



**Australian Government**

**Department of Health**



# Schedule of Pharmaceutical Benefits

Summary of Changes

**Effective 1 March 2016**



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# Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 March 2016 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	\$6.93
	Dangerous drug fee	\$2.91
	Extemporaneously-prepared	\$8.97
	Allowable additional patient charge*	\$4.33
Additional Fees (for safety net prices):	Ready-prepared	\$1.17
	Extemporaneously-prepared	\$1.53
Patient Co-payments:	General	\$38.30
	Concessional	\$6.20
Safety Net Thresholds:	General	\$1475.70
	Concessional	\$372.00
Safety Net Card Issue Fee:		\$9.61

\* 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.

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# Summary of Changes

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 March 2016. The Schedule is updated on the first day of each month and is available on the internet at [www.pbs.gov.au](http://www.pbs.gov.au).

The General Statement for Drugs for the Treatment of Hepatitis C can be found on page 46.

## General Pharmaceutical Benefits Additions

### Addition – Item

- 10632N **AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERAL AND TRACE ELEMENTS WITHOUT PHENYLALANINE**, amino acid formula with fat, carbohydrate, vitamins, mineral and trace elements without phenylalanine oral liquid: powder for, 30 x 34 g bottles (*PKU Easy Shake & Go*)
- 10645G **DACLATASVIR**, daclatasvir 30 mg tablet, 28 (*Daklinza*)
- 10671P **DACLATASVIR**, daclatasvir 30 mg tablet, 28 (*Daklinza*)
- 10642D **DACLATASVIR**, daclatasvir 60 mg tablet, 28 (*Daklinza*)
- 10659B **DACLATASVIR**, daclatasvir 60 mg tablet, 28 (*Daklinza*)
- 10627H **EMPAGLIFLOZIN + METFORMIN**, empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60 (*Jardiamet 5 mg/1000 mg*)
- 10649L **EMPAGLIFLOZIN + METFORMIN**, empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60 (*Jardiamet 5 mg/1000 mg*)
- 10626G **EMPAGLIFLOZIN + METFORMIN**, empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60 (*Jardiamet 5 mg/500 mg*)
- 10650M **EMPAGLIFLOZIN + METFORMIN**, empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60 (*Jardiamet 5 mg/500 mg*)
- 10640B **EMPAGLIFLOZIN + METFORMIN**, empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60 (*Jardiamet 12.5 mg/1000 mg*)
- 10677Y **EMPAGLIFLOZIN + METFORMIN**, empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60 (*Jardiamet 12.5 mg/1000 mg*)
- 10633P **EMPAGLIFLOZIN + METFORMIN**, empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60 (*Jardiamet 12.5 mg/500 mg*)
- 10639Y **EMPAGLIFLOZIN + METFORMIN**, empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60 (*Jardiamet 12.5 mg/500 mg*)
- 10652P **GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS**, glycomacropeptide and essential amino acids with vitamins and minerals oral liquid: powder for, 30 x 49 g sachets (*Camino Pro Bettermilk*)
- 10628J **LEDIPASVIR + SOFOSBUVIR**, ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28 (*Harvoni*)
- 10668L **LEDIPASVIR + SOFOSBUVIR**, ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28 (*Harvoni*)
- 10670N **LEDIPASVIR + SOFOSBUVIR**, ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28 (*Harvoni*)
- 10656W **LEUPRORELIN**, leuprorelin acetate 45 mg injection: modified release [1 syringe] (&) inert substance diluent [1 syringe], 1 pack (*Lucrin Depot 6-Month*)
- 10636T **PEGINTERFERON ALFA-2A (&) RIBAVIRIN**, peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [140 tablets], 1 pack (*Pegasys RBV*)

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10634Q	<b>PEGINTERFERON ALFA-2A (&amp;) RIBAVIRIN</b> , peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [168 tablets], 1 pack ( <i>Pegasys RBV</i> )
10658Y	<b>PROTEIN FORMULA WITH AMINO ACIDS, CARBOHYDRATES, VITAMINS AND MINERALS WITHOUT PHENYLALANINE, AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID</b> , protein formula with amino acids, carbohydrates, vitamins and minerals without phenylalanine, and supplemented with docosahexaenoic acid oral liquid, 30 x 130 mL pouches ( <i>PKU Easy</i> )
10647J	<b>RIBAVIRIN</b> , ribavirin 400 mg tablet, 28 ( <i>Ibavyr</i> )
10673R	<b>RIBAVIRIN</b> , ribavirin 400 mg tablet, 28 ( <i>Ibavyr</i> )
10665H	<b>RIBAVIRIN</b> , ribavirin 600 mg tablet, 28 ( <i>Ibavyr</i> )
10666J	<b>RIBAVIRIN</b> , ribavirin 600 mg tablet, 28 ( <i>Ibavyr</i> )
10624E	<b>SOFOSBUVIR</b> , sofosbuvir 400 mg tablet, 28 ( <i>Sovaldi</i> )
10657X	<b>SOFOSBUVIR</b> , sofosbuvir 400 mg tablet, 28 ( <i>Sovaldi</i> )

**Addition – Brand**

8114C	<i>APO-Cabergoline, TX</i> – <b>CABERGOLINE</b> , cabergoline 500 microgram tablet, 8
8115D	<i>APO-Cabergoline, TX</i> – <b>CABERGOLINE</b> , cabergoline 500 microgram tablet, 2
9155W	<i>Duloxetine Sandoz, HX</i> – <b>DULOXETINE</b> , duloxetine 30 mg capsule: enteric, 28
9156X	<i>Duloxetine Sandoz, HX</i> – <b>DULOXETINE</b> , duloxetine 60 mg capsule: enteric, 28
5449T	<i>Leflunomide APOTEX, GX</i> – <b>LEFLUNOMIDE</b> , leflunomide 10 mg tablet, 30
8374R	<i>Leflunomide APOTEX, GX</i> – <b>LEFLUNOMIDE</b> , leflunomide 10 mg tablet, 30
5450W	<i>Leflunomide APOTEX, GX</i> – <b>LEFLUNOMIDE</b> , leflunomide 20 mg tablet, 30
8375T	<i>Leflunomide APOTEX, GX</i> – <b>LEFLUNOMIDE</b> , leflunomide 20 mg tablet, 30
8655M	<i>Levetiracetam GH, GQ</i> – <b>LEVETIRACETAM</b> , levetiracetam 500 mg tablet, 60
8170B	<i>Olanzacor 2.5, CR</i> – <b>OLANZAPINE</b> , olanzapine 2.5 mg tablet, 28
8185T	<i>Olanzacor 5, CR</i> – <b>OLANZAPINE</b> , olanzapine 5 mg tablet, 28
8186W	<i>Olanzacor 7.5, CR</i> – <b>OLANZAPINE</b> , olanzapine 7.5 mg tablet, 28
8187X	<i>Olanzacor 10, CR</i> – <b>OLANZAPINE</b> , olanzapine 10 mg tablet, 28
1166J	<i>Amdipharm Mercury (Australia) Pty Limited, GH</i> – <b>PHENOXYBENZAMINE</b> , phenoxybenzamine hydrochloride 10 mg capsule, 30
3418X	<i>APO-Pramipexole ER, TX</i> – <b>PRAMIPEXOLE</b> , pramipexole hydrochloride monohydrate 375 microgram tablet: modified release, 30 tablets
3419Y	<i>APO-Pramipexole ER, TX</i> – <b>PRAMIPEXOLE</b> , pramipexole hydrochloride monohydrate 750 microgram tablet: modified release, 30 tablets
3420B	<i>APO-Pramipexole ER, TX</i> – <b>PRAMIPEXOLE</b> , pramipexole hydrochloride monohydrate 1.5 mg tablet: modified release, 30 tablets
5143Q	<i>APO-Pramipexole ER, TX</i> – <b>PRAMIPEXOLE</b> , pramipexole hydrochloride monohydrate 2.25 mg tablet: modified release, 30 tablets
3421C	<i>APO-Pramipexole ER, TX</i> – <b>PRAMIPEXOLE</b> , pramipexole hydrochloride monohydrate 3 mg tablet: modified release, 30 tablets
5145T	<i>APO-Pramipexole ER, TX</i> – <b>PRAMIPEXOLE</b> , pramipexole hydrochloride monohydrate 3.75 mg tablet: modified release, 30 tablets
3422D	<i>APO-Pramipexole ER, TX</i> – <b>PRAMIPEXOLE</b> , pramipexole hydrochloride monohydrate 4.5 mg tablet: modified release, 30 tablets
2590H	<i>Rosuvastatin AMNEAL, EF</i> – <b>ROSUVASTATIN</b> , rosuvastatin 5 mg tablet, 30
2606E	<i>Rosuvastatin AMNEAL, EF</i> – <b>ROSUVASTATIN</b> , rosuvastatin 5 mg tablet, 30
3402C	<i>Rosuvastatin AMNEAL, EF</i> – <b>ROSUVASTATIN</b> , rosuvastatin 5 mg tablet, 30
9042X	<i>Rosuvastatin AMNEAL, EF</i> – <b>ROSUVASTATIN</b> , rosuvastatin 5 mg tablet, 30
2584B	<i>Rosuvastatin AMNEAL, EF</i> – <b>ROSUVASTATIN</b> , rosuvastatin 10 mg tablet, 30

2628H	<i>Rosuvastatin AMNEAL, EF</i> – <b>ROSUVASTATIN</b> , rosuvastatin 10 mg tablet, 30
3403D	<i>Rosuvastatin AMNEAL, EF</i> – <b>ROSUVASTATIN</b> , rosuvastatin 10 mg tablet, 30
9043Y	<i>Rosuvastatin AMNEAL, EF</i> – <b>ROSUVASTATIN</b> , rosuvastatin 10 mg tablet, 30
2574L	<i>Rosuvastatin AMNEAL, EF</i> – <b>ROSUVASTATIN</b> , rosuvastatin 20 mg tablet, 30
2609H	<i>Rosuvastatin AMNEAL, EF</i> – <b>ROSUVASTATIN</b> , rosuvastatin 20 mg tablet, 30
3404E	<i>Rosuvastatin AMNEAL, EF</i> – <b>ROSUVASTATIN</b> , rosuvastatin 20 mg tablet, 30
9044B	<i>Rosuvastatin AMNEAL, EF</i> – <b>ROSUVASTATIN</b> , rosuvastatin 20 mg tablet, 30
2594M	<i>Rosuvastatin AMNEAL, EF</i> – <b>ROSUVASTATIN</b> , rosuvastatin 40 mg tablet, 30
2636R	<i>Rosuvastatin AMNEAL, EF</i> – <b>ROSUVASTATIN</b> , rosuvastatin 40 mg tablet, 30
3405F	<i>Rosuvastatin AMNEAL, EF</i> – <b>ROSUVASTATIN</b> , rosuvastatin 40 mg tablet, 30
9045C	<i>Rosuvastatin AMNEAL, EF</i> – <b>ROSUVASTATIN</b> , rosuvastatin 40 mg tablet, 30
8448P	<i>Ursodox GH, GQ</i> – <b>URSODEOXYCHOLIC ACID</b> , ursodeoxycholic acid 250 mg capsule, 100
10173K	<i>Vttack, AF</i> – <b>VORICONAZOLE</b> , voriconazole 50 mg tablet, 56
9363T	<i>Vttack, AF</i> – <b>VORICONAZOLE</b> , voriconazole 50 mg tablet, 56
10198R	<i>Vttack, AF</i> – <b>VORICONAZOLE</b> , voriconazole 200 mg tablet, 56
9364W	<i>Vttack, AF</i> – <b>VORICONAZOLE</b> , voriconazole 200 mg tablet, 56

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

3418X	<i>Sifrol ER, BY</i> – <b>PRAMIPEXOLE</b> , pramipexole hydrochloride monohydrate 375 microgram tablet: modified release, 30 tablets
3419Y	<i>Sifrol ER, BY</i> – <b>PRAMIPEXOLE</b> , pramipexole hydrochloride monohydrate 750 microgram tablet: modified release, 30 tablets
3420B	<i>Sifrol ER, BY</i> – <b>PRAMIPEXOLE</b> , pramipexole hydrochloride monohydrate 1.5 mg tablet: modified release, 30 tablets
5143Q	<i>Sifrol ER, BY</i> – <b>PRAMIPEXOLE</b> , pramipexole hydrochloride monohydrate 2.25 mg tablet: modified release, 30 tablets
3421C	<i>Sifrol ER, BY</i> – <b>PRAMIPEXOLE</b> , pramipexole hydrochloride monohydrate 3 mg tablet: modified release, 30 tablets
5145T	<i>Sifrol ER, BY</i> – <b>PRAMIPEXOLE</b> , pramipexole hydrochloride monohydrate 3.75 mg tablet: modified release, 30 tablets
3422D	<i>Sifrol ER, BY</i> – <b>PRAMIPEXOLE</b> , pramipexole hydrochloride monohydrate 4.5 mg tablet: modified release, 30 tablets

