Australian Government
Department of Health and Aged Care

PBS

Schedule of Pharmaceutical Benefits

Summary of Changes

Effective 1 February 2023

Fees, Patient Contributions and Safety Net Thresholds

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

Prescriber Bag

Deletions

Deletion – Brand

3497C *APO-Salbutamol, TX* – **SALBUTAMOL**, salbutamol 5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules

Advance Notices

1 March 2023
Deletion – Brand

3495Y *Asmol CFC-free, AL* – **SALBUTAMOL**, salbutamol 100 microgram/actuation inhalation, 200 actuations

1 April 2023
Deletion – Brand

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

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

General Pharmaceutical Benefits

Additions

Addition – Item

13205B **BECLOMETASONE + FORMOTEROL (EFORMOTEROL)**, beclometasone dipropionate 200 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation inhalation, 120 actuations *(Fostair 200/6)*

13206C **OPICAPONE**, opicapone 50 mg capsule, 30 *(Ongentys)*

Addition – Brand

8189B *Acarbose Viatris, AL* – **ACARBOSE**, acarbose 100 mg tablet, 90

1153Q *WP Carbimazole, TN* – **CARBIMAZOLE**, carbimazole 5 mg tablet, 100

9158B *Cinacalcet Viatris, AL* – **CINACALCET**, cinacalcet 60 mg tablet, 28

2896K *APO-DIMETHYL FUMARATE, XT* – **DIMETHYL FUMARATE**, dimethyl fumarate 120 mg enteric capsule, 14

2896K *Dimethyl Fumarate MSN, LR* – **DIMETHYL FUMARATE**, dimethyl fumarate 120 mg enteric capsule, 14

2943X *APO-DIMETHYL FUMARATE, XT* – **DIMETHYL FUMARATE**, dimethyl fumarate 120 mg enteric capsule, 14

2943X *Dimethyl Fumarate MSN, LR* – **DIMETHYL FUMARATE**, dimethyl fumarate 120 mg enteric capsule, 14

2966D *APO-DIMETHYL FUMARATE, XT* – **DIMETHYL FUMARATE**, dimethyl fumarate 240 mg enteric capsule, 56

2966D *Dimethyl Fumarate MSN, LR* – **DIMETHYL FUMARATE**, dimethyl fumarate 240 mg enteric capsule, 56

1347X *APO-DOMPERIDONE, TX* – **DOMPERIDONE**, domperidone 10 mg tablet, 25

5262Y *Fynod, AF* – **FINGOLIMOD**, fingolimod 500 microgram capsule, 28

1526H *Flopen Viatris, MQ* – **FLUCLOXACILLIN**, flucloxacillin 250 mg capsule, 24

5090X *Flopen Viatris, MQ* – **FLUCLOXACILLIN**, flucloxacillin 250 mg capsule, 24

10788T *Flopen Viatris, MQ* – **FLUCLOXACILLIN**, flucloxacillin 500 mg capsule, 24

1527J *Flopen Viatris, MQ* – **FLUCLOXACILLIN**, flucloxacillin 500 mg capsule, 24

5091Y *Flopen Viatris, MQ* – **FLUCLOXACILLIN**, flucloxacillin 500 mg capsule, 24

12931N *VesiCulture, LM* – **MYCOBACTERIUM BOVIS BCG DANISH STRAIN**, Mycobacterium bovis BCG Danish strain 30 mg injection, 4 vials

5524R *Optix, PP* – **POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL**, polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL

8676P *Optix, PP* – **POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL**, polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL

9219F *Optix, PP* – **POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL**, polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL

11572C *Sitaglo, CR* – **SITAGLIPTIN**, sitagliptin 25 mg tablet, 28

9180E *Sitaglo, CR* – **SITAGLIPTIN**, sitagliptin 25 mg tablet, 28

11573D *Sitaglo, CR* – **SITAGLIPTIN**, sitagliptin 50 mg tablet, 28

9181F *Sitaglo, CR* – **SITAGLIPTIN**, sitagliptin 50 mg tablet, 28

11576G *Sitaglo, CR* – **SITAGLIPTIN**, sitagliptin 100 mg tablet, 28

9182G *Sitaglo, CR* – **SITAGLIPTIN**, sitagliptin 100 mg tablet, 28

8378Y *Temizole 5, AL* – **TEMOZOLOMIDE**, temozolomide 5 mg capsule, 5

8819E *Temizole 5, AL* – **TEMOZOLOMIDE**, temozolomide 5 mg capsule, 5

13128Y *TNKase (Canada) Medsurge Healthcare Pty Ltd, DZ* – **TENECTEPLASE**, tenecteplase 50 mg injection [1 vial] (&) inert substance diluent [10 mL syringe], 1 pack

1330B *Tetrabenazine SUN, RA* – **TETRABENAZINE**, tetrabenazine 25 mg tablet, 112

1356J *Tobramycin Viatris, AL* – **TOBRAMYCIN**, tobramycin 80 mg/2 mL injection, 5 x 2 mL vials

