Australian Government

Department of Health

PBS

Schedule of Pharmaceutical Benefits

Summary of Changes

Effective 1 February 2018

Fees, Patient Contributions and Safety Net Thresholds

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

Dispensing Fees:	Ready-prepared	$7.15
	Dangerous drug fee	$3.01
	Extemporaneously-prepared	$9.19
	Allowable additional patient charge*	$4.45
Additional Fees (for safety net prices):	Ready-prepared	$1.21
	Extemporaneously-prepared	$1.57
Patient Co-payments:	General	$39.50
	Concessional	$6.40
Safety Net Thresholds:	General	$1521.80
	Concessional	$384.00
Safety Net Card Issue Fee:		$9.91

* The allowable additional patient charge is a discretionary charge to general patients if a pharmaceutical item has a dispensed price for maximum quantity less than the general patient co-payment. The pharmacist may charge general patients the allowable additional fee but the fee cannot take the cost of the prescription above the general patient co-payment for the medicine. This fee does not count towards the Safety Net threshold.

Summary of Changes

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 February 2018. The Schedule is updated on the first day of each month and is available on the internet at www.pbs.gov.au.

Prescriber Bag

Additions

Addition – Item

11233F **NALOXONE**, naloxone hydrochloride 400 microgram/mL injection, 10 x 1 mL ampoules *(NARCAN)*

Deletions

Deletion – Item

3457Y **BENZATROPINE**, benzatropine mesilate 2 mg/2 mL injection, 5 x 2 mL ampoules *(Cogentin)*

Alterations

Alteration – Manufacturer Code

		From	*To*
3496B	*Salbutamol AN* – **SALBUTAMOL**, salbutamol 2.5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules	JU	ED
3497C	*Salbutamol AN* – **SALBUTAMOL**, salbutamol 5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules	JU	ED

General Pharmaceutical Benefits

Additions

Addition – Item

11227X **CEFUROXIME**, cefuroxime 250 mg tablet, 20 *(Zinnat)*

11228Y **CEFUROXIME**, cefuroxime 250 mg tablet, 20 *(Zinnat)*

11245W **GLYCOMACROPEPTIDE FORMULA WITH LONG CHAIN POLYUNSATURATED FATTY ACID AND DOCOSAHEXAENOIC ACID AND LOW PHENYLALANINE**, glycomacropeptide formula with long chain polyunsaturated fatty acid and docosahexaenoic acid and low phenylalanine powder for oral liquid, 30 x 27 g sachets *(PKU Sphere15)*

Addition – Brand

5541P *APO-Dorzolamide, TX* – **DORZOLAMIDE**, dorzolamide 2% eye drops, 5 mL

8488R *APO-Dorzolamide, TX* – **DORZOLAMIDE**, dorzolamide 2% eye drops, 5 mL

5542Q *APO-Dorzolamide/Timolol 20/5, TX* – **DORZOLAMIDE + TIMOLOL**, dorzolamide 2% + timolol 0.5% eye drops, 5 mL

8567X *APO-Dorzolamide/Timolol 20/5, TX* – **DORZOLAMIDE + TIMOLOL**, dorzolamide 2% + timolol 0.5% eye drops, 5 mL

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

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

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

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

Deletions

Deletion – Item

3038X **BENZATROPINE**, benzatropine mesilate 2 mg/2 mL injection, 5 x 2 mL ampoules *(Cogentin)*

5031T **BENZATROPINE**, benzatropine mesilate 2 mg/2 mL injection, 5 x 2 mL ampoules *(Cogentin)*

2878L **CROMOGLYCATE**, sodium cromoglycate 20 mg powder for inhalation, 100 capsules *(Intal Spincaps)*

1798P **CYPROHEPTADINE**, cyproheptadine hydrochloride 4 mg tablet, 100 *(Periactin)*

1821W **METRONIDAZOLE**, metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags *(Metronidazole Sandoz IV)*

1832K **METRONIDAZOLE**, metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags *(Metronidazole Sandoz IV)*

8282X **MILK POWDER LACTOSE FREE FORMULA**, milk powder lactose free formula powder for oral liquid, 900 g *(S-26 LF)*

