patch, 28

5465P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	50.02	30.00	Nicabate P [GJ]

nicotine 7 mg/24 hours patch, 28

5573H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	50.02	30.00	Nicotinell Step 3 [ON]

■ PHENOXYMETHYLPENICILLIN

Note Pharmaceutical Benefits that have the form phenoxymethylpenicillin 250 mg/5 mL powder for oral liquid, 100 mL are equivalent for the purpose of substitution in case of a shortage.

phenoxymethylpenicillin 250 mg/5 mL powder for oral liquid, 100 mL

13282C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	1	..	*#68.82	30.00	^a Penopen [QY]

phenoxymethylpenicillin 250 mg/5 mL powder for oral liquid, 100 mL

13291M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	2	..	..	*#68.82	30.00	^a Penopen [QY]

phenoxymethylpenicillin 250 mg/5 mL powder for oral liquid, 100 mL

5029Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	2	..	..	*#24.04	25.72	^a Phenoxymethylpenicillin-AFT [AE]

phenoxymethylpenicillin 250 mg/5 mL powder for oral liquid, 100 mL

8977L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	1	..	*#24.04	25.72	^a Phenoxymethylpenicillin-AFT [AE]

Highly Specialised Drugs Program (Private Hospital)

▪ LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed: Revlimid - i-access program; Cipla Lenalidomide - Pregnancy Prevention Program; Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program; Lenalide - Juno Connected™; Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program; Lenalidomide Teva - Pregnancy Prevention Program; Lenalidomide Viatris - Viatris Care.

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

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment of triple therapy (this drug, bortezomib and dexamethasone) for treatment cycles 5 and 6 (administered using 28-day treatment cycles)

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug under the treatment phase covering cycles 1 to 4, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- The treatment must not exceed a total of 2 cycles under this restriction.

lenalidomide 10 mg capsule, 21

12050F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	1569.12	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

lenalidomide 15 mg capsule, 21

12011E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	1880.07	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

lenalidomide 25 mg capsule, 21

12037M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	2445.03	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

lenalidomide 5 mg capsule, 21

12038N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	1209.08	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

▪ LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed: Revlimid - i-access program; Cipla Lenalidomide - Pregnancy

Prevention Program; Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program; Lenalide - Juno Connected™; Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program; Lenalidomide Teva - Pregnancy Prevention Program; Lenalidomide Viatris - Viatris Care.

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

Authority required

Multiple myeloma

Treatment Phase: Initial treatment with triple therapy (this drug, bortezomib and dexamethasone) for the first 4 treatment cycles (cycles 1 to 4) administered in a 28-day treatment cycle

Clinical criteria:

- The condition must be newly diagnosed, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- Patient must not have been treated with lenalidomide or bortezomib for this condition, **AND**
- The treatment must not exceed a total of 4 cycles under this restriction.

The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

- (1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma; and
- (2) nomination of which disease activity parameters will be used to assess response.

To enable confirmation of eligibility for treatment, details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f), of at least one of the following must be provided:

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine - the percentage of plasma cells; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held on the patient's medical records.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) 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).

lenalidomide 10 mg capsule, 21

12060R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	1569.12	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

lenalidomide 15 mg capsule, 21

12020P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	1880.07	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

lenalidomide 25 mg capsule, 21

12068E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	2445.03	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

lenalidomide 5 mg capsule, 21

12071H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	1209.08	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

▪ LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed: Revlimid - i-access program; Cipla Lenalidomide - Pregnancy Prevention Program; Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program; Lenalide - Juno Connected™; Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program; Lenalidomide Teva - Pregnancy Prevention Program; Lenalidomide Viatris - Viatris Care.

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

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Triple combination therapy consisting of elotuzumab, lenalidomide and dexamethasone

Treatment criteria:

- Patient must be undergoing concurrent treatment with elotuzumab obtained through the PBS, **AND**
- Patient must not be undergoing simultaneous treatment with this drug obtained under another PBS listing.

lenalidomide 10 mg capsule, 21

12980E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1569.12	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

lenalidomide 15 mg capsule, 21

12986L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1880.07	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

lenalidomide 25 mg capsule, 21

12993W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	2445.03	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

lenalidomide 5 mg capsule, 21

12984J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1209.08	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

▪ LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed: Revlimid - i-access program; Cipla Lenalidomide - Pregnancy Prevention Program; Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program; Lenalide - Juno Connected™; Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program; Lenalidomide Teva - Pregnancy Prevention Program; Lenalidomide Viatris - Viatris Care.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Myelodysplastic syndrome

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be limited to a maximum duration of 16 weeks, **AND**
- Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS), **AND**
- Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities, **AND**
- Patient must be red blood cell transfusion dependent.

