



Australian Government

Department of Health and Ageing

**SCHEDULE OF PHARMACEUTICAL
BENEFITS**

SUMMARY OF CHANGES

EFFECTIVE 1 April 2013

PHARMACEUTICAL BENEFITS

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 April 2013. The Schedule is updated on the first day of each month and is available on the Internet at www.pbs.gov.au.

Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 April 2013 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	\$6.52
	Dangerous drug fee	\$2.71
	Extemporaneously-prepared	\$8.56
	Allowable additional patient charge*	\$4.11
Additional Fees (for safety net prices):	Ready-prepared	\$1.11
	Extemporaneously-prepared	\$1.45
Patient Co-payments:	General	\$36.10
	Concessional	\$5.90
Safety Net Thresholds:	General	\$1390.60
	Concessional	\$354.00
Safety Net Card Issue Fee:		\$9.06

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

SUMMARY OF CHANGES

Additions

Addition – Item

2416E	Levonorgestrel + Ethinylloestradiol , levonorgestrel 100 microgram + ethinylloestradiol 20 microgram tablet [84 tablets] (&) inert substance tablet [28 tablets], 112 [4 x 28 tablets] (<i>Femme-Tab ED 20/100</i>)
2385M	Rotigotine , rotigotine 2 mg/24 hours patch, 28 (<i>Neupro</i>)
2384L	Rotigotine , rotigotine 4 mg/24 hours patch, 28 (<i>Neupro</i>)
2410W	Rotigotine , rotigotine 6 mg/24 hours patch, 28 (<i>Neupro</i>)
2391W	Simvastatin + Sitagliptin , simvastatin 10 mg + sitagliptin 100 mg tablet: film-coated, 28 (<i>Juvicor</i>)
2377D	Simvastatin + Sitagliptin , simvastatin 20 mg + sitagliptin 100 mg tablet: film-coated, 28 (<i>Juvicor</i>)
2383K	Simvastatin + Sitagliptin , simvastatin 40 mg + sitagliptin 100 mg tablet: film-coated, 28 (<i>Juvicor</i>)

Addition – Brand

2751T	<i>Amlor 5, QA</i> – Amlodipine , amlodipine 5 mg tablet, 30
2752W	<i>Amlor 10, QA</i> – Amlodipine , amlodipine 10 mg tablet, 30
8495D	<i>APO-Donepezil, TX</i> – Donepezil , donepezil hydrochloride 5 mg tablet, 28
8495D	<i>Arazil, AF</i> – Donepezil , donepezil hydrochloride 5 mg tablet, 28
8495D	<i>Aridon 5, QA</i> – Donepezil , donepezil hydrochloride 5 mg tablet, 28
8495D	<i>Chem mart Donepezil, CH</i> – Donepezil , donepezil hydrochloride 5 mg tablet, 28
8495D	<i>Donepezil-DRLA, RZ</i> – Donepezil , donepezil hydrochloride 5 mg tablet, 28
8495D	<i>Donepezil-GA, GM</i> – Donepezil , donepezil hydrochloride 5 mg tablet, 28
8495D	<i>Donepezil generichealth, GQ</i> – Donepezil , donepezil hydrochloride 5 mg tablet, 28
8495D	<i>Donepezil RBX, RA</i> – Donepezil , donepezil hydrochloride 5 mg tablet, 28
8495D	<i>Donepezil Sandoz, SZ</i> – Donepezil , donepezil hydrochloride 5 mg tablet, 28
8495D	<i>Donepezil-Synthon, ZT</i> – Donepezil , donepezil hydrochloride 5 mg tablet, 28
8495D	<i>STADA Donepezil, TD</i> – Donepezil , donepezil hydrochloride 5 mg tablet, 28
8495D	<i>Terry White Chemists Donepezil, TW</i> – Donepezil , donepezil hydrochloride 5 mg tablet, 28
8496E	<i>APO-Donepezil, TX</i> – Donepezil , donepezil hydrochloride 10 mg tablet, 28
8496E	<i>Arazil, AF</i> – Donepezil , donepezil hydrochloride 10 mg tablet, 28
8496E	<i>Aridon 10, QA</i> – Donepezil , donepezil hydrochloride 10 mg tablet, 28
8496E	<i>Chem mart Donepezil, CH</i> – Donepezil , donepezil hydrochloride 10 mg tablet, 28
8496E	<i>Donepezil-DRLA, RZ</i> – Donepezil , donepezil hydrochloride 10 mg tablet, 28
8496E	<i>Donepezil-GA, GM</i> – Donepezil , donepezil hydrochloride 10 mg tablet, 28
8496E	<i>Donepezil generichealth, GQ</i> – Donepezil , donepezil hydrochloride 10 mg tablet, 28
8496E	<i>Donepezil RBX, RA</i> – Donepezil , donepezil hydrochloride 10 mg tablet, 28
8496E	<i>Donepezil Sandoz, SZ</i> – Donepezil , donepezil hydrochloride 10 mg tablet, 28
8496E	<i>Donepezil-Synthon, ZT</i> – Donepezil , donepezil hydrochloride 10 mg tablet, 28
8496E	<i>STADA Donepezil, TD</i> – Donepezil , donepezil hydrochloride 10 mg tablet, 28
8496E	<i>Terry White Chemists Donepezil, TW</i> – Donepezil , donepezil hydrochloride 10 mg tablet, 28
9155W	<i>Andepra, EL</i> – Duloxetine , duloxetine 30 mg capsule: enteric, 28
9155W	<i>APO-Duloxetine, TX</i> – Duloxetine , duloxetine 30 mg capsule: enteric, 28
9155W	<i>Chem mart Duloxetine, CH</i> – Duloxetine , duloxetine 30 mg capsule: enteric, 28
9155W	<i>Terry White Chemists Duloxetine, TW</i> – Duloxetine , duloxetine 30 mg capsule: enteric, 28
9156X	<i>Andepra, EL</i> – Duloxetine , duloxetine 60 mg capsule: enteric, 28
9156X	<i>APO-Duloxetine, TX</i> – Duloxetine , duloxetine 60 mg capsule: enteric, 28
9156X	<i>Chem mart Duloxetine, CH</i> – Duloxetine , duloxetine 60 mg capsule: enteric, 28
9156X	<i>Terry White Chemists Duloxetine, TW</i> – Duloxetine , duloxetine 60 mg capsule: enteric, 28
8101J	<i>Extavia, NV</i> – Interferon Beta-1b , interferon beta-1b 8 million international units (250 microgram) injection [15 x 250 microgram vials] (&) inert substance diluent [15 x 1.2 mL syringes], 1 pack
8246B	<i>Abisart, AF</i> – Irbesartan , irbesartan 75 mg tablet, 30
8246B	<i>APO-Irbesartan, TX</i> – Irbesartan , irbesartan 75 mg tablet, 30
8246B	<i>Chem mart Irbesartan, CH</i> – Irbesartan , irbesartan 75 mg tablet, 30
8246B	<i>Irbesartan-DRLA, RZ</i> – Irbesartan , irbesartan 75 mg tablet, 30
8246B	<i>Irbesartan-GA, GM</i> – Irbesartan , irbesartan 75 mg tablet, 30
8246B	<i>Irbesartan RBX, RA</i> – Irbesartan , irbesartan 75 mg tablet, 30
8246B	<i>Irbesartan Sandoz, SZ</i> – Irbesartan , irbesartan 75 mg tablet, 30
8246B	<i>Irbesartan Winthrop, WA</i> – Irbesartan , irbesartan 75 mg tablet, 30
8246B	<i>Irbesat, GQ</i> – Irbesartan , irbesartan 75 mg tablet, 30
8246B	<i>Karbesat 75, QA</i> – Irbesartan , irbesartan 75 mg tablet, 30
8246B	<i>Terry White Chemists Irbesartan, TW</i> – Irbesartan , irbesartan 75 mg tablet, 30
8247C	<i>Abisart, AF</i> – Irbesartan , irbesartan 150 mg tablet, 30