#### **Deletions**

##### **Deletion – Brand**

2751T	<i>Amlodipine-DRLA, RZ</i> – <b>AMLODIPINE</b> , amlodipine 5 mg tablet, 30
2752W	<i>Amlodipine-DRLA, RZ</i> – <b>AMLODIPINE</b> , amlodipine 10 mg tablet, 30
1892N	<i>Clamoxyl, AL</i> – <b>AMOXYCILLIN + CLAVULANIC ACID</b> , amoxicillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL oral liquid: powder for, 75 mL
5009P	<i>Clamoxyl, AL</i> – <b>AMOXYCILLIN + CLAVULANIC ACID</b> , amoxicillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL oral liquid: powder for, 75 mL ( <b>Dental</b> )
5011R	<i>Clamoxyl Duo 400, AL</i> – <b>AMOXYCILLIN + CLAVULANIC ACID</b> , amoxicillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL oral liquid: powder for, 60 mL ( <b>Dental</b> )
8319W	<i>Clamoxyl Duo 400, AL</i> – <b>AMOXYCILLIN + CLAVULANIC ACID</b> , amoxicillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL oral liquid: powder for, 60 mL
1891M	<i>Clamoxyl Duo, AL</i> – <b>AMOXYCILLIN + CLAVULANIC ACID</b> , amoxicillin 500 mg + clavulanic acid 125 mg tablet, 10
5008N	<i>Clamoxyl Duo, AL</i> – <b>AMOXYCILLIN + CLAVULANIC ACID</b> , amoxicillin 500 mg + clavulanic acid 125 mg tablet, 10 ( <b>Dental</b> )
5006L	<i>Clamoxyl Duo forte, AL</i> – <b>AMOXYCILLIN + CLAVULANIC ACID</b> , amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10 ( <b>Dental</b> )
8254K	<i>Clamoxyl Duo forte, AL</i> – <b>AMOXYCILLIN + CLAVULANIC ACID</b> , amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10

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8179L	<i>Anastrozole-DRLA, RZ</i> – <b>ANASTROZOLE</b> , anastrozole 1 mg tablet, 30
8179L	<i>Pharmacy Choice Anastrozole, RI</i> – <b>ANASTROZOLE</b> , anastrozole 1 mg tablet, 30
1208N	<i>Ciprofloxacin-DRLA, RZ</i> – <b>CIPROFLOXACIN</b> , ciprofloxacin 250 mg tablet, 14
1209P	<i>Ciprofloxacin-DRLA, RZ</i> – <b>CIPROFLOXACIN</b> , ciprofloxacin 500 mg tablet, 14
1210Q	<i>Ciprofloxacin-DRLA, RZ</i> – <b>CIPROFLOXACIN</b> , ciprofloxacin 750 mg tablet, 14
9155W	<i>Duloxetine-DRLA, RZ</i> – <b>DULOXETINE</b> , duloxetine 30 mg capsule: enteric, 28
9156X	<i>Duloxetine-DRLA, RZ</i> – <b>DULOXETINE</b> , duloxetine 60 mg capsule: enteric, 28
8246B	<i>Irbesartan-DRLA, RZ</i> – <b>IRBESARTAN</b> , irbesartan 75 mg tablet, 30
8247C	<i>Irbesartan-DRLA, RZ</i> – <b>IRBESARTAN</b> , irbesartan 150 mg tablet, 30
8248D	<i>Irbesartan-DRLA, RZ</i> – <b>IRBESARTAN</b> , irbesartan 300 mg tablet, 30
8063J	<i>Lamogine, AF</i> – <b>LAMOTRIGINE</b> , lamotrigine 5 mg tablet, 56
2848X	<i>Lamogine, AF</i> – <b>LAMOTRIGINE</b> , lamotrigine 25 mg tablet, 56
2849Y	<i>Lamogine, AF</i> – <b>LAMOTRIGINE</b> , lamotrigine 50 mg tablet, 56
2850B	<i>Lamogine, AF</i> – <b>LAMOTRIGINE</b> , lamotrigine 100 mg tablet, 56
2851C	<i>Lamogine, AF</i> – <b>LAMOTRIGINE</b> , lamotrigine 200 mg tablet, 56
8245Y	<i>Letrozole-DRLA, RZ</i> – <b>LETROZOLE</b> , letrozole 2.5 mg tablet, 30
8245Y	<i>Pharmacy Choice Letrozole, RI</i> – <b>LETROZOLE</b> , letrozole 2.5 mg tablet, 30
8655M	<i>Levetiracetam generichealth, GQ</i> – <b>LEVETIRACETAM</b> , levetiracetam 500 mg tablet, 60
2456G	<i>Lisinopril-DRLA, RZ</i> – <b>LISINOPRIL</b> , lisinopril 5 mg tablet, 30
2457H	<i>Lisinopril-DRLA, RZ</i> – <b>LISINOPRIL</b> , lisinopril 10 mg tablet, 30
2458J	<i>Lisinopril-DRLA, RZ</i> – <b>LISINOPRIL</b> , lisinopril 20 mg tablet, 30
1324Q	<i>Metatar, FM</i> – <b>METOPROLOL TARTRATE</b> , METOPROLOL TARTRATE Tablet 50 mg, 100
1325R	<i>Metatar, FM</i> – <b>METOPROLOL TARTRATE</b> , METOPROLOL TARTRATE Tablet 100 mg, 60
8170B	<i>Pharmacor Olanzapine 2.5, CR</i> – <b>OLANZAPINE</b> , olanzapine 2.5 mg tablet, 28
8170B	<i>Pharmacy Choice Olanzapine, RI</i> – <b>OLANZAPINE</b> , olanzapine 2.5 mg tablet, 28
3381Y	<i>Pharmacy Choice Olanzapine ODT, RI</i> – <b>OLANZAPINE</b> , OLANZAPINE Tablet 5 mg (orally disintegrating), 28
8185T	<i>Pharmacor Olanzapine 5, CR</i> – <b>OLANZAPINE</b> , olanzapine 5 mg tablet, 28
8185T	<i>Pharmacy Choice Olanzapine, RI</i> – <b>OLANZAPINE</b> , olanzapine 5 mg tablet, 28
8186W	<i>Pharmacor Olanzapine 7.5, CR</i> – <b>OLANZAPINE</b> , olanzapine 7.5 mg tablet, 28
8186W	<i>Pharmacy Choice Olanzapine, RI</i> – <b>OLANZAPINE</b> , olanzapine 7.5 mg tablet, 28
3382B	<i>Pharmacy Choice Olanzapine ODT, RI</i> – <b>OLANZAPINE</b> , OLANZAPINE Tablet 10 mg (orally disintegrating), 28
8187X	<i>Pharmacor Olanzapine 10, CR</i> – <b>OLANZAPINE</b> , olanzapine 10 mg tablet, 28
8187X	<i>Pharmacy Choice Olanzapine, RI</i> – <b>OLANZAPINE</b> , olanzapine 10 mg tablet, 28
3050M	<i>Indopril 2, QA</i> – <b>PERINDOPRIL</b> , perindopril erbumine 2 mg tablet, 30
3051N	<i>Indopril 4, QA</i> – <b>PERINDOPRIL</b> , perindopril erbumine 4 mg tablet, 30
8704D	<i>Indopril 8, QA</i> – <b>PERINDOPRIL</b> , perindopril erbumine 8 mg tablet, 30
1166J	<i>Dibenyline, GH</i> – <b>PHENOXYBENZAMINE</b> , phenoxybenzamine hydrochloride 10 mg capsule, 30
8456C	<i>Pharmacy Choice Quetiapine, RI</i> – <b>QUETIAPINE</b> , quetiapine 25 mg tablet, 60
8457D	<i>Pharmacy Choice Quetiapine, RI</i> – <b>QUETIAPINE</b> , quetiapine 100 mg tablet, 90
8458E	<i>Pharmacy Choice Quetiapine, RI</i> – <b>QUETIAPINE</b> , quetiapine 200 mg tablet, 60
8580N	<i>Pharmacy Choice Quetiapine, RI</i> – <b>QUETIAPINE</b> , quetiapine 300 mg tablet, 60
8787L	<i>Risperidone-DRLA, RZ</i> – <b>RISPERIDONE</b> , risperidone 500 microgram tablet, 60
8869T	<i>Risperidone-DRLA, RZ</i> – <b>RISPERIDONE</b> , risperidone 500 microgram tablet, 60
3169T	<i>Risperidone-DRLA, RZ</i> – <b>RISPERIDONE</b> , risperidone 1 mg tablet, 60

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8789N	<i>Risperidone-DRLA, RZ – RISPERSIDONE</i> , risperidone 1 mg tablet, 60
3170W	<i>Risperidone-DRLA, RZ – RISPERSIDONE</i> , risperidone 2 mg tablet, 60
9079W	<i>Risperidone-DRLA, RZ – RISPERSIDONE</i> , risperidone 2 mg tablet, 60
3171X	<i>Risperidone-DRLA, RZ – RISPERSIDONE</i> , risperidone 3 mg tablet, 60
3172Y	<i>Risperidone-DRLA, RZ – RISPERSIDONE</i> , risperidone 4 mg tablet, 60
2236Q	<i>Sertraline-DRLA, RZ – SERTRALINE</i> , sertraline 50 mg tablet, 30
2237R	<i>Sertraline-DRLA, RZ – SERTRALINE</i> , sertraline 100 mg tablet, 30
2011W	<i>Simvastatin-DRLA, RZ – SIMVASTATIN</i> , simvastatin 10 mg tablet, 30
9242K	<i>Simvastatin-DRLA, RZ – SIMVASTATIN</i> , simvastatin 10 mg tablet, 30
2012X	<i>Simvastatin-DRLA, RZ – SIMVASTATIN</i> , simvastatin 20 mg tablet, 30
9243L	<i>Simvastatin-DRLA, RZ – SIMVASTATIN</i> , simvastatin 20 mg tablet, 30
8173E	<i>Simvastatin-DRLA, RZ – SIMVASTATIN</i> , simvastatin 40 mg tablet, 30
9244M	<i>Simvastatin-DRLA, RZ – SIMVASTATIN</i> , simvastatin 40 mg tablet, 30
8313M	<i>Simvastatin-DRLA, RZ – SIMVASTATIN</i> , simvastatin 80 mg tablet, 30
9245N	<i>Simvastatin-DRLA, RZ – SIMVASTATIN</i> , simvastatin 80 mg tablet, 30
8144P	<i>Sumatab, AF – SUMATRIPTAN</i> , SUMATRIPTAN Tablet 50 mg (as succinate), 2
2285G	<i>Pharmacy Choice Terbinafine, RI – TERBINAFINE</i> , terbinafine 250 mg tablet, 42
2804N	<i>Pharmacy Choice Terbinafine, RI – TERBINAFINE</i> , terbinafine 250 mg tablet, 42

## Alterations

### Alteration – Restriction

The following items have additions, deletions or alterations to restrictions, notes and/or cautions.

1002R	<b>ACICLOVIR</b> , aciclovir 3% eye ointment, 4.5 g ( <i>AciVision, Zovirax</i> )
1003T	<b>ACICLOVIR</b> , aciclovir 200 mg tablet, 25 ( <i>Aciclovir Sandoz, Acyclo-V 200, Lovir, Zovirax 200 mg</i> )
1007B	<b>ACICLOVIR</b> , aciclovir 200 mg tablet, 90 ( <i>Aciclovir 200, Aciclovir GH, Aciclovir Sandoz, Acyclo-V 200, Chem mart Aciclovir, GenRx Aciclovir, Lovir, Ozvir, Terry White Chemists Aciclovir, Zovirax 200 mg</i> )
1052J	<b>ACICLOVIR</b> , aciclovir 800 mg tablet, 35 ( <i>Aciclovir 800, Aciclovir Sandoz, Acyclo-V 800, GenRx Aciclovir, Zovirax 800 mg</i> )
1555W	<b>ACICLOVIR</b> , aciclovir 200 mg tablet, 50 ( <i>GenRx Aciclovir</i> )
5501M	<b>ACICLOVIR</b> , aciclovir 3% eye ointment, 4.5 g ( <i>AciVision, Zovirax</i> )( <b>Optometrical</b> )
8234J	<b>ACICLOVIR</b> , aciclovir 800 mg tablet, 120 ( <i>Acyclo-V 800</i> )
10522T	<b>AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES</b> , amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides oral liquid: powder for, 400 g ( <i>Alfamino Junior</i> )
10527C	<b>AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES</b> , amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides oral liquid: powder for, 400 g ( <i>Alfamino Junior</i> )
2900P	<b>AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES</b> , amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides oral liquid: powder for, 400 g ( <i>Alfamino</i> )
2928D	<b>AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES</b> , amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides oral liquid: powder for, 400 g ( <i>Alfamino</i> )
10075G	<b>CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE</b> , betamethasone (as dipropionate) 0.05% + calcipotriol 0.005% gel, 60 g ( <i>Daivobet 50/500 gel</i> )
5276Q	<b>CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE</b> , calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% gel, 30 g ( <i>Daivobet 50/500 gel</i> )
10202Y	<b>EMPAGLIFLOZIN</b> , empagliflozin 25 mg tablet, 30 ( <i>Jardiance</i> )
10206E	<b>EMPAGLIFLOZIN</b> , empagliflozin 10 mg tablet, 30 ( <i>Jardiance</i> )