3113W *Vancomycin BNM 125mg, BZ* – **VANCOMYCIN**, vancomycin 125 mg capsule, 20

3114X *Vancomycin BNM 250mg, BZ* – **VANCOMYCIN**, vancomycin 250 mg capsule, 20

Addition – Equivalence Indicator

1153Q *Neo-Mercazole, GH* – **CARBIMAZOLE**, carbimazole 5 mg tablet, 100

1347X *Motilium, JT* – **DOMPERIDONE**, domperidone 10 mg tablet, 25

5524R *Systane, AQ* – **POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL**, polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL

8676P *Systane, AQ* – **POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL**, polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL

9219F *Systane, AQ* – **POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL**, polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL

1330B *iNova Pharmaceuticals (Australia) Pty Ltd, IL* – **TETRABENAZINE**, tetrabenazine 25 mg tablet, 112

3113W *Vancocin, AS* – **VANCOMYCIN**, vancomycin 125 mg capsule, 20

3114X *Vancocin, AS* – **VANCOMYCIN**, vancomycin 250 mg capsule, 20

Addition – Note

3440C **METHYLPHENIDATE**, methylphenidate hydrochloride 10 mg modified release capsule, 30 *(Ritalin LA)*

2276T **METHYLPHENIDATE**, methylphenidate hydrochloride 20 mg modified release capsule, 30 *(Ritalin LA)*

2280B **METHYLPHENIDATE**, methylphenidate hydrochloride 30 mg modified release capsule, 30 *(Ritalin LA)*

2283E **METHYLPHENIDATE**, methylphenidate hydrochloride 40 mg modified release capsule, 30 *(Ritalin LA)*

12116Q **METHYLPHENIDATE**, methylphenidate hydrochloride 60 mg modified release capsule, 30 *(Ritalin LA)*

8839F **METHYLPHENIDATE**, methylphenidate hydrochloride 10 mg tablet, 100 *(Artige, Ritalin 10)*

2387P **METHYLPHENIDATE**, methylphenidate hydrochloride 18 mg modified release tablet, 30 *(Concerta, METHYLPHENIDATE-TEVA XR, Methylphenidate XR ARX)*

2172H **METHYLPHENIDATE**, methylphenidate hydrochloride 27 mg modified release tablet, 30 *(Concerta, METHYLPHENIDATE-TEVA XR, Methylphenidate XR ARX)*

2388Q **METHYLPHENIDATE**, methylphenidate hydrochloride 36 mg modified release tablet, 30 *(Concerta, METHYLPHENIDATE-TEVA XR, Methylphenidate XR ARX)*

2432B **METHYLPHENIDATE**, methylphenidate hydrochloride 54 mg modified release tablet, 30 *(Concerta, METHYLPHENIDATE-TEVA XR, Methylphenidate XR ARX)*

Deletions

Deletion – Item

3423E **EXENATIDE**, exenatide 5 microgram/0.02 mL injection, 1.2 mL pen device *(Byetta 5 microgram)*

3424F **EXENATIDE**, exenatide 10 microgram/0.04 mL injection, 2.4 mL pen device *(Byetta 10 microgram)*

8885P **SUMATRIPTAN**, SUMATRIPTAN Tablet (fast disintegrating) 50 mg (as succinate), 2 *(Imigran FDT)*

Deletion – Brand

12931N *BCG Culture SSI, LM* – **MYCOBACTERIUM BOVIS BCG DANISH STRAIN**, Mycobacterium bovis BCG Danish strain 30 mg injection, 4 vials

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

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

2001H *APO-Salbutamol, TX* – **SALBUTAMOL**, salbutamol 5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules

8378Y *Temozolomide Alphapharm, AF* – **TEMOZOLOMIDE**, temozolomide 5 mg capsule, 5

8819E *Temozolomide Alphapharm, AF* – **TEMOZOLOMIDE**, temozolomide 5 mg capsule, 5

Deletion – Note

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

12831H **UPADACITINIB**, upadacitinib 15 mg modified release tablet, 28 *(Rinvoq)*

12829F **UPADACITINIB**, upadacitinib 30 mg modified release tablet, 28 *(Rinvoq)*

Deletion – Restriction

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

12831H **UPADACITINIB**, upadacitinib 15 mg modified release tablet, 28 *(Rinvoq)*

12829F **UPADACITINIB**, upadacitinib 30 mg modified release tablet, 28 *(Rinvoq)*

Alterations

Alteration – Restriction

12910L **MOLNUPIRAVIR**, molnupiravir 200 mg capsule, 40 *(Lagevrio)*

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

12301K **ROMOSOZUMAB**, romosozumab 105 mg/1.17 mL injection, 2 x 1.17 mL syringes *(Evenity)*

Advance Notices

1 March 2023

Deletion – Brand

1196Y *Largactil, SW* – **CHLORPROMAZINE**, chlorpromazine hydrochloride 10 mg tablet, 100

8358X *Blooms the Chemist Clopidogrel, IB* – **CLOPIDOGREL**, clopidogrel 75 mg tablet, 28