Classification of a patient as Low risk requires a score of 0 on the IPSS, achieved with the following combination: less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias.

Classification of a patient as Intermediate-1 requires a score of 0.5 to 1 on the IPSS, achieved with the following possible combinations:

1. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias; OR
2. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR
3. less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR
4. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 2/3 cytopenias; OR
5. 5%-10% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR
6. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR
7. less than 5% marrow blasts with poor karyotypic status (complex, greater than 3 abnormalities), and 0/1 cytopenias.

Classification of a patient as red blood cell transfusion dependent requires that:

- (i) the patient has been transfused within the last 8 weeks; and
- (ii) the patient has received at least 8 units of red blood cell in the last 6 months prior to commencing PBS-subsidised therapy with lenalidomide; and would be expected to continue this requirement without lenalidomide treatment.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

- (a) details (date, unique identifying number/code or provider number) of the bone marrow biopsy report from an Approved Pathology Authority demonstrating that the patient has myelodysplastic syndrome; and
- (b) details (date, unique identifying number/code or provider number) of the full blood examination report; and
- (c) details (date, unique identifying number/code or provider number) of the pathology report and details of the cytogenetics demonstrating Low risk or Intermediate-1 disease according to the IPSS (note: using Fluorescence in Situ Hybridization (FISH) to demonstrate MDS -5q is acceptable); and
- (d) details of transfusion requirements including: (i) the date of most recent transfusion and the number of red blood cell units transfused; and (ii) the total number of red blood cell units transfused in the 4 and 6 months preceding the date of this application.

All the reports must be documented in the patient's medical records.

If the application is submitted through HPOS upload or mail, it must include:

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

Authority required

Myelodysplastic syndrome

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received PBS-subsidised initial therapy with lenalidomide for myelodysplastic syndrome, **AND**
- Patient must have achieved and maintained transfusion independence; or at least a 50% reduction in red blood cell unit transfusion requirements compared with the four month period prior to commencing initial PBS-subsidised therapy with lenalidomide, **AND**
- Patient must not have progressive disease, **AND**
- The condition must not have progressed to acute myeloid leukaemia.

The first authority application for continuing supply must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail. Subsequent authority applications for continuing supply may be made via the Online PBS Authorities System or by telephone.

The following evidence of response must be provided at each application:

- (i) a haemoglobin level taken within the last 4 weeks; and
- (ii) the date of the last transfusion; and
- (iii) a statement of the number of units of red cells transfused in the 4 months immediately preceding this application;

All reports must be documented in the patient's medical records.

For first continuing applications, if the application is submitted through HPOS form upload or mail, it must include:

- (a) a completed authority prescription form; and
- (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).

lenalidomide 10 mg capsule, 21

2796E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	1569.12	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

lenalidomide 5 mg capsule, 21

2798G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	1209.08	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

■ LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed: Revlimid - i-access program; Cipla Lenalidomide - Pregnancy Prevention Program; Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program; Lenalide - Juno Connected™; Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program; Lenalidomide Teva - Pregnancy Prevention Program; Lenalidomide Viatris - Viatris Care.

Authority required

Multiple myeloma

Treatment Phase: Initial treatment in combination with dexamethasone, of newly diagnosed disease in a patient ineligible for stem cell transplantation

Clinical criteria:

- The condition must be newly diagnosed, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must be ineligible for a primary stem cell transplantation, **AND**
- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma, and

(2) confirmation of ineligibility for prior stem cell transplant; and

(3) nomination of which disease activity parameters will be used to assess response.

To enable confirmation of eligibility for treatment, details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f), of at least one of the following must be provided:

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine - the percentage of plasma cells; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held on the patient's medical records.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) 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).