8864M **PREPARED COAL TAR**, prepared coal tar 1% w/w lotion, 100 mL *(Exorex)*

2114G **TESTOSTERONE ENANTATE**, testosterone enantate 250 mg/mL injection, 3 x 1 mL syringes *(Primoteston Depot)*

10113G **TICARCILLIN + CLAVULANIC ACID**, ticarcillin 3 g + clavulanic acid 100 mg injection, 3.1 g vial *(Timentin)*

10125X **TICARCILLIN + CLAVULANIC ACID**, ticarcillin 3 g + clavulanic acid 100 mg injection, 3.1 g vial *(Timentin)*

Deletion – Brand

8188Y *GLYBOSAY, RW* – **ACARBOSE**, acarbose 50 mg tablet, 90

8189B *GLYBOSAY, RW* – **ACARBOSE**, acarbose 100 mg tablet, 90

8511Y *Alendronate AN, EA* – **ALENDRONATE**, alendronate 70 mg tablet, 4

5006L *AmoxyClav GH 875/125, GQ* – **AMOXICILLIN + CLAVULANIC ACID**, amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10

8254K *AmoxyClav GH 875/125, GQ* – **AMOXICILLIN + CLAVULANIC ACID**, amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10

8295N *Candesartan GH, GQ* – **CANDESARTAN**, candesartan cilexetil 4 mg tablet, 30

1169M *Ozcef, RA* – **CEFACLOR**, cefaclor 375 mg modified release tablet, 10

5045M *Ozcef, RA* – **CEFACLOR**, cefaclor 375 mg modified release tablet, 10

8019C *Procur 100, ED* – **CYPROTERONE**, cyproterone acetate 100 mg tablet, 50

2532G *Donepezil-GA, ED* – **DONEPEZIL**, donepezil hydrochloride 5 mg tablet, 28

8495D *Donepezil-GA, ED* – **DONEPEZIL**, donepezil hydrochloride 5 mg tablet, 28

2479L *Donepezil-GA, ED* – **DONEPEZIL**, donepezil hydrochloride 10 mg tablet, 28

8496E *Donepezil-GA, ED* – **DONEPEZIL**, donepezil hydrochloride 10 mg tablet, 28

9155W *Duloxetine GH, GQ* – **DULOXETINE**, duloxetine 30 mg enteric capsule, 28

9156X *Duloxetine GH, GQ* – **DULOXETINE**, duloxetine 60 mg enteric capsule, 28

2487X *Pepzan, ED* – **FAMOTIDINE**, famotidine 20 mg tablet, 60

2488Y *Pepzan, ED* – **FAMOTIDINE**, famotidine 40 mg tablet, 30

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

8405J *Irbesartan HCTZ AN 300/12.5, EA* – **IRBESARTAN + HYDROCHLOROTHIAZIDE**, irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet, 30

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

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

2430X *Metformin-GA, ED* – **METFORMIN**, metformin hydrochloride 500 mg tablet, 100

1801T *Metformin-GA, ED* – **METFORMIN**, metformin hydrochloride 850 mg tablet, 60

8607B *Metformin-GA, ED* – **METFORMIN**, metformin hydrochloride 1 g tablet, 90

9151P *Pramipexole GH, GQ* – **PRAMIPEXOLE**, pramipexole dihydrochloride monohydrate 125 microgram tablet, 30

9152Q *Pramipexole GH, GQ* – **PRAMIPEXOLE**, pramipexole dihydrochloride monohydrate 250 microgram tablet, 100

9153R *Pramipexole GH, GQ* – **PRAMIPEXOLE**, pramipexole dihydrochloride monohydrate 1 mg tablet, 100