2274Q	<b>FAMCICLOVIR</b> , famciclovir 250 mg tablet, 20 ( <i>APO-Famciclovir, Ezovir, Famciclovir AN, Famciclovir Sandoz, Famciclovir-GA, Famvir, Favic 250</i> )
8002E	<b>FAMCICLOVIR</b> , famciclovir 250 mg tablet, 21 ( <i>APO-Famciclovir, Auro-Famciclovir 250, Ezovir, Famciclovir AN, Famciclovir SCP 250, Famciclovir Sandoz, Famciclovir generichealth 250, Famciclovir-GA, Famlo, Famvir, Favic 250</i> )
8092X	<b>FAMCICLOVIR</b> , famciclovir 125 mg tablet, 40 ( <i>APO-Famciclovir, Auro-Famciclovir 125, Ezovir, Famciclovir AN, Famciclovir-GA, Famvir, Favic 125</i> )
8217L	<b>FAMCICLOVIR</b> , famciclovir 250 mg tablet, 56 ( <i>APO-Famciclovir, Auro-Famciclovir 250, Ezovir, Famciclovir AN, Famciclovir SCP 250, Famciclovir Sandoz, Famciclovir generichealth 250, Famciclovir-GA, Famlo, Famvir, Favic 250</i> )
8896F	<b>FAMCICLOVIR</b> , famciclovir 500 mg tablet, 56 ( <i>APO-Famciclovir, Auro-Famciclovir 500, Chem mart Famciclovir, Ezovir, Famciclovir AN, Famciclovir Sandoz, Famciclovir generichealth 500, Famciclovir-GA, Famvir, Favic 500, Terry White Chemists Famciclovir</i> )
8897G	<b>FAMCICLOVIR</b> , famciclovir 500 mg tablet, 30 ( <i>APO-Famciclovir, Auro-Famciclovir 500, Chem mart Famciclovir, Famciclovir AN, Famciclovir Sandoz, Famvir, Favic 500, Terry White Chemists Famciclovir</i> )
2308L	<b>FOLINIC ACID</b> , folinic acid 15 mg tablet, 10 ( <i>Leucovorin Calcium (Hospira Pty Limited)</i> )
2732T	<b>NITRAZEPAM</b> , nitrazepam 5 mg tablet, 25 ( <i>Alodorm, Mogadon</i> )
2088X	<b>TEMAZEPAM</b> , temazepam 10 mg tablet, 25 ( <i>APO-Temazepam, Normison, Temaze, Temtabs</i> )
5480K	<b>VALACICLOVIR</b> , valaciclovir 500 mg tablet, 30 ( <i>APO-Valaciclovir, Chem mart Valaciclovir, Shilova 500, Terry White Chemists Valaciclovir, Vaclovir, Valaciclovir AN, Valaciclovir Actavis, Valaciclovir GA, Valaciclovir RBX, Valaciclovir SZ, Valaciclovir generichealth, Valacor 500, Valnir, Valtrex, Zelitrex</i> )
8064K	<b>VALACICLOVIR</b> , valaciclovir 500 mg tablet, 42 ( <i>APO-Valaciclovir, Chem mart Valaciclovir, Terry White Chemists Valaciclovir, Vaclovir, Valaciclovir AN, Valaciclovir Actavis, Valaciclovir GA, Valaciclovir RBX, Valaciclovir Sandoz, Valaciclovir generichealth, Valacor 500, Valnir, Valtrex, Zelitrex</i> )
8133C	<b>VALACICLOVIR</b> , valaciclovir 500 mg tablet, 10 ( <i>APO-Valaciclovir, Vaclovir, Valaciclovir AN, Valaciclovir Actavis, Valaciclovir GA, Valaciclovir Sandoz, Valnir, Valtrex, Zelitrex</i> )
8134D	<b>VALACICLOVIR</b> , valaciclovir 500 mg tablet, 30 ( <i>APO-Valaciclovir, Chem mart Valaciclovir, Shilova 500, Terry White Chemists Valaciclovir, Vaclovir, Valaciclovir AN, Valaciclovir Actavis, Valaciclovir GA, Valaciclovir RBX, Valaciclovir SZ, Valaciclovir Sandoz, Valaciclovir generichealth, Valacor 500, Valnir, Valtrex, Zelitrex</i> )

#### **Alteration – Manufacturer Code**

		<i>From</i>	<i>To</i>
2343H	<i>Rithmik 200</i> – <b>AMIODARONE</b> , amiodarone hydrochloride 200 mg tablet, 30	QA	RW
8596K	<i>Amipride 400</i> – <b>AMISULPRIDE</b> , amisulpride 400 mg tablet, 60	QA	RW
1081X	<i>Tensig</i> – <b>ATENOLOL</b> , atenolol 50 mg tablet, 30	QA	RW
8213G	<i>Torvastat 10</i> – <b>ATORVASTATIN</b> , atorvastatin 10 mg tablet, 30	QA	RW
9230T	<i>Torvastat 10</i> – <b>ATORVASTATIN</b> , atorvastatin 10 mg tablet, 30	QA	RW
8214H	<i>Torvastat 20</i> – <b>ATORVASTATIN</b> , atorvastatin 20 mg tablet, 30	QA	RW
9231W	<i>Torvastat 20</i> – <b>ATORVASTATIN</b> , atorvastatin 20 mg tablet, 30	QA	RW
8215J	<i>Torvastat 40</i> – <b>ATORVASTATIN</b> , atorvastatin 40 mg tablet, 30	QA	RW
9232X	<i>Torvastat 40</i> – <b>ATORVASTATIN</b> , atorvastatin 40 mg tablet, 30	QA	RW
8521L	<i>Torvastat 80</i> – <b>ATORVASTATIN</b> , atorvastatin 80 mg tablet, 30	QA	RW
9233Y	<i>Torvastat 80</i> – <b>ATORVASTATIN</b> , atorvastatin 80 mg tablet, 30	QA	RW
2687K	<i>Azapin</i> – <b>AZATHIOPRINE</b> , azathioprine 50 mg tablet, 100	QA	RW
2502Q	<i>Kosteo</i> – <b>CALCITRIOL</b> , calcitriol 0.25 microgram capsule, 100	QA	RW
8295N	<i>Candesartan Aspen 4</i> – <b>CANDESARTAN</b> , candesartan cilexetil 4 mg tablet, 30	QA	RW
8296P	<i>Candesartan Aspen 8</i> – <b>CANDESARTAN</b> , candesartan cilexetil 8 mg tablet, 30	QA	RW
8297Q	<i>Candesartan Aspen 16</i> – <b>CANDESARTAN</b> , candesartan cilexetil 16 mg tablet, 30	QA	RW
8889W	<i>Candesartan Aspen 32</i> – <b>CANDESARTAN</b> , candesartan cilexetil 32 mg tablet, 30	QA	RW
8504N	<i>Candesartan Combi Aspen 16/12.5</i> – <b>CANDESARTAN + HYDROCHLOROTHIAZIDE</b> ,	QA	RW

	candesartan cilexetil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30		
9314F	<i>Candesartan Combi Aspen 32/12.5</i> – <b>CANDESARTAN + HYDROCHLOROTHIAZIDE</b> , candesartan cilexetil 32 mg + hydrochlorothiazide 12.5 mg tablet, 30	QA	RW
9315G	<i>Candesartan Combi Aspen 32/25</i> – <b>CANDESARTAN + HYDROCHLOROTHIAZIDE</b> , candesartan cilexetil 32 mg + hydrochlorothiazide 25 mg tablet, 30	QA	RW
8898H	<i>Gliadel</i> – <b>CARMUSTINE</b> , carmustine 7.7 mg implant, 8	OA	EI
8255L	<i>Vedilol 3.125</i> – <b>CARVEDILOL</b> , carvedilol 3.125 mg tablet, 30	QA	RW
8256M	<i>Vedilol 6.25</i> – <b>CARVEDILOL</b> , carvedilol 6.25 mg tablet, 60	QA	RW
8257N	<i>Vedilol 12.5</i> – <b>CARVEDILOL</b> , carvedilol 12.5 mg tablet, 60	QA	RW
8258P	<i>Vedilol 25</i> – <b>CARVEDILOL</b> , carvedilol 25 mg tablet, 60	QA	RW
8439E	<i>Celexi</i> – <b>CELECOXIB</b> , celecoxib 100 mg capsule, 60	QA	RW
8440F	<i>Celexi</i> – <b>CELECOXIB</b> , celecoxib 200 mg capsule, 30	QA	RW
8702B	<i>Talam</i> – <b>CITALOPRAM</b> , citalopram 10 mg tablet, 28	QA	RW
8703C	<i>Talam</i> – <b>CITALOPRAM</b> , citalopram 40 mg tablet, 28	QA	RW
3138E	<i>Calindamin</i> – <b>CLINDAMYCIN</b> , clindamycin 150 mg capsule, 24	QA	RW
5057E	<i>Calindamin</i> – <b>CLINDAMYCIN</b> , clindamycin 150 mg capsule, 24 ( <b>Dental</b> )	QA	RW
2275R	<i>Clovix 75</i> – <b>CLOPIDOGREL</b> , clopidogrel 75 mg tablet, 28	QA	RW
2275R	<i>Plidogrel</i> – <b>CLOPIDOGREL</b> , clopidogrel 75 mg tablet, 28	FM	RF
9354H	<i>Clovix 75</i> – <b>CLOPIDOGREL</b> , clopidogrel 75 mg tablet, 28	QA	RW
9354H	<i>Plidogrel</i> – <b>CLOPIDOGREL</b> , clopidogrel 75 mg tablet, 28	FM	RF
1299J	<i>Clonac 25</i> – <b>DICLOFENAC</b> , diclofenac sodium 25 mg tablet: enteric, 50 tablets	QA	RW
5076E	<i>Clonac 25</i> – <b>DICLOFENAC</b> , diclofenac sodium 25 mg tablet: enteric, 50 tablets ( <b>Dental</b> )	QA	RW
1300K	<i>Clonac 50</i> – <b>DICLOFENAC</b> , diclofenac sodium 50 mg tablet: enteric, 50 tablets	QA	RW
5077F	<i>Clonac 50</i> – <b>DICLOFENAC</b> , diclofenac sodium 50 mg tablet: enteric, 50 tablets ( <b>Dental</b> )	QA	RW
8382E	<i>Diasp SR</i> – <b>DIPYRIDAMOLE + ASPIRIN</b> , dipyridamole 200 mg + aspirin 25 mg capsule: modified release, 60 capsules	QA	RW
9106G	<i>Frakas</i> – <b>DOXYCYCLINE</b> , doxycycline 50 mg tablet, 25	QA	RW
8512B	<i>Faverin 50</i> – <b>FLUVOXAMINE</b> , fluvoxamine maleate 50 mg tablet, 30	QA	RW
8174F	<i>Faverin 100</i> – <b>FLUVOXAMINE</b> , fluvoxamine maleate 100 mg tablet, 30	QA	RW
2463P	<i>Gamine XR</i> – <b>GALANTAMINE</b> , galantamine 8 mg capsule: modified release, 28 capsules	QA	RW
8770N	<i>Gamine XR</i> – <b>GALANTAMINE</b> , galantamine 8 mg capsule: modified release, 28 capsules	QA	RW
2537M	<i>Gamine XR</i> – <b>GALANTAMINE</b> , galantamine 16 mg capsule: modified release, 28 capsules	QA	RW
8771P	<i>Gamine XR</i> – <b>GALANTAMINE</b> , galantamine 16 mg capsule: modified release, 28 capsules	QA	RW
2531F	<i>Gamine XR</i> – <b>GALANTAMINE</b> , galantamine 24 mg capsule: modified release, 28 capsules	QA	RW
8772Q	<i>Gamine XR</i> – <b>GALANTAMINE</b> , galantamine 24 mg capsule: modified release, 28 capsules	QA	RW
8404H	<i>KSART HCT 150/12.5</i> – <b>IRBESARTAN + HYDROCHLOROTHIAZIDE</b> , irbesartan 150 mg + hydrochlorothiazide 12.5 mg tablet, 30	QA	RW
8405J	<i>KSART HCT 300/12.5</i> – <b>IRBESARTAN + HYDROCHLOROTHIAZIDE</b> , irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet, 30	QA	RW
2136K	<i>KSART HCT 300/25</i> – <b>IRBESARTAN + HYDROCHLOROTHIAZIDE</b> , irbesartan 300 mg + hydrochlorothiazide 25 mg tablet, 30	QA	RW
8534E	<i>Lercan</i> – <b>LERCANIDIPINE</b> , lercanidipine hydrochloride 10 mg tablet, 28	QA	RW
8679T	<i>Lercan</i> – <b>LERCANIDIPINE</b> , lercanidipine hydrochloride 20 mg tablet, 28	QA	RW
8654L	<i>Levi 250</i> – <b>LEVETIRACETAM</b> , levetiracetam 250 mg tablet, 60	FM	RW