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system

(see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment until progression in patients initiated on dual combination therapy (this drug and dexamethasone), or, in patients initiated on triple therapy (this drug, bortezomib and dexamethasone during treatment cycles 1 up to 8) and are now being treated with treatment cycle 9 or beyond

Clinical criteria:

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

- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

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

lenalidomide 10 mg capsule, 21

11063G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	1569.12	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

lenalidomide 15 mg capsule, 21

11042E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	1880.07	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

lenalidomide 25 mg capsule, 21

11055W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	2445.03	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

lenalidomide 5 mg capsule, 21

11036W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	1209.08	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

■ LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed: Revlimid - i-access program; Cipla Lenalidomide - Pregnancy Prevention Program; Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program; Lenalide - Juno Connected™;

Authority required

Multiple myeloma

Treatment Phase: Initial treatment with lenalidomide monotherapy in newly diagnosed disease

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must have undergone an autologous stem cell transplant (ASCT) as part of frontline therapy for newly diagnosed multiple myeloma, **AND**
- Patient must not have progressive disease following autologous stem cell transplant (ASCT).

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma; and

(2) the date the autologous stem cell transplant was performed; and

(3) nomination of which disease activity parameters will be used to assess progression.

To enable confirmation of eligibility for treatment, the details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f) of at least one of the following must be provided:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine - the percentage of plasma cells; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine progression, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held in the patient's medical records.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) 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).

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment with lenalidomide monotherapy following initial treatment with lenalidomide therapy in newly diagnosed disease

Clinical criteria:

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

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
 (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
 (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

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

lenalidomide 5 mg capsule, 28

11966T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1596.16	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB]	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [CJ]

lenalidomide 10 mg capsule, 28

11969Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	2076.22	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB]	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [CJ]

lenalidomide 15 mg capsule, 28

11965R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	2490.82	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB]	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [CJ]

■ LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed: Revlimid - i-access program; Cipla Lenalidomide - Pregnancy Prevention Program; Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program; Lenalide - Juno Connected™; Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program; Lenalidomide Teva - Pregnancy Prevention Program; Lenalidomide Viatris - Viatris Care.

Authority required

Multiple myeloma

Treatment Phase: Initial treatment with triple therapy (this drug, bortezomib and dexamethasone) for the first 4 treatment cycles (cycles 1 to 4) administered in a 21-day treatment cycle

Clinical criteria:

- The condition must be newly diagnosed, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- Patient must not have been treated with lenalidomide or bortezomib for this condition, **AND**
- The treatment must not exceed a total of 4 cycles under this restriction.

The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma; and

(2) nomination of which disease activity parameters will be used to assess response.

To enable confirmation of eligibility for treatment, details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f), of at least one of the following must be provided:

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine - the percentage of plasma cells; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held on the patient's medical records.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) 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).

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

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment of triple therapy (this drug, bortezomib and dexamethasone) for treatment cycles 5 to 8 inclusive (administered using 21-day treatment cycles)

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug under the treatment phase covering cycles 1 to 4, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- The treatment must not exceed a total of 4 cycles under this restriction.

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

lenalidomide 10 mg capsule, 14

12004T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	1062.02	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB]	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [CJ]

lenalidomide 15 mg capsule, 14

12069F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	1269.32	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB]	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [CJ]

lenalidomide 25 mg capsule, 14

12018M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	1645.96	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB]	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [CJ]

lenalidomide 5 mg capsule, 14

12058P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	812.96	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB]	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [CJ]

■ LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed: Revlimid - i-access program; Cipla Lenalidomide - Pregnancy Prevention Program; Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program; Lenalide - Juno Connected™; Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program; Lenalidomide Teva - Pregnancy Prevention Program; Lenalidomide Viatris - Viatris Care.

Authority required

Multiple myeloma

Treatment Phase: Initial treatment as monotherapy or dual combination therapy with dexamethasone for progressive disease

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must be as monotherapy; OR

- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy, **AND**
- Patient must have undergone or be ineligible for a primary stem cell transplant.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

- (1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma; and
- (2) prior treatments including name(s) of drug(s) and date of most recent treatment cycle; and
- (3) date of prior stem cell transplant or confirmation of ineligibility for prior stem cell transplant; and
- (4) details of the basis of the diagnosis of progressive disease or failure to respond; and
- (5) nomination of which disease activity parameters will be used to assess response.

To enable confirmation of eligibility for treatment, details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f), of at least one of the following must be provided:

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine - the percentage of plasma cells; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held in the patient's medical records.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) 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).