1316G *Ramipril Winthrop, WA* – **RAMIPRIL**, ramipril 10 mg tablet, 30

2011W *Simvastatin-GA 10, ED* – **SIMVASTATIN**, simvastatin 10 mg tablet, 30

9242K *Simvastatin-GA 10, ED* – **SIMVASTATIN**, simvastatin 10 mg tablet, 30

2012X *Simvastatin-GA 20, ED* – **SIMVASTATIN**, simvastatin 20 mg tablet, 30

9243L *Simvastatin-GA 20, ED* – **SIMVASTATIN**, simvastatin 20 mg tablet, 30

8173E *Simvastatin-GA 40, ED* – **SIMVASTATIN**, simvastatin 40 mg tablet, 30

9244M *Simvastatin-GA 40, ED* – **SIMVASTATIN**, simvastatin 40 mg tablet, 30

8313M *Simvastatin-GA 80, ED* – **SIMVASTATIN**, simvastatin 80 mg tablet, 30

9245N *Simvastatin-GA 80, ED* – **SIMVASTATIN**, simvastatin 80 mg tablet, 30

2285G *Sebifin 250, RA* – **TERBINAFINE**, terbinafine 250 mg tablet, 42

2804N *Sebifin 250, RA* – **TERBINAFINE**, terbinafine 250 mg tablet, 42

8523N *GA Tramadol SR 100mg, ED* – **TRAMADOL**, tramadol hydrochloride 100 mg modified release tablet, 20

8525Q *GA Tramadol SR 200mg, ED* – **TRAMADOL**, tramadol hydrochloride 200 mg modified release tablet, 20

2269K *Vycin IV, EA* – **VANCOMYCIN**, vancomycin 1 g injection, 1 vial

2270L *Vycin IV, EA* – **VANCOMYCIN**, vancomycin 1 g injection, 1 vial

5083M *Vycin IV, EA* – **VANCOMYCIN**, vancomycin 1 g injection, 1 vial

Deletion – Note

10703H **RITUXIMAB**, rituximab 1.4 g/11.7 mL injection, 11.7 mL vial *(Mabthera SC)*

10719E **RITUXIMAB**, rituximab 1.4 g/11.7 mL injection, 11.7 mL vial *(Mabthera SC)*

Deletion – Restriction

10958R **EVOLOCUMAB**, evolocumab 140 mg/mL injection, 1 mL injection device *(Repatha)*

Alterations

Alteration – Item Description

From
1976B **ICATIBANT**, ICATIBANT Injection 30 mg (as acetate) in 3 mL single use pre-filled syringe, 1 *(Firazyr)*
To
1976B **ICATIBANT**, icatibant 30 mg/3 mL injection, 3 mL syringe *(Firazyr)*

From
2096H **SULFASALAZINE**, SULFASALAZINE Tablet 500 mg (enteric coated), 100 *(Pyralin EN, Salazopyrin-EN)*
To
2096H **SULFASALAZINE**, sulfasalazine 500 mg enteric tablet, 100 *(Pyralin EN, Salazopyrin-EN)*

From
9209Q **SULFASALAZINE**, SULFASALAZINE Tablet 500 mg (enteric coated), 100 *(Pyralin EN, Salazopyrin-EN)*
To
9209Q **SULFASALAZINE**, sulfasalazine 500 mg enteric tablet, 100 *(Pyralin EN, Salazopyrin-EN)*

From
9411H **TERIPARATIDE**, teriparatide 20 microgram injection, 2.4 mL cartridge *(Forteo)*
To
9411H **TERIPARATIDE**, teriparatide 20 microgram/dose injection, 28 doses *(Forteo)*

Alteration – Brand Name

From
11071Q *PKU Sphere, VF* – **GLYCOMACROPEPTIDE FORMULA WITH LONG CHAIN POLYUNSATURATED FATTY ACID AND DOCOSAHEXAENOIC ACID AND LOW PHENYLALANINE**, glycomacropeptide formula with long chain polyunsaturated fatty acid and docosahexaenoic acid and low phenylalanine powder for oral liquid, 30 x 35 g sachets
To
11071Q *PKU Sphere20, VF* – **GLYCOMACROPEPTIDE FORMULA WITH LONG CHAIN POLYUNSATURATED FATTY ACID AND DOCOSAHEXAENOIC ACID AND LOW PHENYLALANINE**, glycomacropeptide formula with long chain polyunsaturated fatty acid and docosahexaenoic acid and low phenylalanine powder for oral liquid, 30 x 35 g sachets

Alteration – Restriction

11170X **IDELALISIB**, idelalisib 100 mg tablet, 60 *(Zydelig)*

11162L **IDELALISIB**, idelalisib 150 mg tablet, 60 *(Zydelig)*

10703H **RITUXIMAB**, rituximab 1.4 g/11.7 mL injection, 11.7 mL vial *(Mabthera SC)*