5452Y *Cozavan, AF* – **LOSARTAN**, losartan potassium 25 mg tablet, 30

8203R *Cozavan, AF* – **LOSARTAN**, losartan potassium 50 mg tablet, 30

1750D *Ircal, PE* – **PARAFFIN**, paraffin 1 g/g eye ointment, 2 x 3.5 g

5522P *Ircal, PE* – **PARAFFIN**, paraffin 1 g/g eye ointment, 2 x 3.5 g

9218E *Ircal, PE* – **PARAFFIN**, paraffin 1 g/g eye ointment, 2 x 3.5 g

1895R *Mobilis D-10, AF* – **PIROXICAM**, piroxicam 10 mg dispersible tablet, 50

1897W *Feldene, PF* – **PIROXICAM**, piroxicam 10 mg capsule, 50

5201R *Mobilis D-10, AF* – **PIROXICAM**, piroxicam 10 mg dispersible tablet, 50

5203W *Feldene, PF* – **PIROXICAM**, piroxicam 10 mg capsule, 50

5532E *Systane, AQ* – **POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL**, polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses

9170P *Systane, AQ* – **POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL**, polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses

2682E *Liquifilm Tears, AG* – **POLYVINYL ALCOHOL**, polyvinyl alcohol 1.4% eye drops, 15 mL

2682E *PVA Tears, PE* – **POLYVINYL ALCOHOL**, polyvinyl alcohol 1.4% eye drops, 15 mL

5526W *Liquifilm Tears, AG* – **POLYVINYL ALCOHOL**, polyvinyl alcohol 1.4% eye drops, 15 mL

5526W *PVA Tears, PE* – **POLYVINYL ALCOHOL**, polyvinyl alcohol 1.4% eye drops, 15 mL

9220G *Liquifilm Tears, AG* – **POLYVINYL ALCOHOL**, polyvinyl alcohol 1.4% eye drops, 15 mL

9220G *PVA Tears, PE* – **POLYVINYL ALCOHOL**, polyvinyl alcohol 1.4% eye drops, 15 mL

2335X *Pregabalin-Teva, TB* – **PREGABALIN**, pregabalin 75 mg capsule, 56

2348N *Pregabalin-Teva, TB* – **PREGABALIN**, pregabalin 25 mg capsule, 56

2355Y *Pregabalin-Teva, TB* – **PREGABALIN**, pregabalin 150 mg capsule, 56

2363J *Pregabalin-Teva, TB* – **PREGABALIN**, pregabalin 300 mg capsule, 56

2899N *Deralin 160, AF* – **PROPRANOLOL**, propranolol hydrochloride 160 mg tablet, 50

8288F *Asmol CFC-free, AL* – **SALBUTAMOL**, salbutamol 100 microgram/actuation inhalation, 200 actuations

1 April 2023
Deletion – Brand

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

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

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

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

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

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

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

9299K *Jurnista, JC* – **HYDROMORPHONE**, hydromorphone hydrochloride 4 mg modified release tablet, 14

9406C *Jurnista, JC* – **HYDROMORPHONE**, hydromorphone hydrochloride 8 mg modified release tablet, 14

9407D *Jurnista, JC* – **HYDROMORPHONE**, hydromorphone hydrochloride 16 mg modified release tablet, 14

9408E *Jurnista, JC* – **HYDROMORPHONE**, hydromorphone hydrochloride 32 mg modified release tablet, 14

9409F *Jurnista, JC* – **HYDROMORPHONE**, hydromorphone hydrochloride 64 mg modified release tablet, 14

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

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

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

1645N *DBL Morphine Sulfate Pentahydrate, PF* – **MORPHINE**, morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules

1647Q *DBL Morphine Sulfate Pentahydrate, PF* – **MORPHINE**, morphine sulfate pentahydrate 30 mg/mL injection, 5 x 1 mL ampoules

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

5169C *DBL Morphine Sulfate Pentahydrate, PF* – **MORPHINE**, morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules

5170D *DBL Morphine Sulfate Pentahydrate, PF* – **MORPHINE**, morphine sulfate pentahydrate 30 mg/mL injection, 5 x 1 mL ampoules

1 August 2023
Deletion – Brand

2418G *Amitriptyline Alphapharm 25, MQ* – **AMITRIPTYLINE**, amitriptyline hydrochloride 25 mg tablet, 50

1358L *Dosulepin Mylan, MQ* – **DOSULEPIN (DOTHIEPIN)**, dosulepin (dothiepin) hydrochloride 75 mg tablet, 30

1500Y *Hydrocortisone Mylan 20, MQ* – **HYDROCORTISONE**, hydrocortisone 20 mg tablet, 60

Palliative Care
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1 April 2023
Deletion – Brand

12473L *Jurnista, JC* – **HYDROMORPHONE**, hydromorphone hydrochloride 16 mg modified release tablet, 14

12482Y *Jurnista, JC* – **HYDROMORPHONE**, hydromorphone hydrochloride 8 mg modified release tablet, 14

12496Q *Jurnista, JC* – **HYDROMORPHONE**, hydromorphone hydrochloride 4 mg modified release tablet, 14

12535R *Jurnista, JC* – **HYDROMORPHONE**, hydromorphone hydrochloride 64 mg modified release tablet, 14

12543E *Jurnista, JC* – **HYDROMORPHONE**, hydromorphone hydrochloride 32 mg modified release tablet, 14