8655M	<i>Levi 500</i> – <b>LEVETIRACETAM</b> , levetiracetam 500 mg tablet, 60	FM	RW
8656N	<i>Levi 1000</i> – <b>LEVETIRACETAM</b> , levetiracetam 1 g tablet, 60	FM	RW
8612G	<i>Chemists' Own Macrogol with Electrolytes</i> – <b>MACROGOL-3350 + SODIUM CHLORIDE + POTASSIUM CHLORIDE + BICARBONATE</b> , macrogol-3350 13.12 g + sodium chloride 350.7 mg + potassium chloride 46.6 mg (0.63 mmol potassium) + sodium bicarbonate 178.5 mg solution, 30 sachets	FM	RW
8612G	<i>Macrovic</i> – <b>MACROGOL-3350 + SODIUM CHLORIDE + POTASSIUM CHLORIDE + BICARBONATE</b> , macrogol-3350 13.12 g + sodium chloride 350.7 mg + potassium chloride 46.6 mg (0.63 mmol potassium) + sodium bicarbonate 178.5 mg solution, 30 sachets	QA	RF
1956Y	<i>Memanza</i> – <b>MEMANTINE</b> , memantine hydrochloride 10 mg tablet, 56	QA	RW
2492E	<i>Memanza</i> – <b>MEMANTINE</b> , memantine hydrochloride 10 mg tablet, 56	QA	RW
2430X	<i>Formet Aspen 500</i> – <b>METFORMIN</b> , metformin hydrochloride 500 mg tablet, 100	AS	RW
1801T	<i>Formet Aspen 850</i> – <b>METFORMIN</b> , metformin hydrochloride 850 mg tablet, 60	AS	RW
8732N	<i>Metrol-XL 23.75</i> – <b>METOPROLOL SUCCINATE</b> , METOPROLOL SUCCINATE Tablet 23.75 mg (controlled release), 15	QA	RW
8733P	<i>Metrol-XL 47.5</i> – <b>METOPROLOL SUCCINATE</b> , METOPROLOL SUCCINATE Tablet 47.5 mg (controlled release), 30	QA	RW
8734Q	<i>Metrol-XL 95</i> – <b>METOPROLOL SUCCINATE</b> , METOPROLOL SUCCINATE Tablet 95 mg (controlled release), 30	QA	RW
8735R	<i>Metrol-XL 190</i> – <b>METOPROLOL SUCCINATE</b> , METOPROLOL SUCCINATE Tablet 190 mg (controlled release), 30	QA	RW
1324Q	<i>Metrol 50</i> – <b>METOPROLOL TARTRATE</b> , METOPROLOL TARTRATE Tablet 50 mg, 100	QA	RW
1325R	<i>Metrol 100</i> – <b>METOPROLOL TARTRATE</b> , METOPROLOL TARTRATE Tablet 100 mg, 60	QA	RW
8513C	<i>Mirtazon</i> – <b>MIRTAZAPINE</b> , mirtazapine 30 mg tablet, 30	QA	RW
8883M	<i>Mirtazon</i> – <b>MIRTAZAPINE</b> , mirtazapine 45 mg tablet, 30	QA	RW
8627C	<i>Respikast 4</i> – <b>MONTELUKAST</b> , montelukast 4 mg tablet: chewable, 28	QA	RW
8628D	<i>Respikast 5</i> – <b>MONTELUKAST</b> , montelukast 5 mg tablet: chewable, 28	QA	RW
1653B	<i>Momex SR 10</i> – <b>MORPHINE</b> , morphine sulfate 10 mg tablet: modified release, 28 tablets	QA	RW
1654C	<i>Momex SR 30</i> – <b>MORPHINE</b> , morphine sulfate 30 mg tablet: modified release, 28 tablets	QA	RW
1655D	<i>Momex SR 60</i> – <b>MORPHINE</b> , morphine sulfate 60 mg tablet: modified release, 28 tablets	QA	RW
1656E	<i>Momex SR 100</i> – <b>MORPHINE</b> , morphine sulfate 100 mg tablet: modified release, 28 tablets	QA	RW
1906H	<i>Addos XR 30</i> – <b>NIFEDIPINE</b> , nifedipine 30 mg tablet: modified release, 30 tablets	QA	RW
1907J	<i>Addos XR 60</i> – <b>NIFEDIPINE</b> , nifedipine 60 mg tablet: modified release, 30 tablets	QA	RW
1326T	<i>Pemzo</i> – <b>OMEPRAZOLE</b> , omeprazole 20 mg capsule, 30	QA	RW
1327W	<i>Pemzo</i> – <b>OMEPRAZOLE</b> , omeprazole 20 mg capsule, 30	QA	RW
8456C	<i>Quetia 25</i> – <b>QUETIAPINE</b> , quetiapine 25 mg tablet, 60	FM	RW
8456C	<i>Seronia 25</i> – <b>QUETIAPINE</b> , quetiapine 25 mg tablet, 60	QA	RF
8457D	<i>Quetia 100</i> – <b>QUETIAPINE</b> , quetiapine 100 mg tablet, 90	FM	RW
8458E	<i>Quetia 200</i> – <b>QUETIAPINE</b> , quetiapine 200 mg tablet, 60	FM	RW
8580N	<i>Quetia 300</i> – <b>QUETIAPINE</b> , quetiapine 300 mg tablet, 60	FM	RW
8507R	<i>Parbezol</i> – <b>RABEPRAZOLE</b> , rabeprazole sodium 10 mg tablet: enteric, 28	QA	RW
8508T	<i>Parbezol</i> – <b>RABEPRAZOLE</b> , rabeprazole sodium 20 mg tablet: enteric, 30	QA	RW
8509W	<i>Parbezol</i> – <b>RABEPRAZOLE</b> , rabeprazole sodium 20 mg tablet: enteric, 30	QA	RW
8470T	<i>Prilace 10</i> – <b>RAMIPRIL</b> , ramipril 10 mg capsule, 30	QA	RW
1945J	<i>Prilace 2.5</i> – <b>RAMIPRIL</b> , ramipril 2.5 mg tablet, 30	QA	RW
1946K	<i>Prilace 5</i> – <b>RAMIPRIL</b> , ramipril 5 mg tablet, 30	QA	RW

1849H	<i>Sumatran</i> – <b>SUMATRIPTAN</b> , sumatriptan 50 mg tablet, 4	QA	OW
8144P	<i>Sumatran</i> – <b>SUMATRIPTAN</b> , SUMATRIPTAN Tablet 50 mg (as succinate), 2	QA	OW
8266C	<i>Zoltrip</i> – <b>ZOLMITRIPTAN</b> , zolmitriptan 2.5 mg tablet, 2	QA	RW

## Advance Notices

### 1 April 2016

#### Deletion – Brand

8114C	<i>Dostan, GN</i> – <b>CABERGOLINE</b> , cabergoline 500 microgram tablet, 8
8115D	<i>Dostan, GN</i> – <b>CABERGOLINE</b> , cabergoline 500 microgram tablet, 2
8393R	<i>Cobasol, GN</i> – <b>CABERGOLINE</b> , cabergoline 1 mg tablet, 30
8394T	<i>Cobasol, GN</i> – <b>CABERGOLINE</b> , cabergoline 2 mg tablet, 30
1705R	<i>Cilopen VK, GN</i> – <b>PHENOXYMETHYLPENICILLIN</b> , phenoxymethylpenicillin 250 mg capsule, 50
1789E	<i>Cilopen VK, GN</i> – <b>PHENOXYMETHYLPENICILLIN</b> , phenoxymethylpenicillin 250 mg capsule, 50
2965C	<i>Cilopen VK, GN</i> – <b>PHENOXYMETHYLPENICILLIN</b> , phenoxymethylpenicillin 500 mg capsule, 50
3363B	<i>Cilopen VK, GN</i> – <b>PHENOXYMETHYLPENICILLIN</b> , phenoxymethylpenicillin 250 mg capsule, 50 <b>(Dental)</b>
3364C	<i>Cilopen VK, GN</i> – <b>PHENOXYMETHYLPENICILLIN</b> , phenoxymethylpenicillin 500 mg capsule, 50 <b>(Dental)</b>
3065H	<i>Visken 15, NV</i> – <b>PINDOLOL</b> , pindolol 15 mg tablet, 50

### 1 May 2016

#### Deletion – Brand

2022K	<i>Ridaura, GH</i> – <b>AURANOFIN</b> , AURANOFIN Capsule 3 mg, 60
1967M	<i>Micronor, JC</i> – <b>NORETHISTERONE</b> , norethisterone 350 microgram tablet, 112 [4 x 28]
2895J	<i>Stemetil, SW</i> – <b>PROCHLORPERAZINE</b> , prochlorperazine maleate 25 mg suppository, 5
5208D	<i>Stemetil, SW</i> – <b>PROCHLORPERAZINE</b> , prochlorperazine maleate 25 mg suppository, 5 <b>(Dental)</b>
8668F	<i>Tritace Titration Pack, SW</i> – <b>RAMIPRIL</b> , ramipril 2.5 mg tablet [7 tablets] (&) ramipril 5 mg tablet [21 tablets] (&) ramipril 10 mg capsule [10 capsules], 1 pack
8788M	<i>Risperdal Quicklet, JC</i> – <b>RISPERIDONE</b> , risperidone 500 microgram tablet: orally disintegrating, 28
8790P	<i>Risperdal Quicklet, JC</i> – <b>RISPERIDONE</b> , risperidone 1 mg tablet: orally disintegrating, 28
8792R	<i>Risperdal Quicklet, JC</i> – <b>RISPERIDONE</b> , risperidone 1 mg tablet: orally disintegrating, 28
8794W	<i>Risperdal Quicklet, JC</i> – <b>RISPERIDONE</b> , risperidone 2 mg tablet: orally disintegrating, 28
8870W	<i>Risperdal Quicklet, JC</i> – <b>RISPERIDONE</b> , risperidone 500 microgram tablet: orally disintegrating, 28
9075P	<i>Risperdal Quicklet, JC</i> – <b>RISPERIDONE</b> , risperidone 3 mg tablet: orally disintegrating, 28
9076Q	<i>Risperdal Quicklet, JC</i> – <b>RISPERIDONE</b> , risperidone 4 mg tablet: orally disintegrating, 28
9080X	<i>Risperdal Quicklet, JC</i> – <b>RISPERIDONE</b> , risperidone 2 mg tablet: orally disintegrating, 28
8267D	<i>Skelid, SW</i> – <b>TILUDRONATE</b> , tiludronate 200 mg tablet, 56

### 1 June 2016

#### Deletion – Brand

9195Y	<i>Clexane, SW</i> – <b>ENOXAPARIN SODIUM</b> , enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL ampoules
9196B	<i>Clexane, SW</i> – <b>ENOXAPARIN SODIUM</b> , enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL ampoules
1588N	<i>Orudis, SW</i> – <b>KETOPROFEN</b> , ketoprofen 100 mg suppository, 20
5139L	<i>Orudis, SW</i> – <b>KETOPROFEN</b> , ketoprofen 100 mg suppository, 20 <b>(Dental)</b>

## Palliative Care Alterations

### Alteration – Manufacturer Code

		From	To
5361E	<i>Clonac 25</i> – <b>DICLOFENAC</b> , diclofenac sodium 25 mg tablet: enteric, 50 tablets	QA	RW
5364H	<i>Clonac 25</i> – <b>DICLOFENAC</b> , diclofenac sodium 25 mg tablet: enteric, 50 tablets	QA	RW
5362F	<i>Clonac 50</i> – <b>DICLOFENAC</b> , diclofenac sodium 50 mg tablet: enteric, 50 tablets	QA	RW
5365J	<i>Clonac 50</i> – <b>DICLOFENAC</b> , diclofenac sodium 50 mg tablet: enteric, 50 tablets	QA	RW
5389P	<i>Chemists' Own Macrogol with Electrolytes</i> – <b>MACROGOL-3350 + SODIUM CHLORIDE + POTASSIUM CHLORIDE + BICARBONATE</b> , macrogol-3350 13.12 g + sodium chloride 350.7 mg + potassium chloride 46.6 mg (0.63 mmol potassium) + sodium bicarbonate 178.5 mg solution, 30 sachets	FM	RW
5389P	<i>Macrovic</i> – <b>MACROGOL-3350 + SODIUM CHLORIDE + POTASSIUM CHLORIDE + BICARBONATE</b> , macrogol-3350 13.12 g + sodium chloride 350.7 mg + potassium chloride 46.6 mg (0.63 mmol potassium) + sodium bicarbonate 178.5 mg solution, 30 sachets	QA	RF
5390Q	<i>Chemists' Own Macrogol with Electrolytes</i> – <b>MACROGOL-3350 + SODIUM CHLORIDE + POTASSIUM CHLORIDE + BICARBONATE</b> , macrogol-3350 13.12 g + sodium chloride 350.7 mg + potassium chloride 46.6 mg (0.63 mmol potassium) + sodium bicarbonate 178.5 mg solution, 30 sachets	FM	RW
5390Q	<i>Macrovic</i> – <b>MACROGOL-3350 + SODIUM CHLORIDE + POTASSIUM CHLORIDE + BICARBONATE</b> , macrogol-3350 13.12 g + sodium chloride 350.7 mg + potassium chloride 46.6 mg (0.63 mmol potassium) + sodium bicarbonate 178.5 mg solution, 30 sachets	QA	RF

## Highly Specialised Drugs Program (Private Hospital) Additions

### Addition – Item

10630L	<b>DACLATASVIR</b> , daclatasvir 30 mg tablet, 28 ( <i>Daklinza</i> )
10643E	<b>DACLATASVIR</b> , daclatasvir 30 mg tablet, 28 ( <i>Daklinza</i> )
10631M	<b>DACLATASVIR</b> , daclatasvir 60 mg tablet, 28 ( <i>Daklinza</i> )
10644F	<b>DACLATASVIR</b> , daclatasvir 60 mg tablet, 28 ( <i>Daklinza</i> )
10653Q	<b>LEDIPASVIR + SOFOSBUVIR</b> , ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28 ( <i>Harvoni</i> )
10672Q	<b>LEDIPASVIR + SOFOSBUVIR</b> , ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28 ( <i>Harvoni</i> )
10679C	<b>LEDIPASVIR + SOFOSBUVIR</b> , ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28 ( <i>Harvoni</i> )
10674T	<b>PEGINTERFERON ALFA-2A (&amp;) RIBAVIRIN</b> , peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [140 tablets], 1 pack ( <i>Pegasys RBV</i> )
10662E	<b>PEGINTERFERON ALFA-2A (&amp;) RIBAVIRIN</b> , peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [168 tablets], 1 pack ( <i>Pegasys RBV</i> )
10623D	<b>RIBAVIRIN</b> , ribavirin 400 mg tablet, 28 ( <i>Ibavyr</i> )
10635R	<b>RIBAVIRIN</b> , ribavirin 400 mg tablet, 28 ( <i>Ibavyr</i> )
10637W	<b>RIBAVIRIN</b> , ribavirin 600 mg tablet, 28 ( <i>Ibavyr</i> )
10675W	<b>RIBAVIRIN</b> , ribavirin 600 mg tablet, 28 ( <i>Ibavyr</i> )
10654R	<b>SOFOSBUVIR</b> , sofosbuvir 400 mg tablet, 28 ( <i>Sovaldi</i> )
10676X	<b>SOFOSBUVIR</b> , sofosbuvir 400 mg tablet, 28 ( <i>Sovaldi</i> )

## Alterations

### Alteration – Restriction

The following items have additions, deletions or alterations to restrictions, notes and/or cautions.