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment as monotherapy or dual combination therapy with dexamethasone following initial treatment for progressive disease

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for relapsed or refractory multiple myeloma, **AND**
- The treatment must be as monotherapy; OR
- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone.

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

lenalidomide 10 mg capsule, 21

9643M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	1569.12	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

lenalidomide 15 mg capsule, 21

9644N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	1880.07	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

lenalidomide 25 mg capsule, 21

9645P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	2445.03	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

lenalidomide 5 mg capsule, 21

9642L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	1209.08	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

■ SELINEXOR

Caution This drug is a Category D drug and must not be given to pregnant women. If this drug is taken during pregnancy, a teratogenic effect in humans cannot be ruled out.

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

Note 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

Relapsed and/or refractory multiple myeloma

Treatment Phase: Initial treatment - Dose requirement of 80 mg, 60 mg or 40 mg per week

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must be undergoing triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; OR
- Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy, **AND**
- Patient must not have previously received this drug for this condition.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Details of: the histological diagnosis of multiple myeloma; prior treatments including name(s) of drug(s) and date of most recent treatment cycle; the basis of the diagnosis of progressive disease or failure to respond; and which disease activity parameters will be used to assess response, must be documented in the patient's medical records.

Confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient's medical records:

- (a) the level of serum monoclonal protein; or

- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters must be used to determine response, results for either (a) or (b) or (c) should be documented for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) must be documented in the patient's medical records. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be documented in the patient's medical records.

Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment - Dose requirement of 80 mg, 60 mg or 40 mg per week

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be undergoing triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; OR
- Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Grandfather treatment - Transitioning from non-PBS to PBS-subsidised supply - Dose requirement of 80 mg, 60 mg or 40 mg per week

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 June 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: (a) the condition was confirmed by histological diagnosis, (b) the treatment is/was being used as part of combination therapy limited to this drug in combination with either: (i) dexamethasone, (ii) dexamethasone plus bortezomib, (c) the condition progressed (see definition of progressive disease below) after at least one prior therapy, (d) the patient had never been treated with this drug, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

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

selinexor 20 mg tablet, 16

13099K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	9407.82	Xpovio [TG]

■ SELINEXOR

Caution This drug is a Category D drug and must not be given to pregnant women. If this drug is taken during pregnancy, a teratogenic effect in humans cannot be ruled out.

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

Note 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

Relapsed and/or refractory multiple myeloma

Treatment Phase: Initial treatment - Dose requirement of 100 mg per week

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must be undergoing triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; OR
- Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy, **AND**
- Patient must not have previously received this drug for this condition.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment - Dose requirement of 100 mg per week

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be undergoing triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; OR
- Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Grandfather treatment - Transitioning from non-PBS to PBS-subsidised supply - Dose requirement of 100 mg per week

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 June 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: (a) the condition was confirmed by histological diagnosis, (b) the treatment is/was being used as part of combination therapy limited to this drug in combination with either: (i) dexamethasone, (ii) dexamethasone plus bortezomib, (c) the condition progressed (see definition of progressive disease below) after at least one prior therapy, (d) the patient had never been treated with this drug, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition. Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

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

selinexor 20 mg tablet, 20

13103P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	11747.82	Xpovio [TG]

SELINEXOR

Caution This drug is a Category D drug and must not be given to pregnant women. If this drug is taken during pregnancy, a teratogenic effect in humans cannot be ruled out.

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

Note 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

Relapsed and/or refractory multiple myeloma

Treatment Phase: Initial treatment - Dose requirement of 160 mg per week

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy, **AND**
- Patient must not have previously received this drug for this condition.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment - Dose requirement of 160 mg per week

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
 - Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
 - Patient must not have developed disease progression while receiving treatment with this drug for this condition.
- Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Grandfather treatment - Transitioning from non-PBS to PBS-subsidised supply - Dose requirement of 160 mg per week

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 September 2022, **AND**
- The treatment must be in combination with dexamethasone, **AND**
- Patient must have progressive disease after at least four prior lines of therapy, prior to initiating non-PBS-subsidised therapy with this drug for this condition, **AND**
- Patient must have demonstrated refractory disease to prior treatments, prior to initiating non-PBS-subsidised therapy with this drug for this condition, which must include: (i) a minimum of two proteasome inhibitors; and (ii) a minimum of two immunomodulators; and (iii) an anti-CD38 monoclonal antibody, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of the following: (i) proteasome inhibitors, (ii) Immunomodulators, (iii) anti-CD38 monoclonal antibody.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