12499W *DBL Morphine Sulfate Pentahydrate, PF* – **MORPHINE**, morphine sulfate pentahydrate 10 mg/mL injection, 5 x 1 mL ampoules

12503C *DBL Morphine Sulfate Pentahydrate, PF* – **MORPHINE**, morphine sulfate pentahydrate 30 mg/mL injection, 5 x 1 mL ampoules

12548K *DBL Morphine Sulfate Pentahydrate, PF* – **MORPHINE**, morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules

Highly Specialised Drugs Program (Private Hospital)
Additions
Addition – Brand

12180C *Ambrisentan Viatris, AL* – **AMBRISENTAN**, ambrisentan 10 mg tablet, 30

9649W *Ambrisentan Viatris, AL* – **AMBRISENTAN**, ambrisentan 10 mg tablet, 30

11889R *Cinacalcet Viatris, AL* – **CINACALCET**, cinacalcet 60 mg tablet, 28

9626P *Cinacalcet Viatris, AL* – **CINACALCET**, cinacalcet 60 mg tablet, 28

11036W *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

11036W *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

11036W *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

11036W *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

11036W *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

11966T *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 28

11966T *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 28

11966T *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 28

11966T *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 28

11966T *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 28

12038N *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

12038N *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

12038N *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

12038N *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

12038N *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

12058P *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 14

12058P *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 14

12058P *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 14

12058P *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 14

12058P *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 14

12071H *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

12071H *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

12071H *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

12071H *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

12071H *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

12984J *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

12984J *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

12984J *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

12984J *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

12984J *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

2798G *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

2798G *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

2798G *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

2798G *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

2798G *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

9642L *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

9642L *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

9642L *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

9642L *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

9642L *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

11063G *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

11063G *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

11063G *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

11063G *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

11063G *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

11969Y *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 28

11969Y *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 28

11969Y *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 28

11969Y *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 28

11969Y *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 28

12004T *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 14

12004T *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 14

12004T *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 14

12004T *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 14

12004T *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 14

12050F *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

12050F *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

12050F *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

12050F *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

12050F *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

12060R *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

12060R *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

12060R *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

12060R *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

12060R *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

12980E *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

12980E *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

12980E *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

12980E *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

12980E *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

2796E *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

2796E *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

2796E *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

2796E *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

2796E *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

9643M *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

9643M *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

9643M *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

9643M *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

9643M *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

11042E *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

11042E *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

11042E *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

11042E *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

11042E *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

11965R *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 28

11965R *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 28

11965R *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 28

11965R *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 28

11965R *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 28

12011E *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

12011E *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

12011E *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

12011E *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

12011E *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

12020P *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

12020P *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

12020P *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

12020P *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

12020P *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

12069F *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 14

12069F *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 14

12069F *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 14

12069F *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 14

12069F *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 14

12986L *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

12986L *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

12986L *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

12986L *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

12986L *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

9644N *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

9644N *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

9644N *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

9644N *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

9644N *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

11055W *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

11055W *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

11055W *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

11055W *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

11055W *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12018M *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 14

12018M *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 14

12018M *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 14

12018M *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 14

12018M *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 14

12037M *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12037M *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12037M *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12037M *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12037M *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12068E *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12068E *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12068E *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12068E *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12068E *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12993W *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12993W *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12993W *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12993W *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12993W *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

9645P *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

9645P *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

9645P *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

9645P *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

9645P *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

Addition – Note

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

11966T **LENALIDOMIDE**, lenalidomide 5 mg capsule, 28 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12038N **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12058P **LENALIDOMIDE**, lenalidomide 5 mg capsule, 14 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12071H **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12984J **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

2798G **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

9642L **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

11063G **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

11969Y **LENALIDOMIDE**, lenalidomide 10 mg capsule, 28 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12004T **LENALIDOMIDE**, lenalidomide 10 mg capsule, 14 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12050F **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12060R **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12980E **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

2796E **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

9643M **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

11042E **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

11965R **LENALIDOMIDE**, lenalidomide 15 mg capsule, 28 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12011E **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12020P **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12069F **LENALIDOMIDE**, lenalidomide 15 mg capsule, 14 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12986L **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

9644N **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

11055W **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12018M **LENALIDOMIDE**, lenalidomide 25 mg capsule, 14 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12037M **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12068E **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12993W **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

9645P **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

Alterations

Alteration – Restriction

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

11966T **LENALIDOMIDE**, lenalidomide 5 mg capsule, 28 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12038N **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12058P **LENALIDOMIDE**, lenalidomide 5 mg capsule, 14 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12071H **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12984J **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

2798G **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

9642L **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

11063G **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

11969Y **LENALIDOMIDE**, lenalidomide 10 mg capsule, 28 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12004T **LENALIDOMIDE**, lenalidomide 10 mg capsule, 14 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12050F **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12060R **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12980E **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

2796E **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

9643M **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

11042E **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

11965R **LENALIDOMIDE**, lenalidomide 15 mg capsule, 28 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12011E **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12020P **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12069F **LENALIDOMIDE**, lenalidomide 15 mg capsule, 14 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12986L **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