6280M	<b>VALACICLOVIR</b> , valaciclovir 500 mg tablet, 100 ( <i>APO-Valaciclovir, Valaciclovir RBX, Valtrex, Zelitrex</i> )
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### Alteration – Manufacturer Code

		<i>From</i>	<i>To</i>
6249X	<i>Liposomal Doxorubicin SUN</i> – <b>DOXORUBICIN HYDROCHLORIDE-PEGYLATED LIPOSOMAL</b> , doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial	ZF	RA
6227R	<i>Octreotide (SUN)</i> – <b>OCTREOTIDE</b> , octreotide 50 microgram/mL injection, 5 x 1 mL ampoules	ZF	RA
6228T	<i>Octreotide (SUN)</i> – <b>OCTREOTIDE</b> , octreotide 100 microgram/mL injection, 5 x 1 mL ampoules	ZF	RA
6229W	<i>Octreotide (SUN)</i> – <b>OCTREOTIDE</b> , octreotide 500 microgram/mL injection, 5 x 1 mL ampoules	ZF	RA

### Advance Notices

**1 April 2016**

#### Deletion – Brand

9607P	<i>Apomine, HH</i> – <b>APOMORPHINE</b> , apomorphine hydrochloride 20 mg/2 mL injection, 5 x 2 mL ampoules
9640J	<i>Apomine, HH</i> – <b>APOMORPHINE</b> , apomorphine hydrochloride 50 mg/5 mL injection, 5 x 5 mL ampoules

### Highly Specialised Drugs Program (Public Hospital) Additions

#### Addition – Item

10629K	<b>DACLATASVIR</b> , daclatasvir 30 mg tablet, 28 ( <i>Daklinza</i> )
10651N	<b>DACLATASVIR</b> , daclatasvir 30 mg tablet, 28 ( <i>Daklinza</i> )
10641C	<b>DACLATASVIR</b> , daclatasvir 60 mg tablet, 28 ( <i>Daklinza</i> )
10660C	<b>DACLATASVIR</b> , daclatasvir 60 mg tablet, 28 ( <i>Daklinza</i> )
10661D	<b>LEDIPASVIR + SOFOSBUVIR</b> , ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28 ( <i>Harvoni</i> )
10667K	<b>LEDIPASVIR + SOFOSBUVIR</b> , ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28 ( <i>Harvoni</i> )
10669M	<b>LEDIPASVIR + SOFOSBUVIR</b> , ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28 ( <i>Harvoni</i> )
10664G	<b>PEGINTERFERON ALFA-2A (&amp;) RIBAVIRIN</b> , peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [140 tablets], 1 pack ( <i>Pegasys RBV</i> )
10655T	<b>PEGINTERFERON ALFA-2A (&amp;) RIBAVIRIN</b> , peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [168 tablets], 1 pack ( <i>Pegasys RBV</i> )
10646H	<b>RIBAVIRIN</b> , ribavirin 400 mg tablet, 28 ( <i>Ibavyr</i> )
10678B	<b>RIBAVIRIN</b> , ribavirin 400 mg tablet, 28 ( <i>Ibavyr</i> )
10638X	<b>RIBAVIRIN</b> , ribavirin 600 mg tablet, 28 ( <i>Ibavyr</i> )
10663F	<b>RIBAVIRIN</b> , ribavirin 600 mg tablet, 28 ( <i>Ibavyr</i> )
10625F	<b>SOFOSBUVIR</b> , sofosbuvir 400 mg tablet, 28 ( <i>Sovaldi</i> )
10648K	<b>SOFOSBUVIR</b> , sofosbuvir 400 mg tablet, 28 ( <i>Sovaldi</i> )

### Alterations

#### Alteration – Restriction

The following items have additions, deletions or alterations to restrictions, notes and/or cautions.

10200W	<b>SIMEPREVIR</b> , simeprevir sodium 150 mg capsule, 7 ( <i>Olysio</i> )
9568N	<b>VALACICLOVIR</b> , valaciclovir 500 mg tablet, 100 ( <i>APO-Valaciclovir, Valaciclovir RBX, Valtrex, Zelitrex</i> )

#### Alteration – Restriction Level

		<i>From</i>	<i>To</i>
10200W	<b>SIMEPREVIR</b> , simeprevir sodium 150 mg capsule, 7 ( <i>Olysio</i> )	streamlined	authority-required

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### Alteration – Manufacturer Code

		<i>From</i>	<i>To</i>
5705G	<i>Liposomal Doxorubicin SUN</i> – <b>DOXORUBICIN HYDROCHLORIDE-PEGYLATED LIPOSOMAL</b> , doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial	ZF	RA
9508K	<i>Octreotide (SUN)</i> – <b>OCTREOTIDE</b> , octreotide 50 microgram/mL injection, 5 x 1 mL ampoules	ZF	RA
9509L	<i>Octreotide (SUN)</i> – <b>OCTREOTIDE</b> , octreotide 100 microgram/mL injection, 5 x 1 mL ampoules	ZF	RA
9510M	<i>Octreotide (SUN)</i> – <b>OCTREOTIDE</b> , octreotide 500 microgram/mL injection, 5 x 1 mL ampoules	ZF	RA

### Advance Notices

**1 April 2016**

#### Deletion – Brand

5609F	<i>Apomine, HH</i> – <b>APOMORPHINE</b> , apomorphine hydrochloride 20 mg/2 mL injection, 5 x 2 mL ampoules
5610G	<i>Apomine, HH</i> – <b>APOMORPHINE</b> , apomorphine hydrochloride 50 mg/5 mL injection, 5 x 5 mL ampoules

### Repatriation Pharmaceutical Benefits Additions

#### Addition – Brand

4170L	<i>Prodeinextra, SW</i> – <b>PARACETAMOL + CODEINE</b> , paracetamol 500 mg + codeine phosphate 15 mg tablet, 20
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#### Deletions

##### Deletion – Item

4918W	<b>DRESSING HYDROACTIVE CAVITY WOUND</b> , dressing hydroactive cavity wound 5 cm x 6 cm dressing, 10 ( <i>Allewyn Plus Cavity 66047571</i> )
4919X	<b>DRESSING HYDROACTIVE CAVITY WOUND</b> , dressing hydroactive cavity wound 10 cm x 10 cm dressing, 5 ( <i>Allewyn Plus Cavity 66047573</i> )

##### Deletion – Brand

4170L	<i>Prodeine 15, SW</i> – <b>PARACETAMOL + CODEINE</b> , paracetamol 500 mg + codeine phosphate 15 mg tablet, 20
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### Alterations

#### Alteration – Restriction

The following items have additions, deletions or alterations to restrictions, notes and/or cautions.

2194L	<b>ALENDRONATE + COLECALCIFEROL</b> , alendronate 70 mg + colecalciferol 70 microgram tablet, 4 ( <i>Alendronate plus D3-DRLA, FonatPlus, Fosamax Plus</i> )
2224C	<b>ALENDRONATE + COLECALCIFEROL</b> , alendronate 70 mg + colecalciferol 140 microgram tablet, 4 ( <i>Alendronate plus D3-DRLA, FonatPlus, Fosamax Plus 70 mg/140 mcg</i> )
2273P	<b>ALENDRONATE + COLECALCIFEROL (&amp;) CALCIUM CARBONATE</b> , alendronate 70 mg + colecalciferol 140 microgram tablet [4] (&) calcium (as carbonate) 500 mg tablet [48], 1 pack ( <i>Fosamax Plus D-Cal</i> )
2191H	<b>RISEDRONATE</b> , RISEDRONATE SODIUM Tablet 35 mg (enteric coated), 4 ( <i>Actonel EC</i> )
4443W	<b>RISEDRONATE</b> , risedronate sodium 5 mg tablet, 28 ( <i>Actonel</i> )
4444X	<b>RISEDRONATE</b> , risedronate sodium 35 mg tablet, 4 ( <i>APO-Risedronate, Acris Once-a-Week, Risedro once a week, Risedronate AN, Risedronate Sandoz, Risedronate-GA</i> )
2220W	<b>RISEDRONATE (&amp;) CALCIUM CARBONATE</b> , 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 ( <i>Actonel EC Combi</i> )
4059P	<b>RISEDRONATE (&amp;) CALCIUM CARBONATE</b> , risedronate sodium 35 mg tablet [4] (&) calcium (as carbonate) 500

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mg tablet [24], 28 (*Acris Combi*)

2254P **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 (*Actonel EC Combi D*)

**Alteration – Manufacturer Code**

		<i>From</i>	<i>To</i>
4115N	<i>Zedd 500</i> – <b>AZITHROMYCIN</b> , azithromycin 500 mg tablet, 3	QA	RW
4198Y	<i>Chemists' Own Laxative with Senna</i> – <b>DOCUSATE + SENNOSIDES</b> , docusate sodium 50 mg + sennosides 11.27 mg tablet, 90	AS	RW
4233T	<i>Finnacar</i> – <b>FINASTERIDE</b> , finasteride 5 mg tablet, 30	QA	RW
4497Q	<i>Z.S.C.</i> – <b>ZINC OXIDE + MAIZE STARCH + CHLORPHENESIN + TALC-PURIFIED</b> , zinc oxide 25% (250 mg/g) + maize starch 55.85% (558.5 mg/g) + chlorphenesin 1% (10 mg/g) + talc-purified 18.07% (180.7 mg/g) powder: dusting, 100 g	QA	RW

# General Pharmaceutical Benefits

## ■ ACICLOVIR

### Restricted benefit

Herpes simplex keratitis

### aciclovir 3% eye ointment, 4.5 g

5501M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
OP	‡1	..	..	37.41	38.30	Acivision [DZ]	Zovirax [GK]

## ■ ACICLOVIR

### Authority required (STREAMLINED)

**5946**

Advanced human immunodeficiency virus (HIV) disease

Clinical criteria:

Patient must have CD4 cell counts of less than 150 million per litre.

### aciclovir 800 mg tablet, 120

8234J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	143.68	38.30	Acyclo-V 800 [AF]

## ■ ACICLOVIR

**Note** Shared Care Model:

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

### Restricted benefit

Herpes simplex keratitis

### aciclovir 3% eye ointment, 4.5 g

1002R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	‡1	..	..	37.41	38.30	Acivision [DZ]	Zovirax [GK]

## ■ ACICLOVIR

**Note** Aciclovir 200 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

### Authority required (STREAMLINED)

**5942**

Recurrent moderate to severe genital herpes

Treatment Phase: Episodic treatment or suppressive therapy

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

### aciclovir 200 mg tablet, 90

1007B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	42.55	38.30	<sup>a</sup> Aciclovir 200 [CR] <sup>a</sup> Aciclovir Sandoz [HX] <sup>a</sup> Chem mart Aciclovir [CH] <sup>a</sup> Lovir [GN] <sup>a</sup> Terry White Chemists Aciclovir [TW]	<sup>a</sup> Aciclovir GH [GQ] <sup>a</sup> Acyclo-V 200 [AF] <sup>a</sup> GenRx Aciclovir [GX] <sup>a</sup> Ozvir [RA]
			<sup>b</sup> 1.19	43.74	38.30	<sup>a</sup> Zovirax 200 mg [GK]	

## ■ ACICLOVIR

**Note** This drug is only effective if commenced within 72 hours of onset of rash.

**Note** Aciclovir 800 mg is not PBS-subsidised for herpes simplex or chickenpox.

**Note** No applications for repeats will be authorised.

**Authority required (STREAMLINED)**

**5967**

Herpes zoster

Clinical criteria:

The treatment must be administered within 72 hours of the onset of the rash.