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

selinexor 20 mg tablet, 32

13105R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	18767.82	Xpovio [TG]

Highly Specialised Drugs Program (Public Hospital)

▪ LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed: Revlimid - i-access program; Cipla Lenalidomide - Pregnancy Prevention Program; Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program; Lenalide - Juno Connected™; Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program; Lenalidomide Teva - Pregnancy Prevention Program; Lenalidomide Viatris - Viatris Care.

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

Authority required

Multiple myeloma

Treatment Phase: Initial treatment with triple therapy (this drug, bortezomib and dexamethasone) for the first 4 treatment cycles (cycles 1 to 4) administered in a 28-day treatment cycle

Clinical criteria:

- The condition must be newly diagnosed, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- Patient must not have been treated with lenalidomide or bortezomib for this condition, **AND**
- The treatment must not exceed a total of 4 cycles under this restriction.

The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma; and

(2) nomination of which disease activity parameters will be used to assess response.

To enable confirmation of eligibility for treatment, details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f), of at least one of the following must be provided:

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine - the percentage of plasma cells; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held on the patient's medical records.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) 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).

lenalidomide 10 mg capsule, 21

12061T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	1521.30	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

lenalidomide 15 mg capsule, 21

1206Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	1832.25	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

lenalidomide 25 mg capsule, 21

12059Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	2397.21	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

lenalidomide 5 mg capsule, 21

12034J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	1161.26	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

■ LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed: Revlimid - i-access program; Cipla Lenalidomide - Pregnancy Prevention Program; Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program; Lenalide - Juno Connected™; Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program; Lenalidomide Teva - Pregnancy Prevention Program; Lenalidomide Viatris - Viatris Care.

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

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment of triple therapy (this drug, bortezomib and dexamethasone) for treatment cycles 5 and 6 (administered using 28-day treatment cycles)

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug under the treatment phase covering cycles 1 to 4, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- The treatment must not exceed a total of 2 cycles under this restriction.

lenalidomide 10 mg capsule, 21

12057N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	1521.30	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

lenalidomide 15 mg capsule, 21

12062W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	1832.25	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

lenalidomide 25 mg capsule, 21

12036L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	2397.21	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

lenalidomide 5 mg capsule, 21

12039P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	1161.26	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

■ LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed: Revlimid - i-access program; Cipla Lenalidomide - Pregnancy Prevention Program; Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program; Lenalide - Juno Connected™; Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program; Lenalidomide Teva - Pregnancy Prevention Program; Lenalidomide Viatris - Viatris Care.

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

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Triple combination therapy consisting of elotuzumab, lenalidomide and dexamethasone

Treatment criteria:

- Patient must be undergoing concurrent treatment with elotuzumab obtained through the PBS, **AND**
- Patient must not be undergoing simultaneous treatment with this drug obtained under another PBS listing.

lenalidomide 10 mg capsule, 21

12988N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1521.30	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

lenalidomide 15 mg capsule, 21

12991R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1832.25	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

lenalidomide 25 mg capsule, 21

12979D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	2397.21	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

lenalidomide 5 mg capsule, 21

12985K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1161.26	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

■ LENALIDOMIDE

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Note Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed: Revlimid - i-access program; Cipla Lenalidomide - Pregnancy Prevention Program; Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program; Lenalide - Juno Connected™; Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program; Lenalidomide Teva - Pregnancy Prevention Program; Lenalidomide Viatris - Viatris Care.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Myelodysplastic syndrome

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be limited to a maximum duration of 16 weeks, **AND**
- Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS), **AND**
- Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities, **AND**
- Patient must be red blood cell transfusion dependent.

Classification of a patient as Low risk requires a score of 0 on the IPSS, achieved with the following combination: less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias.

Classification of a patient as Intermediate-1 requires a score of 0.5 to 1 on the IPSS, achieved with the following possible combinations:

1. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias; OR
2. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR
3. less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR
4. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 2/3 cytopenias; OR
5. 5%-10% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR
6. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR
7. less than 5% marrow blasts with poor karyotypic status (complex, greater than 3 abnormalities), and 0/1 cytopenias.