10719E **RITUXIMAB**, rituximab 1.4 g/11.7 mL injection, 11.7 mL vial *(Mabthera SC)*

Alteration – Manufacturer Code

		From	*To*
2000G	*Salbutamol AN* – **SALBUTAMOL**, salbutamol 2.5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules	JU	ED
2001H	*Salbutamol AN* – **SALBUTAMOL**, salbutamol 5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules	JU	ED

Alteration – Number of Repeats

		From	*To*
10703H	**RITUXIMAB**, rituximab 1.4 g/11.7 mL injection, 11.7 mL vial *(Mabthera SC)*	2	6
10719E	**RITUXIMAB**, rituximab 1.4 g/11.7 mL injection, 11.7 mL vial *(Mabthera SC)*	6	5

Advance Notices

1 March 2018

Deletion – Brand

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 May 2018

Deletion – Brand

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

Highly Specialised Drugs Program (Private Hospital)

Additions

Addition – Item

11237K **OCRELIZUMAB**, ocrelizumab 300 mg/10 mL injection, 10 mL vial *(Ocrevus)*

Alterations

Alteration – Restriction

11036W **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 *(Revlimid)*

9642L **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 *(Revlimid)*

11063G **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 *(Revlimid)*

9643M **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 *(Revlimid)*

11042E **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21 *(Revlimid)*

9644N **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21 *(Revlimid)*

11055W **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21 *(Revlimid)*

9645P **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21 *(Revlimid)*

10417G **POMALIDOMIDE**, pomalidomide 3 mg capsule, 21 *(Pomalyst)*

10386P **POMALIDOMIDE**, pomalidomide 4 mg capsule, 21 *(Pomalyst)*

Alteration – Manufacturer Code

		From	*To*
6101D	*Clozaril 25* – **CLOZAPINE**, clozapine 25 mg tablet, 100	NV	GO
6102E	*Clozaril 100* – **CLOZAPINE**, clozapine 100 mg tablet, 100	NV	GO

Highly Specialised Drugs Program (Public Hospital)

Additions

Addition – Item

11242Q **OCRELIZUMAB**, ocrelizumab 300 mg/10 mL injection, 10 mL vial *(Ocrevus)*

Alterations

Alteration – Restriction

11029L **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 *(Revlimid)*

5783J **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 *(Revlimid)*

11064H **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 *(Revlimid)*

5784K **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 *(Revlimid)*

11062F **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21 *(Revlimid)*

5785L **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21 *(Revlimid)*

11041D **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21 *(Revlimid)*

5786M **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21 *(Revlimid)*

10406Q **POMALIDOMIDE**, pomalidomide 3 mg capsule, 21 *(Pomalyst)*

10387Q **POMALIDOMIDE**, pomalidomide 4 mg capsule, 21 *(Pomalyst)*

Alteration – Manufacturer Code

		From	*To*
5628F	*Clozaril 25* – **CLOZAPINE**, clozapine 25 mg tablet, 100	NV	GO
5629G	*Clozaril 100* – **CLOZAPINE**, clozapine 100 mg tablet, 100	NV	GO

Highly Specialised Drugs Program (Community Access)

Additions

Addition – Item

11246X **ABACAVIR + LAMIVUDINE**, abacavir 600 mg + lamivudine 300 mg tablet, 30 *(Abacavir/Lamivudine GH 600/300)*

11248B **RALTEGRAVIR**, raltegravir 600 mg tablet, 60 *(Isentress HD)*

Addition – Equivalence Indicator

10357D *Kivexa, VI* – **ABACAVIR + LAMIVUDINE**, abacavir 600 mg + lamivudine 300 mg tablet, 30

Addition – Note

10357D **ABACAVIR + LAMIVUDINE**, abacavir 600 mg + lamivudine 300 mg tablet, 30 *(Kivexa)*

Alterations

Alteration – Manufacturer Code

		From	*To*
10289M	*Clozaril 25* – **CLOZAPINE**, clozapine 25 mg tablet, 100	NV	GO
10358E	*Clozaril 100* – **CLOZAPINE**, clozapine 100 mg tablet, 100	NV	GO