**Authority required (STREAMLINED)**

**5959**

Herpes zoster ophthalmicus

**aciclovir 800 mg tablet, 35**

1052J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	49.29	38.30	<sup>a</sup> Aciclovir 800 [CR]	<sup>a</sup> Aciclovir Sandoz [HX]
						<sup>a</sup> Acyclo-V 800 [AF]	<sup>a</sup> GenRx Aciclovir [GX]
				<sup>b</sup> 0.59	49.88	38.30	<sup>a</sup> Zovirax 800 mg [GK]

■ **ACICLOVIR**

**Note** Aciclovir 200 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

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

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

**Note** For item codes 1003T and 1555W, pharmaceutical benefits that have the form tablet 200 mg are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

**5936**

Initial moderate to severe genital herpes

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**aciclovir 200 mg tablet, 25**

1003T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	..	..	*28.27	29.44	<sup>a</sup> Aciclovir Sandoz [HX]	<sup>a</sup> Acyclo-V 200 [AF]
						<sup>a</sup> Lovir [GN]	
				<sup>b</sup> 1.42	*29.69	29.44	<sup>a</sup> Zovirax 200 mg [GK]

**aciclovir 200 mg tablet, 50**

1555W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	28.27	29.44	<sup>a</sup> GenRx Aciclovir [GX]

■ **AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERAL AND TRACE ELEMENTS WITHOUT PHENYLALANINE**

**Restricted benefit**

Phenylketonuria

**amino acid formula with fat, carbohydrate, vitamins, mineral and trace elements without phenylalanine oral liquid: powder for, 30 x 34 g bottles**

10632N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*1539.45	38.30	PKU Easy Shake & Go [OH]

■ **AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES**

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

Clinical criteria:

The condition must not be isolated infant colic or reflux, AND

Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

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

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

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**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

Clinical criteria:

The condition must not be isolated infant colic or reflux.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

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

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

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**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

Clinical criteria:

The condition must not be isolated infant colic or reflux.

Population criteria:

Patient must be older than 24 months of age.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

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

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

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**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

Clinical criteria:

Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

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

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

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**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

Clinical criteria:

Patient must require an amino acid based formula as a component of a dietary elimination program.

Population criteria:

Patient must be 18 years of age or less.

Treatment criteria:

Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and  
(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and

(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

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**amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides  
oral liquid: powder for, 400 g**

10522T



Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8	5	..	*352.61	38.30	Alfamino Junior [NT]

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## ▪ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

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### **Authority required**

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must not be isolated infant colic or reflux, AND

Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

The name of the specialist and the date of birth of the patient must be included in the authority application.

### **Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must not be isolated infant colic or reflux, AND

Patient must have had failure to thrive prior to commencement with initial treatment.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

The name of the specialist and the date of birth of the patient must be included in the authority application.

### **Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must not be isolated infant colic or reflux.

Population criteria:

Patient must be older than 24 months of age.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

### **Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

### **Authority required**

Cows' milk anaphylaxis

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

### **Authority required**

Severe intestinal malabsorption including short bowel syndrome

Clinical criteria:

Patient must have failed to respond to protein hydrolysate formulae; OR

Patient must have been receiving parenteral nutrition.

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**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have responded to an initial course of PBS-subsidised treatment.

Population criteria:

Patient must be 18 years of age or less.

Treatment criteria:

Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

**amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides  
oral liquid: powder for, 400 g**

10527C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	8	5	..	*352.61	38.30	Alfamino Junior [NT]

■ **AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED  
FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES**

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

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**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must not be isolated infant colic or reflux, AND

Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must not be isolated infant colic or reflux, AND

Patient must have had failure to thrive prior to commencement with initial treatment.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must not be isolated infant colic or reflux.

Population criteria:

Patient must be older than 24 months of age.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Cows' milk anaphylaxis

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.  
The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe intestinal malabsorption including short bowel syndrome

Clinical criteria:

Patient must have failed to respond to protein hydrolysate formulae; OR

Patient must have been receiving parenteral nutrition.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have responded to an initial course of PBS-subsidised treatment.

Population criteria:

Patient must be 18 years of age or less.

Treatment criteria:

Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides oral liquid: powder for, 400 g**

2900P



Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8	5	..	*359.57	38.30	Alfamino [NT]

**AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES**

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

Clinical criteria:

The condition must not be isolated infant colic or reflux, AND

Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

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

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

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

Clinical criteria:

The condition must not be isolated infant colic or reflux.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

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

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

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

Clinical criteria:

The condition must not be isolated infant colic or reflux.

Population criteria:

Patient must be older than 24 months of age.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

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

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

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

Clinical criteria:

Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

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

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

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

Clinical criteria:

Patient must require an amino acid based formula as a component of a dietary elimination program.

Population criteria:

Patient must be 18 years of age or less.

Treatment criteria:

Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and

(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and

(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides oral liquid: powder for, 400 g**

2928D

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
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NP

8	5	..	*359.57	38.30	Alfamino [NT]
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▪ **CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE**

**Note** Continuing Therapy Only:

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

**Authority required (STREAMLINED)**

**5963**

Chronic stable plaque type psoriasis vulgaris

Clinical criteria:

The condition must be inadequately controlled with either a vitamin D analogue or potent topical corticosteroid as monotherapy, AND

Patient must require more than 30 grams of product per month.

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**betamethasone (as dipropionate) 0.05% + calcipotriol 0.005% gel, 60 g**

10075G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	1	..	72.35	38.30	Daivobet 50/500 gel [LO]

**■ CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE****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**

Chronic stable plaque type psoriasis vulgaris

Clinical criteria:

The condition must be inadequately controlled with either a vitamin D analogue or potent topical corticosteroid as monotherapy.

**calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% gel, 30 g**

5276G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	1	..	41.39	38.30	Daivobet 50/500 gel [LO]

**■ DACLATASVIR**

**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 hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 12 weeks.

**daclatasvir 30 mg tablet, 28**

10645G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	7813.54	38.30	Daklinza [BQ]

**daclatasvir 60 mg tablet, 28**

10642D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	7813.54	38.30	Daklinza [BQ]

**■ DACLATASVIR**

**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 hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 24 weeks.

**daclatasvir 30 mg tablet, 28**

10671P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	7813.54	38.30	Daklinza [BQ]

**daclatasvir 60 mg tablet, 28**

10659B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	7813.54	38.30	Daklinza [BQ]

**■ EMPAGLIFLOZIN**

**Note** Continuing Therapy Only:

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

**Note** This drug is not PBS subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

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**Authority required (STREAMLINED)**

**5629**

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin, AND

The treatment must be in combination with a sulfonylurea, AND

Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

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**Authority required (STREAMLINED)**

**4983**

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea, AND

Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

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**Authority required (STREAMLINED)**

**4991**

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with insulin, AND

Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

### empagliflozin 10 mg tablet, 30

10206E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	60.97	38.30	Jardiance [BY]

### empagliflozin 25 mg tablet, 30

10202Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	60.97	38.30	Jardiance [BY]

## ▪ EMPAGLIFLOZIN + METFORMIN

**Note** A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Note** This fixed dose combination is not PBS-subsidised for use in combination with a sulfonylurea (triple oral therapy), as initial therapy or in combination with an insulin, a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

#### Authority required (STREAMLINED)

**5953**

Diabetes mellitus type 2

Clinical criteria:

Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

### empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60

10640B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	64.45	38.30	Jardiamet 12.5 mg/1000 mg [BY]

### empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60

10639Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	62.76	38.30	Jardiamet 12.5 mg/500 mg [BY]

### empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60

10649L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	64.45	38.30	Jardiamet 5 mg/1000 mg [BY]

### empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60

10650M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	62.76	38.30	Jardiamet 5 mg/500 mg [BY]

## ▪ EMPAGLIFLOZIN + METFORMIN

**Note** Continuing Therapy Only:

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

#### Authority required (STREAMLINED)

**5966**

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and empagliflozin.

**Note** This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

**Authority required (STREAMLINED)**

**5798**

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with a sulfonylurea, AND

Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Note** This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

**Authority required (STREAMLINED)**

**5657**

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with insulin, AND

Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.


Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.


The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**Note** This fixed dose combination is not PBS-subsidised as initial therapy or for use in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

**empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60**

10677Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	64.45	38.30	Jardiamet 12.5 mg/1000 mg [BY]

**empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60**

10633P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	62.76	38.30	Jardiamet 12.5 mg/500 mg [BY]

**empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60**

10627H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	64.45	38.30	Jardiamet 5 mg/1000 mg [BY]

**empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60**

10626G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	62.76	38.30	Jardiamet 5 mg/500 mg [BY]

**■ FAMCICLOVIR**

**Note** Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

**Authority required (STREAMLINED)****5971**

Recurrent moderate to severe genital herpes

Treatment Phase: Suppressive therapy

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**famciclovir 250 mg tablet, 56**

8217L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	119.47	38.30	<sup>a</sup> APO-Famciclovir [TX] <sup>a</sup> Ezovir [AF] <sup>a</sup> Famciclovir-GA [ED]  <sup>a</sup> Famciclovir Sandoz [SZ] <sup>a</sup> Famlo [RA] <sup>a</sup> Favic 250 [RW]	<sup>a</sup> Auro-Famciclovir 250 [DO] <sup>a</sup> Famciclovir AN [EA] <sup>a</sup> Famciclovir generichealth 250 [GQ] <sup>a</sup> Famciclovir SCP 250 [CR] <sup>a</sup> Famvir [NV]

**■ FAMCICLOVIR**

**Note** Famciclovir 125 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

**Note** Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

**Authority required (STREAMLINED)****5937**

Recurrent moderate to severe genital herpes

Treatment Phase: Episodic treatment

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**famciclovir 125 mg tablet, 40**

8092X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	1	..	49.36	38.30	<sup>a</sup> APO-Famciclovir [TX] <sup>a</sup> Ezovir [AF] <sup>a</sup> Famciclovir-GA [ED] <sup>a</sup> Favic 125 [RW]	<sup>a</sup> Auro-Famciclovir 125 [DO] <sup>a</sup> Famciclovir AN [EA] <sup>a</sup> Famvir [NV]

**famciclovir 250 mg tablet, 20**

2274Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	1	..	49.36	38.30	<sup>a</sup> APO-Famciclovir [TX] <sup>a</sup> Famciclovir AN [EA] <sup>a</sup> Famciclovir Sandoz [SZ] <sup>a</sup> Favic 250 [RW]	<sup>a</sup> Ezovir [AF] <sup>a</sup> Famciclovir-GA [ED] <sup>a</sup> Famvir [NV]

**■ FAMCICLOVIR**

**Note** This drug is only effective if commenced within 72 hours of onset of rash.

**Note** Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

**Note** No applications for repeats will be authorised.

**Authority required (STREAMLINED)****5951**

Herpes zoster

Clinical criteria:

The treatment must be administered within 72 hours of the onset of the rash.

**famciclovir 250 mg tablet, 21**

8002E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	51.31	38.30	<sup>a</sup> APO-Famciclovir [TX] <sup>a</sup> Ezovir [AF] <sup>a</sup> Famciclovir-GA [ED]  <sup>a</sup> Famciclovir Sandoz [SZ] <sup>a</sup> Famlo [RA] <sup>a</sup> Favic 250 [RW]	<sup>a</sup> Auro-Famciclovir 250 [DO] <sup>a</sup> Famciclovir AN [EA] <sup>a</sup> Famciclovir generichealth 250 [GQ] <sup>a</sup> Famciclovir SCP 250 [CR] <sup>a</sup> Famvir [NV]

## ■ FAMCICLOVIR

**Note** This drug is only effective if commenced within 72 hours of onset of rash.

**Note** Famciclovir 500 mg is not PBS-subsidised for chickenpox.

**Note** Famciclovir 500 mg is not PBS-subsidised for herpes zoster, genital herpes or other herpes simplex infections in immunocompetent patients.

**Note** No applications for repeats will be authorised.

### Authority required (STREAMLINED)

**5943**

Herpes zoster

Clinical criteria:

Patient must be immunocompromised, AND

The treatment must be administered within 72 hours of the onset of the rash.

### famciclovir 500 mg tablet, 30

8897G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	68.84	38.30	<sup>a</sup> APO-Famciclovir [TX] <sup>a</sup> Chem mart Famciclovir [CH] <sup>a</sup> Famciclovir Sandoz [SZ] <sup>a</sup> Favic 500 [RW]	<sup>a</sup> Auro-Famciclovir 500 [DO] <sup>a</sup> Famciclovir AN [EA] <sup>a</sup> Famvir [NV] <sup>a</sup> Terry White Chemists Famciclovir [TW]

## ■ FAMCICLOVIR

**Note** Famciclovir 500 mg is not PBS-subsidised for chickenpox.

**Note** Famciclovir 500 mg is not PBS-subsidised for herpes zoster, genital herpes or other herpes simplex infections in immunocompetent patients.

### Authority required (STREAMLINED)

**5954**

Recurrent moderate to severe genital herpes

Treatment Phase: Episodic treatment or suppressive therapy

Clinical criteria:

Patient must be immunocompromised.

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

### Authority required (STREAMLINED)

**5947**

Recurrent moderate to severe oral or labial herpes

Treatment Phase: Episodic treatment

Clinical criteria:

Patient must have HIV infection, AND

Patient must have a CD4 cell count of less than 500 million per litre.

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

### Authority required (STREAMLINED)

**5948**

Recurrent moderate to severe oral or labial herpes

Treatment Phase: Suppressive therapy

Clinical criteria:

Patient must have HIV infection, AND

Patient must have CD4 cell counts of less than 150 million per litre.

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

### Authority required (STREAMLINED)

**5949**

Recurrent moderate to severe oral or labial herpes

Treatment Phase: Suppressive therapy

Clinical criteria:

Patient must have HIV infection, AND

Patient must present with other opportunistic infections or AIDS defining tumours.

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

### famciclovir 500 mg tablet, 56

8896F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	119.47	38.30	<sup>a</sup> APO-Famciclovir [TX] <sup>a</sup> Chem mart Famciclovir [CH] <sup>a</sup> Famciclovir AN [EA]	<sup>a</sup> Auro-Famciclovir 500 [DO] <sup>a</sup> Ezovir [AF] <sup>a</sup> Famciclovir-GA [ED]

<sup>a</sup> Famciclovir generichealth 500 [GQ]    <sup>a</sup> Famciclovir Sandoz [SZ]  
<sup>a</sup> Famvir [NV]    <sup>a</sup> Favic 500 [RW]  
<sup>a</sup> Terry White Chemists  
Famciclovir [TW]

## ▪ FOLINIC ACID

### Restricted benefit

Megaloblastic anaemias

Clinical criteria:

The condition must be a result of folic acid deficiency from the use of folic acid antagonists.