Classification of a patient as red blood cell transfusion dependent requires that:

- (i) the patient has been transfused within the last 8 weeks; and
- (ii) the patient has received at least 8 units of red blood cell in the last 6 months prior to commencing PBS-subsidised therapy with lenalidomide; and would be expected to continue this requirement without lenalidomide treatment.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

- (a) details (date, unique identifying number/code or provider number) of the bone marrow biopsy report from an Approved Pathology Authority demonstrating that the patient has myelodysplastic syndrome; and
- (b) details (date, unique identifying number/code or provider number) of the full blood examination report; and
- (c) details (date, unique identifying number/code or provider number) of the pathology report and details of the cytogenetics demonstrating Low risk or Intermediate-1 disease according to the IPSS (note: using Fluorescence in Situ Hybridization (FISH) to demonstrate MDS -5q is acceptable); and
- (d) details of transfusion requirements including: (i) the date of most recent transfusion and the number of red blood cell units transfused; and (ii) the total number of red blood cell units transfused in the 4 and 6 months preceding the date of this application.

All the reports must be documented in the patient's medical records.

If the application is submitted through HPOS upload or mail, it must include:

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

Authority required

Myelodysplastic syndrome

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received PBS-subsidised initial therapy with lenalidomide for myelodysplastic syndrome, **AND**
- Patient must have achieved and maintained transfusion independence; or at least a 50% reduction in red blood cell unit transfusion requirements compared with the four month period prior to commencing initial PBS-subsidised therapy with lenalidomide, **AND**
- Patient must not have progressive disease, **AND**
- The condition must not have progressed to acute myeloid leukaemia.

The first authority application for continuing supply must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail. Subsequent authority applications for continuing supply may be made via the Online PBS Authorities System or by telephone.

The following evidence of response must be provided at each application:

- (i) a haemoglobin level taken within the last 4 weeks; and
- (ii) the date of the last transfusion; and
- (iii) a statement of the number of units of red cells transfused in the 4 months immediately preceding this application;

All reports must be documented in the patient's medical records.

For first continuing applications, if the application is submitted through HPOS form upload or mail, it must include:

- (a) a completed authority prescription form; and
- (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).

lenalidomide 10 mg capsule, 21

2802L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	1521.30	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

lenalidomide 5 mg capsule, 21

2799H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	1161.26	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

■ LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed: Revlimid - i-access program; Cipla Lenalidomide - Pregnancy Prevention Program; Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program; Lenalide - Juno Connected™; Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program; Lenalidomide Teva - Pregnancy Prevention Program; Lenalidomide Viatris - Viatris Care.

Authority required

Multiple myeloma

Treatment Phase: Initial treatment in combination with dexamethasone, of newly diagnosed disease in a patient ineligible for stem cell transplantation

Clinical criteria:

- The condition must be newly diagnosed, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must be ineligible for a primary stem cell transplantation, **AND**
- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma, and

(2) confirmation of ineligibility for prior stem cell transplant; and

(3) nomination of which disease activity parameters will be used to assess response.

To enable confirmation of eligibility for treatment, details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f), of at least one of the following must be provided:

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine - the percentage of plasma cells; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held on the patient's medical records.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) 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).

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system

(see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment until progression in patients initiated on dual combination therapy (this drug and dexamethasone), or, in patients initiated on triple therapy (this drug, bortezomib and dexamethasone during treatment cycles 1 up to 8) and are now being treated with treatment cycle 9 or beyond

Clinical criteria:

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

- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

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

lenalidomide 10 mg capsule, 21

11064H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	1521.30	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

lenalidomide 15 mg capsule, 21

11062F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	1832.25	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

lenalidomide 25 mg capsule, 21

11041D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	2397.21	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

lenalidomide 5 mg capsule, 21

11029L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	1161.26	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

▪ LENALIDOMIDE

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Note Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed: Revlimid - i-access program; Cipla Lenalidomide - Pregnancy Prevention Program; Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program; Lenalide - Juno Connected™;

Authority required

Multiple myeloma

Treatment Phase: Initial treatment with lenalidomide monotherapy in newly diagnosed disease

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must have undergone an autologous stem cell transplant (ASCT) as part of frontline therapy for newly diagnosed multiple myeloma, **AND**
- Patient must not have progressive disease following autologous stem cell transplant (ASCT).