9644N **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

11055W **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12018M **LENALIDOMIDE**, lenalidomide 25 mg capsule, 14 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12037M **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12068E **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12993W **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

9645P **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

Highly Specialised Drugs Program (Public Hospital)

Additions

Addition – Brand

12186J *Ambrisentan Viatris, AL* – **AMBRISENTAN**, ambrisentan 10 mg tablet, 30

5608E *Ambrisentan Viatris, AL* – **AMBRISENTAN**, ambrisentan 10 mg tablet, 30

11886N *Cinacalcet Viatris, AL* – **CINACALCET**, cinacalcet 60 mg tablet, 28

5622X *Cinacalcet Viatris, AL* – **CINACALCET**, cinacalcet 60 mg tablet, 28

11029L *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

11029L *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

11029L *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

11029L *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

11029L *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

11967W *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 28

11967W *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 28

11967W *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 28

11967W *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 28

11967W *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 28

12034J *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

12034J *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

12034J *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

12034J *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

12034J *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

12035K *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 14

12035K *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 14

12035K *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 14

12035K *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 14

12035K *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 14

12039P *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

12039P *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

12039P *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

12039P *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

12039P *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

12985K *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21
12985K *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21
12985K *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21
12985K *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21
12985K *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21
2799H *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21
2799H *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21
2799H *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21
2799H *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21
2799H *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21
5783J *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21
5783J *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21
5783J *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21
5783J *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21
5783J *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21
11064H *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21
11064H *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21
11064H *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21
11064H *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21
11064H *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21
11968X *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 28
11968X *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 28
11968X *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 28
11968X *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 28
11968X *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 28
12057N *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21
12057N *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21
12057N *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21
12057N *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21
12057N *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21
12061T *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21
12061T *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21
12061T *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21
12061T *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21
12061T *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21
12070G *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 14
12070G *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 14
12070G *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 14
12070G *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 14
12070G *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 14
12988N *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21
12988N *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21
12988N *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21
12988N *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

12988N *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21
2802L *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21
2802L *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21
2802L *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21
2802L *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21
2802L *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21
5784K *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21
5784K *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21
5784K *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21
5784K *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21
5784K *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21
11062F *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21
11062F *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21
11062F *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21
11062F *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21
11062F *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21
11964Q *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 28
11964Q *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 28
11964Q *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 28
11964Q *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 28
11964Q *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 28
12012F *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 14
12012F *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 14
12012F *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 14
12012F *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 14
12012F *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 14
12026Y *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21
12026Y *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21
12026Y *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21
12026Y *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21
12026Y *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21
12062W *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21
12062W *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21
12062W *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21
12062W *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21
12062W *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21
12991R *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21
12991R *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21
12991R *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21
12991R *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21
12991R *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21
5785L *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21
5785L *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21
5785L *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

5785L *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

5785L *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

11041D *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

11041D *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

11041D *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

11041D *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

11041D *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12019N *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 14

12019N *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 14

12019N *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 14

12019N *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 14

12019N *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 14

12036L *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12036L *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12036L *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12036L *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12036L *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12059Q *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12059Q *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12059Q *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12059Q *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12059Q *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12979D *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12979D *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12979D *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12979D *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12979D *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

5786M *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

5786M *Lenalide, JU* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

5786M *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

5786M *Lenalidomide Sandoz, SZ* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

5786M *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

Addition – Note

11029L **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

11967W **LENALIDOMIDE**, lenalidomide 5 mg capsule, 28 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12034J **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12035K **LENALIDOMIDE**, lenalidomide 5 mg capsule, 14 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12039P **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12985K **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

2799H **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

5783J **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

11064H **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

11968X **LENALIDOMIDE**, lenalidomide 10 mg capsule, 28 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12057N **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12061T **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12070G **LENALIDOMIDE**, lenalidomide 10 mg capsule, 14 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12988N **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

2802L **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

5784K **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

11062F **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

11964Q **LENALIDOMIDE**, lenalidomide 15 mg capsule, 28 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12012F **LENALIDOMIDE**, lenalidomide 15 mg capsule, 14 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12026Y **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12062W **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12991R **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

5785L **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

11041D **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12019N **LENALIDOMIDE**, lenalidomide 25 mg capsule, 14 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12036L **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12059Q **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12979D **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

5786M **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

Alterations

Alteration – Restriction

11029L **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

11967W **LENALIDOMIDE**, lenalidomide 5 mg capsule, 28 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12034J **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12035K **LENALIDOMIDE**, lenalidomide 5 mg capsule, 14 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12039P **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12985K **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

2799H **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

5783J **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

11064H **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

11968X **LENALIDOMIDE**, lenalidomide 10 mg capsule, 28 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12057N **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12061T **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12070G **LENALIDOMIDE**, lenalidomide 10 mg capsule, 14 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12988N **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

2802L **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

5784K **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

11062F **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

11964Q **LENALIDOMIDE**, lenalidomide 15 mg capsule, 28 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12012F **LENALIDOMIDE**, lenalidomide 15 mg capsule, 14 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12026Y **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12062W **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12991R **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