### folinic acid 15 mg tablet, 10

2308L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	92.14	38.30	Leucovorin Calcium (Hospira Pty Limited) [HH]

## ▪ GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS

### Restricted benefit

Phenylketonuria

### glycomacropeptide and essential amino acids with vitamins and minerals oral liquid: powder for, 30 x 49 g sachets

10652P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*1569.97	38.30	Camino Pro Bettermilk [QH]

## ▪ LEDIPASVIR + SOFOSBUVIR

**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 hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 12 weeks.

### ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28

10628J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	22213.54	38.30	Harvoni [GI]

## ▪ LEDIPASVIR + SOFOSBUVIR

**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 hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 8 weeks.

### ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28

10668L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	22213.54	38.30	Harvoni [GI]

## ▪ LEDIPASVIR + SOFOSBUVIR

**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 hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 24 weeks.

**ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28**

10670N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	22213.54	38.30	Harvoni [GI]

▪ **LEUPRORELIN**

**Authority required (STREAMLINED)**

**5646**

Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate

**leuprorelin acetate 45 mg injection: modified release [1 syringe] (&) inert substance diluent [1 syringe], 1 pack**

10656W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	2123.34	38.30	Lucrin Depot 6-Month [VE]

▪ **NITRAZEPAM**

**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**

Myoclonic epilepsy

**Authority required**

Malignant neoplasia (late stage)

**Authority required**

Insomnia

Clinical criteria:

Patient must be receiving this drug for the management of insomnia, AND

Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, AND

Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**Authority required**

Insomnia

Clinical criteria:

Patient must be receiving this drug for the management of insomnia, AND

Patient must be receiving long-term nursing care, AND

Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult, AND

Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**nitrazepam 5 mg tablet, 25**

2732T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*13.65	14.82	<sup>a</sup> Alodorm [AF]
			<sup>b</sup> 2.48	*16.13	14.82	<sup>a</sup> Mogadon [IA]

▪ **PEGINTERFERON ALFA-2A (&) RIBAVIRIN**

**Caution** Ribavirin 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 during the 6 months period after cessation of treatment.

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

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

**Authority required**

Chronic hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 12 weeks.

Population criteria:

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [140 tablets], 1 pack**

10636T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1756.22	38.30	Pegasys RBV [RO]

**peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [168 tablets], 1 pack**

10634Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1839.30	38.30	Pegasys RBV [RO]

▪ **PROTEIN FORMULA WITH AMINO ACIDS, CARBOHYDRATES, VITAMINS AND MINERALS WITHOUT PHENYLALANINE, AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID**

Restricted benefit

Phenylketonuria

**protein formula with amino acids, carbohydrates, vitamins and minerals without phenylalanine, and supplemented with docosahexaenoic acid oral liquid, 30 x 130 mL pouches**

10658Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*1538.61	38.30	PKU Easy [OH]

▪ **RIBAVIRIN**

**Caution** Ribavirin 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 during the 6 months period after cessation of treatment.

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

Authority required

Chronic hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND The treatment must be limited to a maximum duration of 12 weeks.

Population criteria:

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**ribavirin 400 mg tablet, 28**

10647J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	160.95	38.30	Ibavyr [IX]

**ribavirin 600 mg tablet, 28**

10665H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	237.81	38.30	Ibavyr [IX]

▪ **RIBAVIRIN**

**Caution** Ribavirin 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 during the 6 months period after cessation of treatment.

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

Authority required

Chronic hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND The treatment must be limited to a maximum duration of 24 weeks.

Population criteria:

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**ribavirin 400 mg tablet, 28**

10673R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	160.95	38.30	Ibavyr [IX]

**ribavirin 600 mg tablet, 28**

10666J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	237.81	38.30	Ibavyr [IX]

▪ **SOFOSBUVIR**

**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 hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 12 weeks.

**sofosbuvir 400 mg tablet, 28**

10624E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	19444.62	38.30	Sovaldi [GI]

**▪ SOFOSBUVIR****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 hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 24 weeks.

**sofosbuvir 400 mg tablet, 28**

10657X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	19444.62	38.30	Sovaldi [GI]

**▪ TEMAZEPAM****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**

Malignant neoplasia (late stage)

**Authority required**

Insomnia

Clinical criteria:

Patient must be receiving this drug for the management of insomnia, AND

Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, AND

Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**Authority required**

Insomnia

Clinical criteria:


Patient must be receiving this drug for the management of insomnia, AND

Patient must be receiving long-term nursing care, AND

Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult, AND

Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**temazepam 10 mg tablet, 25**

2088X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*12.05	13.22	<sup>a</sup> APO-Temazepam [TX]	<sup>a</sup> Temaze [AF]
			<sup>b</sup> 6.96	*19.01	13.22	<sup>a</sup> Temtabs [FM]	
						<sup>a</sup> Normison [QA]	

**▪ VALACICLOVIR****Note** Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.**Authority required (STREAMLINED)****5940**

Recurrent moderate to severe genital herpes

Treatment Phase: Suppressing therapy

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

### valaciclovir 500 mg tablet, 30

5480K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	44.74	38.30	<sup>a</sup> APO-Valaciclovir [TX] <sup>a</sup> Shilova 500 [DO]  <sup>a</sup> Vaclovir [AF] <sup>a</sup> Valaciclovir AN [EA] <sup>a</sup> Valaciclovir generichealth [GQ] <sup>a</sup> Valaciclovir SZ [HX] <sup>a</sup> Valnir [OW] <sup>a</sup> Zelitrex [RF]	<sup>a</sup> Chem mart Valaciclovir [CH] <sup>a</sup> Terry White Chemists Valaciclovir [TW] <sup>a</sup> Valaciclovir Actavis [ED] <sup>a</sup> Valaciclovir GA [GN] <sup>a</sup> Valaciclovir RBX [RA] <sup>a</sup> Valacor 500 [CR] <sup>a</sup> Valtrex [RW]

#### ■ VALACICLOVIR

**Note** Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

##### Authority required (STREAMLINED)

**5961**

Recurrent moderate to severe genital herpes

Treatment Phase: Episodic treatment

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

### valaciclovir 500 mg tablet, 30

8134D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	44.74	38.30	<sup>a</sup> APO-Valaciclovir [TX] <sup>a</sup> Shilova 500 [DO]  <sup>a</sup> Vaclovir [AF] <sup>a</sup> Valaciclovir AN [EA] <sup>a</sup> Valaciclovir generichealth [GQ] <sup>a</sup> Valaciclovir Sandoz [SZ] <sup>a</sup> Valacor 500 [CR] <sup>a</sup> Valtrex [RW]	<sup>a</sup> Chem mart Valaciclovir [CH] <sup>a</sup> Terry White Chemists Valaciclovir [TW] <sup>a</sup> Valaciclovir Actavis [ED] <sup>a</sup> Valaciclovir GA [GN] <sup>a</sup> Valaciclovir RBX [RA] <sup>a</sup> Valaciclovir SZ [HX] <sup>a</sup> Valnir [OW] <sup>a</sup> Zelitrex [RF]

#### ■ VALACICLOVIR

**Note** Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

**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)

**5960**

Initial moderate to severe genital herpes

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

### valaciclovir 500 mg tablet, 10

8133C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	..	..	*33.31	34.48	<sup>a</sup> APO-Valaciclovir [TX] <sup>a</sup> Valaciclovir Actavis [ED] <sup>a</sup> Valaciclovir GA [GN] <sup>a</sup> Valnir [OW] <sup>a</sup> Zelitrex [RF]	<sup>a</sup> Vaclovir [AF] <sup>a</sup> Valaciclovir AN [EA] <sup>a</sup> Valaciclovir Sandoz [SZ] <sup>a</sup> Valtrex [RW]

#### ■ VALACICLOVIR

**Note** This drug is only effective if commenced within 72 hours of onset of rash.

**Note** Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

**Note** No applications for repeats will be authorised.

##### Authority required (STREAMLINED)

**5962**

Herpes zoster

Clinical criteria:

The treatment must be administered within 72 hours of the onset of the rash.

##### Authority required (STREAMLINED)

**5968**

Herpes zoster ophthalmicus

### valaciclovir 500 mg tablet, 42

8064K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	58.47	38.30	<sup>a</sup> APO-Valaciclovir [TX]	<sup>a</sup> Chem mart Valaciclovir [CH]

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<sup>a</sup> Terry White Chemists Valaciclovir [TW]	<sup>a</sup> Vavlovir [AF]
<sup>a</sup> Valaciclovir Actavis [ED]	<sup>a</sup> Valaciclovir AN [EA]
<sup>a</sup> Valaciclovir GA [GN]	<sup>a</sup> Valaciclovir generichealth [GQ]
<sup>a</sup> Valaciclovir RBX [RA]	<sup>a</sup> Valaciclovir Sandoz [SZ]
<sup>a</sup> Valacor 500 [CR]	<sup>a</sup> Valnir [OW]
<sup>a</sup> Valtrex [RW]	<sup>a</sup> Zelitrex [RF]

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# Highly Specialised Drugs Program (Private Hospital)

## ▪ DACLATASVIR

**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 hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 24 weeks.

### daclatasvir 30 mg tablet, 28

10630L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	7713.60	Daklinza [BQ]

### daclatasvir 60 mg tablet, 28

10631M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	7713.60	Daklinza [BQ]

## ▪ DACLATASVIR

**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 hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 12 weeks.

### daclatasvir 30 mg tablet, 28

10643E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	7713.60	Daklinza [BQ]

### daclatasvir 60 mg tablet, 28

10644F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	7713.60	Daklinza [BQ]

## ▪ LEDIPASVIR + SOFOSBUVIR

**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 hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 8 weeks.

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**ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28**

10653Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	1	..	22113.60	Harvoni [GI]

**▪ LEDIPASVIR + SOFOSBUVIR**

**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 hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 12 weeks.

**ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28**

10672Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	22113.60	Harvoni [GI]

**▪ LEDIPASVIR + SOFOSBUVIR**

**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 hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 24 weeks.

**ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28**

10679C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	22113.60	Harvoni [GI]

**▪ PEGINTERFERON ALFA-2A (&) RIBAVIRIN**

**Caution** Ribavirin 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 during the 6 months period after cessation of treatment.

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

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

**Authority required**

Chronic hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 12 weeks.

Population criteria:

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [140 tablets], 1 pack**

10674T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	1669.84	Pegasys RBV [RO]

**peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [168 tablets], 1 pack**

10662E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	1750.11	Pegasys RBV [RO]

**▪ RIBAVIRIN**

**Caution** Ribavirin 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 during the 6 months period after cessation of treatment.

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

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**Authority required**

Chronic hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND The treatment must be limited to a maximum duration of 12 weeks.

Population criteria:

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**ribavirin 400 mg tablet, 28**

10623D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	152.53	Ibavyr [IX]

**ribavirin 600 mg tablet, 28**

10675W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	225.33	Ibavyr [IX]

**▪ RIBAVIRIN**

**Caution** Ribavirin 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 during the 6 months period after cessation of treatment.

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

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**Authority required**

Chronic hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND The treatment must be limited to a maximum duration of 24 weeks.

Population criteria:

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**ribavirin 400 mg tablet, 28**

10635R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	152.53	Ibavyr [IX]

**ribavirin 600 mg tablet, 28**

10637W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	225.33	Ibavyr [IX]

**▪ SOFOSBUVIR**

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

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

**Note** Special Pricing Arrangements apply.

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**Authority required**

Chronic hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND The treatment must be limited to a maximum duration of 12 weeks.

**sofosbuvir 400 mg tablet, 28**

10654R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	19344.68	Sovaldi [GI]

**▪ SOFOSBUVIR**

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

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

**Note** Special Pricing Arrangements apply.

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**Authority required**

Chronic hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND The treatment must be limited to a maximum duration of 24 weeks.

**sofosbuvir 400 mg tablet, 28**

10676X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	19344.68	Sovaldi [GI]

▪ **VALACICLOVIR**

**Authority required**

Cytomegalovirus infection and disease

Treatment Phase: Prophylaxis

Clinical criteria:

Patient must have undergone a renal transplant, AND

Patient must be at risk of cytomegalovirus disease.

**valaciclovir 500 mg tablet, 100**

6280M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	2	..	*560.23	<sup>a</sup> APO-Valaciclovir [TX] <sup>a</sup> Valtrex [RW]	<sup>a</sup> Valaciclovir RBX [RA] <sup>a</sup> Zelitrex [RF]

# Highly Specialised Drugs Program (Public Hospital)

## ▪ DACLATASVIR

**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 hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 24 weeks.

### daclatasvir 30 mg tablet, 28

10629K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	7666.67	Daklinza [BQ]

### daclatasvir 60 mg tablet, 28

10641C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	7666.67	Daklinza [BQ]

## ▪ DACLATASVIR

**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 hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 12 weeks.

### daclatasvir 30 mg tablet, 28

10651N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	7666.67	Daklinza [BQ]

### daclatasvir 60 mg tablet, 28

10660C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	7666.67	Daklinza [BQ]

## ▪ LEDIPASVIR + SOFOSBUVIR

**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 hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 12 weeks.

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**ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28**

10661D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	22066.67	Harvoni [GI]

**▪ LEDIPASVIR + SOFOSBUVIR**

**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 hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 8 weeks.

**ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28**

10667K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	1	..	22066.67	Harvoni [GI]

**▪ LEDIPASVIR + SOFOSBUVIR**

**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 hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 24 weeks.

**ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28**

10669M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	22066.67	Harvoni [GI]

**▪ PEGINTERFERON ALFA-2A (&) RIBAVIRIN**

**Caution** Ribavirin 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 during the 6 months period after cessation of treatment.