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma; and

(2) the date the autologous stem cell transplant was performed; and

(3) nomination of which disease activity parameters will be used to assess progression.

To enable confirmation of eligibility for treatment, the details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f) of at least one of the following must be provided:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine - the percentage of plasma cells; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine progression, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held in the patient's medical records.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) 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).

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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Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment with lenalidomide monotherapy following initial treatment with lenalidomide therapy in newly diagnosed disease

Clinical criteria:

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

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
 (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
 (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

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

lenalidomide 5 mg capsule, 28

11967W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1548.34	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB]	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [CJ]

lenalidomide 10 mg capsule, 28

11968X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	2028.40	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB]	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [CJ]

lenalidomide 15 mg capsule, 28

11964Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	2443.00	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB]	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [CJ]

■ LENALIDOMIDE

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Note Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed: Revlimid - i-access program; Cipla Lenalidomide - Pregnancy Prevention Program; Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program; Lenalide - Juno Connected™; Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program; Lenalidomide Teva - Pregnancy Prevention Program; Lenalidomide Viatris - Viatris Care.

Authority required

Multiple myeloma

Treatment Phase: Initial treatment with triple therapy (this drug, bortezomib and dexamethasone) for the first 4 treatment cycles (cycles 1 to 4) administered in a 21-day treatment cycle

Clinical criteria:

- The condition must be newly diagnosed, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- Patient must not have been treated with lenalidomide or bortezomib for this condition, **AND**
- The treatment must not exceed a total of 4 cycles under this restriction.

The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma; and

(2) nomination of which disease activity parameters will be used to assess response.

To enable confirmation of eligibility for treatment, details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f), of at least one of the following must be provided:

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine - the percentage of plasma cells; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held on the patient's medical records.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) 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).

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

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment of triple therapy (this drug, bortezomib and dexamethasone) for treatment cycles 5 to 8 inclusive (administered using 21-day treatment cycles)

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug under the treatment phase covering cycles 1 to 4, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- The treatment must not exceed a total of 4 cycles under this restriction.

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

lenalidomide 10 mg capsule, 14

12070G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	1014.20	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB]	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [CJ]

lenalidomide 15 mg capsule, 14

12012F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	1221.50	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB]	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [CJ]

lenalidomide 25 mg capsule, 14

12019N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	1598.14	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB]	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [CJ]

lenalidomide 5 mg capsule, 14

12035K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	774.17	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB]	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [CJ]

▪ **LENALIDOMIDE**

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed: Revlimid - i-access program; Cipla Lenalidomide - Pregnancy Prevention Program; Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program; Lenalide - Juno Connected™; Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program; Lenalidomide Teva - Pregnancy Prevention Program; Lenalidomide Viatris - Viatris Care.

Authority required

Multiple myeloma

Treatment Phase: Initial treatment as monotherapy or dual combination therapy with dexamethasone for progressive disease

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must be as monotherapy; OR

- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy, **AND**
- Patient must have undergone or be ineligible for a primary stem cell transplant.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

- (1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma; and
- (2) prior treatments including name(s) of drug(s) and date of most recent treatment cycle; and
- (3) date of prior stem cell transplant or confirmation of ineligibility for prior stem cell transplant; and
- (4) details of the basis of the diagnosis of progressive disease or failure to respond; and
- (5) nomination of which disease activity parameters will be used to assess response.

To enable confirmation of eligibility for treatment, details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f), of at least one of the following must be provided:

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine - the percentage of plasma cells; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held in the patient's medical records.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) 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).

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment as monotherapy or dual combination therapy with dexamethasone following initial treatment for progressive disease

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for relapsed or refractory multiple myeloma, **AND**
- The treatment must be as monotherapy; OR
- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone.

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

lenalidomide 10 mg capsule, 21

5784K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	1521.30	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

lenalidomide 15 mg capsule, 21

5785L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	1832.25	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

lenalidomide 25 mg capsule, 21

5786M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	2397.21	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

lenalidomide 5 mg capsule, 21

5783J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	1161.26	Cipla Lenalidomide [LR] Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB] Revlimid [CJ]	Lenalide [JU] Lenalidomide Sandoz [SZ] Lenalidomide Viatris [AF]

■ SELINEXOR

Caution This drug is a Category D drug and must not be given to pregnant women. If this drug is taken during pregnancy, a teratogenic effect in humans cannot be ruled out.