Growth Hormone Program

Advance Notices

1 April 2018

Deletion – Brand

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

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

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

Repatriation Pharmaceutical Benefits

Deletions

Deletion – Item

10186D **PARACETAMOL + CODEINE**, paracetamol 500 mg + codeine phosphate hemihydrate 15 mg tablet, 20 *(Pharmacy Action Paracetamol Plus Codeine)*

Alterations

Alteration – Item Description

From
4408B **PINE TAR WITH TRIETHANOLAMINE LAURYL SULFATE**, PINE TAR with TRIETHANOLAMINE LAURYL SULFATE Solution 23 mg-60 mg per mL (2.3%-6%), 500 mL, 1 *(Pinetarsol)*

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

Alteration – Brand Name

From
4896Q *DuoDERM Paste H7930, CC* – **DRESSING HYDROCOLLOID CAVITY WOUND**, dressing hydrocolloid cavity wound paste, 30 g

To
4896Q *DuoDERM Paste 187930, CC* – **DRESSING HYDROCOLLOID CAVITY WOUND**, dressing hydrocolloid cavity wound paste, 30 g

From
4907G *DuoDERM Extra Thin H7955, CC* – **DRESSING HYDROCOLLOID SUPERFICIAL WOUND LIGHT EXUDATE**, dressing hydrocolloid superficial wound light exudate 10 cm x 10 cm dressing, 10

To
4907G *DuoDERM Extra Thin 187955, CC* – **DRESSING HYDROCOLLOID SUPERFICIAL WOUND LIGHT EXUDATE**, dressing hydrocolloid superficial wound light exudate 10 cm x 10 cm dressing, 10

From
4897R *DuoDERM CGF H7660, CC* – **DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE**, dressing hydrocolloid superficial wound moderate exudate 10 cm x 10 cm dressing, 5

To
4897R *DuoDERM CGF 187660, CC* – **DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE**, dressing hydrocolloid superficial wound moderate exudate 10 cm x 10 cm dressing, 5

From
4920Y *DuoDERM CGF H7662, CC* – **DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE**, dressing hydrocolloid superficial wound moderate exudate 20 cm x 20 cm dressing, 5

To
4920Y *DuoDERM CGF 187662, CC* – **DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE**, dressing hydrocolloid superficial wound moderate exudate 20 cm x 20 cm dressing, 5

From

4912M *DuoDERM Gel H7990, CC* – **DRESSING HYDROGEL AMORPHOUS**, dressing hydrogel amorphous gel, 10 x 15 g

To

4912M *DuoDERM Gel 187990, CC* – **DRESSING HYDROGEL AMORPHOUS**, dressing hydrogel amorphous gel, 10 x 15 g

Advance Notices

1 March 2018

Deletion – Brand

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

1 May 2018

Deletion – Brand

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

Prescriber Bag

▪ NALOXONE

naloxone hydrochloride 400 microgram/mL injection, 10 x 1 mL ampoules

11233F	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
NP	1	153.88	[a] NARCAN [PL]

General Pharmaceutical Benefits

▪ CEFUROXIME

cefuroxime 250 mg tablet, 20

11227X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	25.50	26.71	Zinnat [AS]

cefuroxime 250 mg tablet, 20

11228Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	1	..	..	25.50	26.71	Zinnat [AS]

▪ GLYCOMACROPEPTIDE FORMULA WITH LONG CHAIN POLYUNSATURATED FATTY ACID AND DOCOSAHEXAENOIC ACID AND LOW PHENYLALANINE

Restricted benefit

Phenylketonuria

glycomacropeptide formula with long chain polyunsaturated fatty acid and docosahexaenoic acid and low phenylalanine powder for oral liquid, 30 x 27 g sachets

11245W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	4	5	..	*1570.63	39.50	PKU Sphere15 [VF]

▪ IDELALISIB

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with rituximab for up to a maximum of 8 doses, followed by monotherapy, **AND**
- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- The condition must be CD20 positive, **AND**
- Patient must have a total cumulative illness rating scale (CIRS) score of greater than 6 (excluding CLL-induced illness or organ damage), **AND**
- Patient must be inappropriate for chemo-immunotherapy.