5785L **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

11041D **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12019N **LENALIDOMIDE**, lenalidomide 25 mg capsule, 14 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12036L **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12059Q **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

12979D **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

5786M **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21 *(Cipla Lenalidomide, Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide-Teva, Revlimid)*

Highly Specialised Drugs Program (Community Access)

Additions

Addition – Brand

11732L *Tenofovir Disoproxil Emtricitabine Efavirenz Viatris 300/200/600, AL* – **TENOFOVIR DISOPROXIL + EMTRICITABINE + EFAVIRENZ**, tenofovir disoproxil maleate 300 mg + emtricitabine 200 mg + efavirenz 600 mg tablet, 30

Addition – Equivalence Indicator

11732L *Tenofovir Disoproxil/Emtricitabine/Efavirenz Mylan 300/200/600, AF* – **TENOFOVIR DISOPROXIL + EMTRICITABINE + EFAVIRENZ**, tenofovir disoproxil maleate 300 mg + emtricitabine 200 mg + efavirenz 600 mg tablet, 30

Growth Hormone Program

Advance Notices

1 March 2023

Deletion – Brand

10429X *Humatrope, LY* – **SOMATROPIN**, somatropin 6 mg injection [1 cartridge] (&) inert substance diluent [3.17 mL syringe], 1 pack

10461N *Humatrope, LY* – **SOMATROPIN**, somatropin 12 mg injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack

10476J *Humatrope, LY* – **SOMATROPIN**, somatropin 24 mg injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack

10482Q *Humatrope, LY* – **SOMATROPIN**, somatropin 6 mg injection [1 cartridge] (&) inert substance diluent [3.17 mL syringe], 1 pack

10487Y *Humatrope, LY* – **SOMATROPIN**, somatropin 12 mg injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack

10502R *Humatrope, LY* – **SOMATROPIN**, somatropin 24 mg injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack

6169Q *Humatrope, LY* – **SOMATROPIN**, somatropin 6 mg injection [1 cartridge] (&) inert substance diluent [3.17 mL syringe], 1 pack

6170R *Humatrope, LY* – **SOMATROPIN**, somatropin 12 mg injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack

6345Y *Humatrope, LY* – **SOMATROPIN**, somatropin 24 mg injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack

Repatriation Pharmaceutical Benefits

Advance Notices

1 March 2023

Deletion – Brand

4179Y *Blooms the Chemist Clopidogrel, IB* – **CLOPIDOGREL**, clopidogrel 75 mg tablet, 28

General Pharmaceutical Benefits

▪ BECLOMETASONE + FORMOTEROL (EFORMOTEROL)

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

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

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

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

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

Note This product is not PBS-subsidised for use as 'maintenance and reliever' therapy.

Note This product is not PBS-subsidised for use as 'anti-inflammatory reliever' therapy for mild asthma.

Authority required (STREAMLINED)

11057

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:

- Patient must be aged 18 years or older.

beclometasone dipropionate 200 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation inhalation, 120 actuations

13205B (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	56.54	30.00	Fostair 200/6 [EU]

▪ METHYLPHENIDATE

Note Where an increase in maximum quantity is sought, under no circumstances will a quantity beyond 2 times the listed quantity be approved.

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

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

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

Authority required

Attention deficit hyperactivity disorder

Treatment must be in accordance with the law of the relevant State or Territory.

methylphenidate hydrochloride 10 mg tablet, 100

8839F (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	26.12	27.43	[a] Artige [NM]
		[B]3.76	29.88	27.43	[a] Ritalin 10 [NV]

▪ METHYLPHENIDATE

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 In accordance with the Therapeutic Goods Administration (TGA)-approved Product Information, this PBS listing currently intends for once daily dosing only. Divided dosing is not intended (e.g. 18 mg in the mornings, 36 mg in the evenings). Where applications (either on the same day or on separate days) for multiple strengths are sought, repeats should only be sought for the listed target strength.

Note A patient may only receive PBS-subsided treatment with one form of long-acting methylphenidate at any one time.

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

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

Authority required

Attention deficit hyperactivity disorder

Population criteria:

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

Clinical criteria:

- Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events, **AND**
- Patient must require continuous coverage over 12 hours, **AND**
- The treatment must not exceed a maximum daily dose of 72 mg with this drug.

methylphenidate hydrochloride 36 mg modified release tablet, 30

2388Q NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	62.94	30.00	[a] Concerta [JC]	[a] METHYLPHENIDATE-TEVA XR [TB]
					[a] Methylphenidate XR ARX [XT]	

▪ METHYLPHENIDATE

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 In accordance with the Therapeutic Goods Administration (TGA)-approved Product Information, this PBS listing currently intends for once daily dosing only. Divided dosing is not intended (e.g. 18 mg in the mornings, 36 mg in the evenings). Where applications (either on the same day or on separate days) for multiple strengths are sought, repeats should only be sought for the listed target strength.

Note A patient may only receive PBS-subsided treatment with one form of long-acting methylphenidate at any one time.