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

Note 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

Relapsed and/or refractory multiple myeloma

Treatment Phase: Initial treatment - Dose requirement of 80 mg, 60 mg or 40 mg per week

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
 - Patient must be undergoing triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; OR
 - Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
 - Patient must have progressive disease after at least one prior therapy, **AND**
 - Patient must not have previously received this drug for this condition.
- Progressive disease is defined as at least 1 of the following:
- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
 - (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
 - (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
 - (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
 - (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
 - (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
 - (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Details of: the histological diagnosis of multiple myeloma; prior treatments including name(s) of drug(s) and date of most recent treatment cycle; the basis of the diagnosis of progressive disease or failure to respond; and which disease activity parameters will be used to assess response, must be documented in the patient's medical records.

Confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient's medical records:

- (a) the level of serum monoclonal protein; or

- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters must be used to determine response, results for either (a) or (b) or (c) should be documented for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) must be documented in the patient's medical records. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be documented in the patient's medical records.

Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment - Dose requirement of 80 mg, 60 mg or 40 mg per week

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be undergoing triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; OR
- Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Grandfather treatment - Transitioning from non-PBS to PBS-subsidised supply - Dose requirement of 80 mg, 60 mg or 40 mg per week

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 June 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: (a) the condition was confirmed by histological diagnosis, (b) the treatment is/was being used as part of combination therapy limited to this drug in combination with either: (i) dexamethasone, (ii) dexamethasone plus bortezomib, (c) the condition progressed (see definition of progressive disease below) after at least one prior therapy, (d) the patient had never been treated with this drug, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

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

selinexor 20 mg tablet, 16

13085Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	9360.00	Xpovio [TG]

■ SELINEXOR

Caution This drug is a Category D drug and must not be given to pregnant women. If this drug is taken during pregnancy, a teratogenic effect in humans cannot be ruled out.

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

Note 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

Relapsed and/or refractory multiple myeloma

Treatment Phase: Initial treatment - Dose requirement of 100 mg per week

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must be undergoing triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; OR
- Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy, **AND**
- Patient must not have previously received this drug for this condition.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment - Dose requirement of 100 mg per week

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be undergoing triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; OR
- Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Grandfather treatment - Transitioning from non-PBS to PBS-subsidised supply - Dose requirement of 100 mg per week

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 June 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: (a) the condition was confirmed by histological diagnosis, (b) the treatment is/was being used as part of combination therapy limited to this drug in combination with either: (i) dexamethasone, (ii) dexamethasone plus bortezomib, (c) the condition progressed (see definition of progressive disease below) after at least one prior therapy, (d) the patient had never been treated with this drug, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition. Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

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

selinexor 20 mg tablet, 20

13086R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	11700.00	Xpovio [TG]

SELINEXOR

Caution This drug is a Category D drug and must not be given to pregnant women. If this drug is taken during pregnancy, a teratogenic effect in humans cannot be ruled out.

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

Note 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

Relapsed and/or refractory multiple myeloma

Treatment Phase: Initial treatment - Dose requirement of 160 mg per week

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy, **AND**
- Patient must not have previously received this drug for this condition.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment - Dose requirement of 160 mg per week

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
 - Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
 - Patient must not have developed disease progression while receiving treatment with this drug for this condition.
- Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Grandfather treatment - Transitioning from non-PBS to PBS-subsidised supply - Dose requirement of 160 mg per week

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 September 2022, **AND**
- The treatment must be in combination with dexamethasone, **AND**
- Patient must have progressive disease after at least four prior lines of therapy, prior to initiating non-PBS-subsidised therapy with this drug for this condition, **AND**
- Patient must have demonstrated refractory disease to prior treatments, prior to initiating non-PBS-subsidised therapy with this drug for this condition, which must include: (i) a minimum of two proteasome inhibitors; and (ii) a minimum of two immunomodulators; and (iii) an anti-CD38 monoclonal antibody, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of the following: (i) proteasome inhibitors, (ii) Immunomodulators, (iii) anti-CD38 monoclonal antibody.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

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

selinexor 20 mg tablet, 32

13104Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	18720.00	Xpovio [TG]