A patient can be considered inappropriate for chemo-immunotherapy when one or more of the following are experienced:

1. Severe neutropenia defined as absolute neutrophil count of less than or equal to 1.0 x 10^9/L; or
2. Severe thrombocytopenia defined as platelet count of less than or equal to 50 x 10^9/L; or
3. Evidence of one or more 17p chromosomal deletions demonstrated by fluorescence in situ hybridisation (FISH).

Full blood count results must be no more than 1 month old at the time of application.

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

a) A completed authority prescription form;

b) A completed CLL/SLL PBS Authority Application - Supporting information form; and

c) Pathology report indicating that the patient can be considered inappropriate for chemo-immunotherapy due to one or more of the following:

1) Recent severe neutropenia; or

2) Recent severe thrombocytopenia; or

3) Presence of 17p chromosomal deletion using fluorescence in situ hybridisation (FISH).

A Grandfathered patient who has previously received non-PBS subsidised treatment with this drug for this condition prior to 1 September 2017 must have met all the initial restriction criteria prior to initiating non-PBS subsidised treatment. A

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

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

Authority required

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Continuing treatment

Clinical criteria:

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

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

idelalisib 100 mg tablet, 60

11170X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	5367.27	39.50	Zydelig [GI]

idelalisib 150 mg tablet, 60

11162L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	5367.27	39.50	Zydelig [GI]

▪ RITUXIMAB

Authority required (STREAMLINED)

7400

Previously untreated or relapsed/refractory CD20 positive lymphoid cancer

Treatment Phase: Induction or re-induction therapy

Clinical criteria:

- The treatment must be for induction or re-induction for CD20 positive lymphoma; OR
- The treatment must be for induction or re-induction for CD20 positive chronic lymphocytic leukaemia; OR
- The treatment must be for induction or consolidation for CD20 positive acute lymphoblastic leukaemia, **AND**
- The treatment must be in combination with chemotherapy, **AND**
- Patient must not receive more than the number of cycles of treatment recommended by standard guidelines for the partner chemotherapy under this restriction.

An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab.

No more than 8 doses in total as per course of treatment will be allowed for lymphoma or chronic lymphocytic leukaemia.

No more than 12 doses in total as per course of treatment will be allowed for acute lymphoblastic leukaemia for induction course (including consolidation course).

rituximab 1.4 g/11.7 mL injection, 11.7 mL vial

10703H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	6	..	2799.22	39.50	Mabthera SC [RO]

▪ RITUXIMAB

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

Authority required (STREAMLINED)

7399

Previously untreated or Relapsed/refractory CD20 positive acute lymphoblastic leukaemia

Treatment Phase: Maintenance therapy

Clinical criteria:

- The treatment must be maintenance therapy, **AND**
- The treatment must be in combination with chemotherapy, **AND**
- Patient must be in complete remission, **AND**
- Patient must not receive more than 6 doses in total under this restriction.

rituximab 1.4 g/11.7 mL injection, 11.7 mL vial

10719E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	2799.22	39.50	Mabthera SC [RO]

Highly Specialised Drugs Program (Private Hospital)

▪ LENALIDOMIDE

Note Special Pricing Arrangements apply.

Authority required

Multiple myeloma

Treatment Phase: Initial PBS-subsidised treatment

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with 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, **AND**
- Patient must not be receiving concomitant PBS-subsidised bortezomib, thalidomide or its analogues.

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 of 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 in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; details of the basis of the diagnosis of progressive disease or failure to respond; and nomination of which disease activity parameters will be used to assess response; and

(3) a signed patient acknowledgment.

To enable confirmation of eligibility for treatment, current diagnostic reports 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; 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 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 provided.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Multiple myeloma

Treatment Phase: Continuing PBS-subsidised treatment

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 be in combination with dexamethasone, **AND**
- Patient must not be receiving concomitant PBS-subsidised bortezomib, thalidomide or its analogues.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

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

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

lenalidomide 15 mg capsule, 21

9644N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	6299.68	Revlimid [CJ]

lenalidomide 5 mg capsule, 21

9642L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	5169.91	Revlimid [CJ]

lenalidomide 25 mg capsule, 21

9645P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	6634.64	Revlimid [CJ]

lenalidomide 10 mg capsule, 21

9643M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	5408.31	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 Special Pricing Arrangements apply.