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

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

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

Authority required

Attention deficit hyperactivity disorder

Population criteria:

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

Clinical criteria:

- Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events, **AND**
- Patient must require continuous coverage over 12 hours, **AND**
- The treatment must not exceed a maximum daily dose of 72 mg with this drug.

methylphenidate hydrochloride 18 mg modified release tablet, 30

2387P NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	54.67	30.00	[a] Concerta [JC]	[a] METHYLPHENIDATE-TEVA XR [TB]
					[a] Methylphenidate XR ARX [XT]	

methylphenidate hydrochloride 27 mg modified release tablet, 30

2172H NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	58.81	30.00	[a] Concerta [JC]	[a] METHYLPHENIDATE-TEVA XR [TB]
					[a] Methylphenidate XR ARX [XT]	

methylphenidate hydrochloride 54 mg modified release tablet, 30

2432B NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	72.09	30.00	[a] Concerta [JC]	[a] METHYLPHENIDATE-TEVA XR [TB]
					[a] Methylphenidate XR ARX [XT]	

▪ METHYLPHENIDATE

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 In accordance with the Therapeutic Goods Administration (TGA)-approved Product Information, this PBS listing currently intends for once daily dosing only. Divided dosing is not intended (e.g. 20 mg in the mornings, 30 mg in the evenings). Where applications (either on the same day or on separate days) for multiple strengths are sought, repeats should only be sought for the listed target strength.

Note A patient may only receive PBS-subsided treatment with one form of long-acting methylphenidate at any one time.

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

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

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

Authority required

Attention deficit hyperactivity disorder

Population criteria:

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

Clinical criteria:

- Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events, **AND**
- Patient must require continuous coverage over 8 hours, **AND**
- The treatment must not exceed a maximum daily dose of 80 mg with this drug.

methylphenidate hydrochloride 40 mg modified release capsule, 30

2283E (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	57.91	30.00	Ritalin LA [NV]

▪ METHYLPHENIDATE

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 In accordance with the Therapeutic Goods Administration (TGA)-approved Product Information, this PBS listing currently intends for once daily dosing only. Divided dosing is not intended (e.g. 20 mg in the mornings, 30 mg in the evenings). Where applications (either on the same day or on separate days) for multiple strengths are sought, repeats should only be sought for the listed target strength.

Note A patient may only receive PBS-subsided treatment with one form of long-acting methylphenidate at any one time.

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

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

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

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

Authority required

Attention deficit hyperactivity disorder

Population criteria:

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

Clinical criteria:

- Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events, **AND**
- Patient must require continuous coverage over 8 hours, **AND**
- The treatment must not exceed a maximum daily dose of 80 mg with this drug.

methylphenidate hydrochloride 60 mg modified release capsule, 30

12116Q (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	71.83	30.00	Ritalin LA [NV]

methylphenidate hydrochloride 10 mg modified release capsule, 30

3440C (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	38.65	30.00	Ritalin LA [NV]

methylphenidate hydrochloride 20 mg modified release capsule, 30

2276T (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	47.92	30.00	Ritalin LA [NV]

methylphenidate hydrochloride 30 mg modified release capsule, 30

2280B (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	55.38	30.00	Ritalin LA [NV]

▪ MOLNUPIRAVIR

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 This drug should be considered for use only if nirmatrelvir (&) ritonavir is contraindicated or otherwise unsuitable.

Authority required (STREAMLINED)

13759

SARS-CoV-2 infection

Clinical criteria:

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

- The treatment must be initiated as soon as possible after a diagnosis is confirmed where asymptomatic.

Population criteria:

- Patient must be at least 70 years of age.

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

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

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

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

Authority required (STREAMLINED)

13824

SARS-CoV-2 infection

Clinical criteria:

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

Population criteria:

- Patient must be at least 18 years of age.

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

1. Any primary or acquired immunodeficiency including:

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

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

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

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

a. Chemotherapy or whole body radiotherapy,

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

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

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

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

4. Others with very high-risk conditions including Down Syndrome, cerebral palsy, congenital heart disease, thalassemia, sickle cell disease and other haemoglobinopathies; OR

5. People with disability with multiple comorbidities and/or frailty.

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

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

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

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

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

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

Authority required (STREAMLINED)

13748

SARS-CoV-2 infection

Clinical criteria:

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

Population criteria:

- Patient must be each of: (i) identify as Aboriginal or Torres Strait Islander, (ii) at least 30 years of age, (iii) at high risk.

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

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

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

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

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

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

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

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

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

Authority required (STREAMLINED)

13765

SARS-CoV-2 infection

Clinical criteria:

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

Population criteria:

- Patient must be both: (i) at least 50 years of age, (ii) at high risk.

For the purpose of administering this restriction, high risk is defined as either a past COVID-19 infection episode resulting in hospitalisation, or the presence of at least two of the following conditions:

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

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

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

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

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

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

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

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

molnupiravir 200 mg capsule, 40

12910L

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	1101.39	30.00	Lagevrio [MK]

▪ NIRMATRELVIR (&) RITONAVIR

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

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

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

Authority required (STREAMLINED)

13759

SARS-CoV-2 infection

Clinical criteria:

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

Population criteria:

- Patient must be at least 70 years of age.

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

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

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

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

Authority required (STREAMLINED)

13821

SARS-CoV-2 infection

Clinical criteria:

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

Population criteria:

- Patient must be at least 18 years of age.