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

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

**Authority required**

Chronic hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 12 weeks.

Population criteria:

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [140 tablets], 1 pack**

10664G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	1622.91	Pegasys RBV [RO]

**peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [168 tablets], 1 pack**

10655T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	1703.18	Pegasys RBV [RO]

**▪ RIBAVIRIN**

**Caution** Ribavirin 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 during the 6 months period after cessation of treatment.

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

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**Authority required**

Chronic hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND The treatment must be limited to a maximum duration of 24 weeks.

Population criteria:

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**ribavirin 400 mg tablet, 28**

10646H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	140.00	Ibavyr [IX]

**ribavirin 600 mg tablet, 28**

10638X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	210.00	Ibavyr [IX]

**▪ RIBAVIRIN**

**Caution** Ribavirin 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 during the 6 months period after cessation of treatment.

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

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**Authority required**

Chronic hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND The treatment must be limited to a maximum duration of 12 weeks.

Population criteria:

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**ribavirin 400 mg tablet, 28**

10678B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	140.00	Ibavyr [IX]

**ribavirin 600 mg tablet, 28**

10663F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	210.00	Ibavyr [IX]

**▪ SIMEPREVIR**

**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** Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

- (a) a nurse educator/counsellor for patients; and
- (b) 24-hour access by patients to medical advice; and
- (c) an established liver clinic.

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**Authority required**

Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease, AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, AND

The treatment must be in combination with peginterferon alfa and ribavirin, AND

The treatment must be limited to a maximum duration of 12 weeks, AND

The treatment must cease if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is 25 IU/mL or greater.

Population criteria:

Patient must be aged 18 years or older, AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised simeprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records.

**Authority required**

Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease, AND

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C, AND

The treatment must be in combination with peginterferon alfa and ribavirin, AND

The treatment must be limited to a maximum duration of 12 weeks, AND

The treatment must cease if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is 25 IU/mL or greater.

Population criteria:

Patient must be 18 years or older, AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised simeprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records.

**simeprevir sodium 150 mg capsule, 7**

10200W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	6	..	..	*14865.72	Olysio [JC]

▪ **SOFOSBUVIR**

**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 hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 12 weeks.

**sofosbuvir 400 mg tablet, 28**

10625F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	19297.75	Sovaldi [GI]

▪ **SOFOSBUVIR**

**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 hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 24 weeks.

**sofosbuvir 400 mg tablet, 28**

10648K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	19297.75	Sovaldi [GI]

▪ **VALACICLOVIR**

**Authority required (STREAMLINED)**

**5975**

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Cytomegalovirus infection and disease

Treatment Phase: Prophylaxis

Clinical criteria:

Patient must have undergone a renal transplant, AND

Patient must be at risk of cytomegalovirus disease.

**valaciclovir 500 mg tablet, 100**

9568N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	2	..	*532.00	<sup>a</sup> APO-Valaciclovir [TX] <sup>a</sup> Valtrex [RW]	<sup>a</sup> Valaciclovir RBX [RA] <sup>a</sup> Zelitrex [RF]

# Repatriation Pharmaceutical Benefits Scheme

## ■ ALENDRONATE + COLECALCIFEROL

### Authority required

Preservation of bone mineral density

Clinical criteria:

Patient must be on long-term glucocorticoid therapy, AND

Patient must be undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day, AND

Patient must be osteopenic (bone mineral density t-score of less than -1.0).

Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more.

### alendronate 70 mg + colecalciferol 140 microgram tablet, 4

2224C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	39.35	6.20	<sup>a</sup> Alendronate plus D3-DRLA [RZ]	<sup>a</sup> FonatPlus [AF]
			..	41.84	6.20	<sup>a</sup> Fosamax Plus 70 mg/140 mcg [MK]	

### alendronate 70 mg + colecalciferol 70 microgram tablet, 4

2194L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	39.35	6.20	<sup>a</sup> Alendronate plus D3-DRLA [RZ]	<sup>a</sup> FonatPlus [AF]
						<sup>a</sup> Fosamax Plus [MK]	

## ■ ALENDRONATE + COLECALCIFEROL (&) CALCIUM CARBONATE

### Authority required

Preservation of bone mineral density

Clinical criteria:

Patient must be on long-term glucocorticoid therapy, AND

Patient must be undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day, AND

Patient must be osteopenic (bone mineral density t-score of less than -1.0).

Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more.

### alendronate 70 mg + colecalciferol 140 microgram tablet [4] (&) calcium (as carbonate) 500 mg tablet [48], 1 pack

2273P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	44.67	6.20	Fosamax Plus D-Cal [MK]

## ■ RISEDRONATE

### Authority required

Preservation of bone mineral density

Clinical criteria:

Patient must be on long-term glucocorticoid therapy, AND

Patient must be undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day, AND

Patient must be osteopenic (bone mineral density t-score of less than -1.0).

Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more.

### RISEDRONATE SODIUM Tablet 35 mg (enteric coated), 4

2191H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	37.73	6.20	Actonel EC [UA]

**risedronate sodium 35 mg tablet, 4**

4444X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	37.73	6.20	<sup>a</sup> Acris Once-a-Week [AF] <sup>a</sup> Risedronate AN [EA] <sup>a</sup> Risedronate Sandoz [SZ]	<sup>a</sup> APO-Risedronate [TX] <sup>a</sup> Risedronate-GA [GN] <sup>a</sup> Risedro once a week [RW]

**risedronate sodium 5 mg tablet, 28**

4443W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	37.73	6.20	Actonel [UA]

**■ RISEDRONATE (&) CALCIUM CARBONATE****Authority required**

Preservation of bone mineral density

Clinical criteria:

Patient must be on long-term glucocorticoid therapy, AND

Patient must be undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day, AND

Patient must be osteopenic (bone mineral density t-score of less than -1.0).

Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more.

**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**

2220W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	44.89	6.20	Actonel EC Combi [UA]

**risedronate sodium 35 mg tablet [4] (&) calcium (as carbonate) 500 mg tablet [24], 28**

4059P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	44.89	6.20	Acris Combi [AF]

**■ RISEDRONATE (&) CALCIUM CARBONATE + COLECALCIFEROL****Authority required**

Preservation of bone mineral density

Clinical criteria:

Patient must be on long-term glucocorticoid therapy, AND

Patient must be undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day, AND

Patient must be osteopenic (bone mineral density t-score of less than -1.0).

Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more.

**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**

2254P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	44.89	6.20	Actonel EC Combi D [UA]

## General Statement for Drugs for the Treatment of Hepatitis C

Use the following criteria to determine patient eligibility for subsidisation under the PBS for hepatitis C treating agents. By writing a PBS prescription, the prescriber is certifying the patient satisfies the qualifying criteria set out below and the use in accordance with the registered indications which differ between agents in this class – refer to the current Product Information for details.

### Population criteria:

Patient must be aged 18 years or older.

### Treatment criteria:

Must be treated by a gastroenterologist, hepatologist or infectious diseases physician experienced in the treatment of chronic hepatitis C infection; or in consultation with a gastroenterologist, hepatologist or infectious diseases physician experienced in the treatment of chronic hepatitis C infection.

The following information must be provided at the time of application:

- the hepatitis C virus genotype; and
- the patient's cirrhotic status (non-cirrhotic or cirrhotic)

The following information must be documented in the patient's medical records:

- evidence of chronic hepatitis C infection (repeatedly antibody to hepatitis C virus (anti-HCV) positive and hepatitis C virus ribonucleic acid (HCV RNA) positive); and
- evidence of the hepatitis C virus genotype

The following matrices identify the regimens which are available for PBS prescription for eligible patients, based on the hepatitis C virus genotype and treatment history.

### HEPATITIS C - NON-CIRRHOTIC PATIENTS

	TREATMENT NAÏVE	TREATMENT EXPERIENCED
Genotype 1	LEDIPASVIR/SOFOSBUVIR [8 or 12 weeks] <sup>1</sup> OR DACLATASVIR and SOFOSBUVIR [12 weeks] OR SOFOSBUVIR and PEG-IFN/RBV [12 weeks]	LEDIPASVIR/SOFOSBUVIR [12 weeks] <sup>2</sup> OR DACLATASVIR and SOFOSBUVIR [12 or 24 weeks] <sup>3</sup> OR SOFOSBUVIR and PEG-IFN/RBV [12 weeks]
Genotype 2	SOFOSBUVIR and RBV [12 weeks]	SOFOSBUVIR and RBV [12 weeks]
Genotype 3	DACLATASVIR and SOFOSBUVIR [12 weeks] OR SOFOSBUVIR and RBV [24 weeks] OR SOFOSBUVIR and PEG-IFN/RBV [12 weeks]	DACLATASVIR and SOFOSBUVIR [12 weeks] <sup>4</sup> OR SOFOSBUVIR and RBV [24 weeks] OR SOFOSBUVIR and PEG-IFN/RBV [12 weeks]
Genotype 4, 5, 6	SOFOSBUVIR and PEG-IFN/RBV [12 weeks]	SOFOSBUVIR and PEG-IFN/RBV [12 weeks]

### KEY

PEG-IFN/RBV – peginterferon alfa-2a (&) ribavirin

RBV – ribavirin

<sup>1</sup> [LEDIPASVIR/SOFOSBUVIR] for treatment-naïve, non-cirrhotic patients:

- consider treatment for 8 weeks where pre-treatment HCV RNA is less than 6 million IU/mL;
- otherwise treatment for 12 weeks where pre-treatment HCV RNA is 6 million IU/mL or greater.

<sup>2</sup> A 12 weeks treatment regimen for [LEDIPASVIR/SOFOSBUVIR] for treatment-experienced, non-cirrhotic patients who have failed prior treatment with either:

- PEG-IFN alfa/RBV; or
- a HCV protease inhibitor + PEG-IFN alfa/RBV.

<sup>3</sup> [DACLATASVIR and SOFOSBUVIR] for treatment-experienced, non-cirrhotic patients:

- consider treatment for 12 weeks in patients who have failed PEG-IFN alfa/RBV; or
- consider treatment for 24 weeks in patients who have failed a protease inhibitor + PEG-IFN/RBV.

<sup>4</sup> [DACLATASVIR and SOFOSBUVIR] for treatment-experienced, non-cirrhotic patients, treatment for 12 weeks in patients:

- who have failed SOFOSBUVIR and RBV; or
- who have failed PEG IFN alfa/RBV.

## HEPATITIS C – CIRRHOTIC PATIENTS

	TREATMENT NAÏVE	TREATMENT EXPERIENCED
Genotype 1	LEDIPASVIR/SOFOSBUVIR [12 weeks] OR DACLATASVIR and SOFOSBUVIR and RBV [12 weeks] OR DACLATASVIR and SOFOSBUVIR [24 weeks] OR SOFOSBUVIR and PEG-IFN/RBV [12 weeks]	LEDIPASVIR/SOFOSBUVIR [24 weeks] <sup>1</sup> OR DACLATASVIR and SOFOSBUVIR [24 weeks] <sup>2</sup> OR DACLATASVIR and SOFOSBUVIR and RBV [12 weeks] <sup>3</sup> OR SOFOSBUVIR and PEG-IFN/RBV [12 weeks]
Genotype 2	SOFOSBUVIR and RBV [12 weeks]	SOFOSBUVIR and RBV [12 weeks]
Genotype 3	SOFOSBUVIR and RBV [24 weeks] OR DACLATASVIR and SOFOSBUVIR [24 weeks] OR SOFOSBUVIR and PEG-IFN/RBV [12 weeks]	DACLATASVIR and SOFOSBUVIR [24 weeks] <sup>4</sup> OR SOFOSBUVIR and RBV [24 weeks] OR SOFOSBUVIR and PEG-IFN/RBV [12 weeks]
Genotype 4, 5, 6	SOFOSBUVIR and PEG-IFN/RBV [12 weeks]	SOFOSBUVIR and PEG-IFN/RBV [12 weeks]

### KEY

PEG-IFN/RBV – peginterferon alfa-2a (&) ribavirin

RBV – ribavirin

<sup>1</sup> A 24 weeks treatment regimen for [LEDIPASVIR/SOFOSBUVIR] for treatment-experienced, cirrhotic patients who have failed prior treatment with either:

- PEG-IFN alfa/RBV; or
- a HCV protease inhibitor + PEG-IFN alfa/RBV.

<sup>2</sup> A 24 weeks treatment regimen for [DACLATASVIR and SOFOSBUVIR] for treatment-experienced, cirrhotic patients who have failed prior treatment with either:

- PEG-IFN alfa/RBV; or
- a HCV protease inhibitor and PEG-IFN/RBV.

<sup>3</sup> [DACLATASVIR and SOFOSBUVIR and RBV] for treatment-experienced cirrhotic patients:

- consider treatment for 12 weeks in patients who have failed PEG-IFN alfa/RBV.

<sup>4</sup> [DACLATASVIR and SOFOSBUVIR] for treatment-experienced cirrhotic patients, treatment for 24 weeks in patients:

- who have failed SOFOSBUVIR and RBV; or
- who have failed PEG IFN alfa/RBV.