Authority required

Multiple myeloma

Treatment Phase: Initial treatment

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**
- Patient must not be receiving concomitant PBS-subsidised bortezomib, thalidomide or its analogues, **AND**
- The treatment must be in combination with dexamethasone.

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

(1) a completed authority prescription form; and

(2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, and ineligibility for prior stem cell transplant; and nomination of which disease activity parameters will be used to assess response; and

(3) a signed patient acknowledgement.

To enable confirmation of eligibility for treatment, current diagnostic reports 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; 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 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 provided.

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

Note Patient must be registered in the i-access risk management program.

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been authorised with a PBS prescription with this drug for the condition, **AND**
- Patient must not have demonstrated progressive disease, **AND**
- Patient must not be receiving concomitant PBS-subsidised bortezomib, thalidomide or its analogues, **AND**
- The treatment must be in combination with 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 of 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.

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

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

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

lenalidomide 15 mg capsule, 21

11042E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	6299.68	Revlimid [CJ]

lenalidomide 5 mg capsule, 21

11036W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	5169.91	Revlimid [CJ]

lenalidomide 25 mg capsule, 21

11055W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	6634.64	Revlimid [CJ]

lenalidomide 10 mg capsule, 21

11063G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	5408.31	Revlimid [CJ]

▪ OCRELIZUMAB

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

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, **AND**
- Patient must be ambulatory (without assistance or support).

Treatment criteria:

- Must be treated by a neurologist.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

Authority required

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

Treatment criteria:

- Must be treated by a neurologist.

ocrelizumab 300 mg/10 mL injection, 10 mL vial

11237K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	..	..	*17580.15	Ocrevus [RO]

▪ POMALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

Note Special Pricing Arrangements apply.

Authority required

Multiple myeloma

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be in combination with dexamethasone, **AND**
- Patient must have undergone or be ineligible for a primary stem cell transplant, **AND**
- Patient must have experienced treatment failure with lenalidomide, **AND**
- Patient must have experienced treatment failure with bortezomib, **AND**
- Patient must not be receiving concomitant PBS-subsidised bortezomib, thalidomide or its analogues.

Bortezomib treatment failure is the absence of achieving at least a partial response or as progressive disease during treatment or within 6 months of discontinuing treatment with bortezomib. Lenalidomide treatment failure is progressive disease during treatment or within 6 months of discontinuing treatment with lenalidomide.

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 of 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 in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Multiple Myeloma pomalidomide Authority Application Supporting Information form; and

(3) reports demonstrating the patient has failed treatment with lenalidomide and bortezomib.

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

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

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must not have progressive disease, **AND**
- The treatment must be in combination with dexamethasone, **AND**
- Patient must not be receiving concomitant PBS-subsidised bortezomib, thalidomide or its analogues.

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 of 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).

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

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

Note Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

pomalidomide 3 mg capsule, 21

10417G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	10547.15	Pomalyst [CJ]

pomalidomide 4 mg capsule, 21

10386P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	10547.15	Pomalyst [CJ]

Highly Specialised Drugs Program (Public Hospital)

▪ LENALIDOMIDE

Note Special Pricing Arrangements apply.

Authority required

Multiple myeloma

Treatment Phase: Initial PBS-subsidised treatment

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with 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, **AND**
- Patient must not be receiving concomitant PBS-subsidised bortezomib, thalidomide or its analogues.

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 of 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 in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; details of the basis of the diagnosis of progressive disease or failure to respond; and nomination of which disease activity parameters will be used to assess response; and

(3) a signed patient acknowledgment.

To enable confirmation of eligibility for treatment, current diagnostic reports 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; 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 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 provided.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Multiple myeloma

Treatment Phase: Continuing PBS-subsidised treatment

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 be in combination with dexamethasone, **AND**
- Patient must not be receiving concomitant PBS-subsidised bortezomib, thalidomide or its analogues.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

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

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

lenalidomide 15 mg capsule, 21

5785L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	6252.53	Revlimid [CJ]

lenalidomide 5 mg capsule, 21

5783J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	5122.76	Revlimid [CJ]

lenalidomide 25 mg capsule, 21

5786M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	6587.49	Revlimid [CJ]

lenalidomide 10 mg capsule, 21

5784K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	5361.16	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 Special Pricing Arrangements apply.