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

1. Any primary or acquired immunodeficiency including:

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

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

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

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

a. Chemotherapy or whole body radiotherapy,

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

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

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

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

4. Others with very high-risk conditions including Down Syndrome, cerebral palsy, congenital heart disease, thalassemia, sickle cell disease and other haemoglobinopathies; OR

5. People with disability with multiple comorbidities and/or frailty.

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

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

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

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

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

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

Authority required (STREAMLINED)

13748

SARS-CoV-2 infection

Clinical criteria:

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

Population criteria:

- Patient must be each of: (i) identify as Aboriginal or Torres Strait Islander, (ii) at least 30 years of age, (iii) at high risk.

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

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

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

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

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

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

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

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

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

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Authority required (STREAMLINED)

13765

SARS-CoV-2 infection

Clinical criteria:

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

Population criteria:

- Patient must be both: (i) at least 50 years of age, (ii) at high risk.

For the purpose of administering this restriction, high risk is defined as either a past COVID-19 infection episode resulting in hospitalisation, or the presence of at least two of the following conditions:

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

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

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

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

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

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

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

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

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

12996B NP

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

▪ OPICAPONE

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

Parkinson disease

Clinical criteria:

- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination, **AND**
- Patient must be experiencing fluctuations in motor function due to end-of-dose effect.

opicapone 50 mg capsule, 30

13206C NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	150.37	30.00	Ongentys [XY]

▪ ROMOSOZUMAB

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

Severe established osteoporosis

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be at very high risk of fracture, **AND**
- Patient must have a bone mineral density (BMD) T-score of -3.0 or less, **AND**
- Patient must have had 2 or more fractures due to minimal trauma, **AND**
- Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must not exceed a lifetime maximum of 12 months therapy, **AND**
- Patient must not have received treatment with PBS-subsidised teriparatide; OR
- Patient must have developed intolerance to teriparatide of a severity necessitating permanent treatment withdrawal within the first 6 months of therapy.

Treatment criteria:

- Must be treated by a consultant physician.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient's medical record at the time treatment with this drug is initiated.

If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy. Details must be documented in the patient's medical record at the time treatment with this drug is initiated.

Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months and zoledronic acid 5 mg per annum.

Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be provided at the time of application.

Authority required

Severe established osteoporosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a lifetime maximum of 12 months therapy.

Treatment criteria:

- Must be treated by a medical practitioner identifying as either: (i) a consultant physician, (ii) a general practitioner.

romosozumab 105 mg/1.17 mL injection, 2 x 1.17 mL syringes

12301K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	404.81	30.00	Evenity [AN]

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.

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

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 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]	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [CJ]

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]	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [CJ]

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]	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [CJ]

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]	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.

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

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 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]	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [CJ]

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]	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [CJ]

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]	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [CJ]

lenalidomide 25 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
12068E	1	3	..	2445.03	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.

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

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 5 mg capsule, 21

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

lenalidomide 10 mg capsule, 21

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

lenalidomide 15 mg capsule, 21

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

lenalidomide 25 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
12993W	1	2	..	2445.03	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.

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

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 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]	Lenalide [JU] Lenalidomide Sandoz [SZ]

					Lenalidomide-Teva [TB]	Revlimid [CJ]

lenalidomide 10 mg capsule, 21

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

Note Special Pricing Arrangements apply.

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 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]	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [CJ]

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]	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [CJ]

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]	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [CJ]

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]	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.

Note Special Pricing Arrangements apply.

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]	Lenalide [JU]
				Lenalidomide Dr.Reddy's [RI]	Lenalidomide Sandoz [SZ]

					Lenalidomide-Teva [TB]	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.

Note Special Pricing Arrangements apply.

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.

Note Special Pricing Arrangements apply.

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 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]	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [CJ]

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]	Lenalide [JU]

					Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB]	Lenalidomide Sandoz [SZ] Revlimid [CJ]

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]	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [CJ]

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]	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [CJ]

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.

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

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 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]	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [CJ]

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]	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [CJ]

lenalidomide 15 mg capsule, 21

12026Y	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]	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [CJ]

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]	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.

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

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 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]	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [CJ]

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]	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [CJ]

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]	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [CJ]

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]	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.

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

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 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]	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [CJ]

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]	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [CJ]

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]	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [CJ]

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]	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.

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

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 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]	Lenalide [JU] Lenalidomide Sandoz [SZ]

					Lenalidomide-Teva [TB]	Revlimid [CJ]

lenalidomide 10 mg capsule, 21

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

Note Special Pricing Arrangements apply.

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 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]	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [CJ]

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]	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [CJ]

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]	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [CJ]

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]	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.

Note Special Pricing Arrangements apply.

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

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

					Lenalidomide-Teva [TB]	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.

Note Special Pricing Arrangements apply.

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.

Note Special Pricing Arrangements apply.

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 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]	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [CJ]

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]	Lenalide [JU]

					Lenalidomide Dr.Reddy's [RI] Lenalidomide-Teva [TB]	Lenalidomide Sandoz [SZ] Revlimid [CJ]

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]	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [CJ]

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]	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [CJ]