Authority required

Multiple myeloma

Treatment Phase: Initial treatment

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**
- Patient must not be receiving concomitant PBS-subsidised bortezomib, thalidomide or its analogues, **AND**
- The treatment must be in combination with dexamethasone.

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

(1) a completed authority prescription form; and

(2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, and ineligibility for prior stem cell transplant; and nomination of which disease activity parameters will be used to assess response; and

(3) a signed patient acknowledgement.

To enable confirmation of eligibility for treatment, current diagnostic reports 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; 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 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 provided.

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

Note Patient must be registered in the i-access risk management program.

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been authorised with a PBS prescription with this drug for the condition, **AND**
- Patient must not have demonstrated progressive disease, **AND**
- Patient must not be receiving concomitant PBS-subsidised bortezomib, thalidomide or its analogues, **AND**
- The treatment must be in combination with 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 of 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.

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

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

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

lenalidomide 15 mg capsule, 21

11062F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	6252.53	Revlimid [CJ]

lenalidomide 5 mg capsule, 21

11029L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	5122.76	Revlimid [CJ]

lenalidomide 25 mg capsule, 21

11041D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	6587.49	Revlimid [CJ]

lenalidomide 10 mg capsule, 21

11064H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	5361.16	Revlimid [CJ]

▪ OCRELIZUMAB

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

7411

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, **AND**
- Patient must be ambulatory (without assistance or support).

Treatment criteria:

- Must be treated by a neurologist.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

Authority required (STREAMLINED)

7386

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

Treatment criteria:

- Must be treated by a neurologist.

ocrelizumab 300 mg/10 mL injection, 10 mL vial

11242Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	..	..	*17533.00	Ocrevus [RO]

▪ POMALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

Note Special Pricing Arrangements apply.

Authority required

Multiple myeloma

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be in combination with dexamethasone, **AND**
- Patient must have undergone or be ineligible for a primary stem cell transplant, **AND**
- Patient must have experienced treatment failure with lenalidomide, **AND**
- Patient must have experienced treatment failure with bortezomib, **AND**
- Patient must not be receiving concomitant PBS-subsidised bortezomib, thalidomide or its analogues.

Bortezomib treatment failure is the absence of achieving at least a partial response or as progressive disease during treatment or within 6 months of discontinuing treatment with bortezomib. Lenalidomide treatment failure is progressive disease during treatment or within 6 months of discontinuing treatment with lenalidomide.

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 of 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 in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Multiple Myeloma pomalidomide Authority Application Supporting Information form; and

(3) reports demonstrating the patient has failed treatment with lenalidomide and bortezomib.

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

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

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must not have progressive disease, **AND**
- The treatment must be in combination with dexamethasone, **AND**
- Patient must not be receiving concomitant PBS-subsidised bortezomib, thalidomide or its analogues.

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 of 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).

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

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

Note Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

pomalidomide 3 mg capsule, 21

10406Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	10500.00	Pomalyst [CJ]

pomalidomide 4 mg capsule, 21

10387Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	10500.00	Pomalyst [CJ]

Highly Specialised Drugs Program (Community Access)

▪ ABACAVIR + LAMIVUDINE

Note Pharmaceutical benefits that have the form tablet containing abacavir 600 mg (as sulfate) with lamivudine 300 mg and pharmaceutical benefits that have the form tablet containing abacavir 600 mg (as hydrochloride) with lamivudine 300 mg are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

4527

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

Population criteria:

- Patient must be aged 12 years or older, **AND**
- Patient must weigh 40 kg or more.

Authority required (STREAMLINED)

4528

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

Population criteria:

- Patient must be aged 12 years or older, **AND**
- Patient must weigh 40 kg or more.

abacavir 600 mg + lamivudine 300 mg tablet, 30

11246X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	..	*611.49	39.50	[a] Abacavir/Lamivudine GH 600/300 [GQ]

abacavir 600 mg + lamivudine 300 mg tablet, 30

10357D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	..	*611.49	39.50	[a] Kivexa [VI]

▪ RALTEGRAVIR

Authority required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

raltegravir 600 mg tablet, 60

11248B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	..	*1311.69	39.50	Isentress HD [MK]