- 8247C *APO-Irbesartan, TX – Irbesartan*, irbesartan 150 mg tablet, 30
- 8247C *Chem mart Irbesartan, CH – Irbesartan*, irbesartan 150 mg tablet, 30
- 8247C *Irbesartan-DRLA, RZ – Irbesartan*, irbesartan 150 mg tablet, 30
- 8247C *Irbesartan-GA, GM – Irbesartan*, irbesartan 150 mg tablet, 30
- 8247C *Irbesartan RBX, RA – Irbesartan*, irbesartan 150 mg tablet, 30
- 8247C *Irbesartan Sandoz, SZ – Irbesartan*, irbesartan 150 mg tablet, 30
- 8247C *Irbesartan Winthrop, WA – Irbesartan*, irbesartan 150 mg tablet, 30
- 8247C *Irbesat, GQ – Irbesartan*, irbesartan 150 mg tablet, 30
- 8247C *Karbesat 150, QA – Irbesartan*, irbesartan 150 mg tablet, 30
- 8247C *Terry White Chemists Irbesartan, TW – Irbesartan*, irbesartan 150 mg tablet, 30
- 8248D *Abisart, AF – Irbesartan*, irbesartan 300 mg tablet, 30
- 8248D *APO-Irbesartan, TX – Irbesartan*, irbesartan 300 mg tablet, 30
- 8248D *Chem mart Irbesartan, CH – Irbesartan*, irbesartan 300 mg tablet, 30
- 8248D *Irbesartan-DRLA, RZ – Irbesartan*, irbesartan 300 mg tablet, 30
- 8248D *Irbesartan-GA, GM – Irbesartan*, irbesartan 300 mg tablet, 30
- 8248D *Irbesartan RBX, RA – Irbesartan*, irbesartan 300 mg tablet, 30
- 8248D *Irbesartan Sandoz, SZ – Irbesartan*, irbesartan 300 mg tablet, 30
- 8248D *Irbesartan Winthrop, WA – Irbesartan*, irbesartan 300 mg tablet, 30
- 8248D *Irbesat, GQ – Irbesartan*, irbesartan 300 mg tablet, 30
- 8248D *Karbesat 300, QA – Irbesartan*, irbesartan 300 mg tablet, 30
- 8248D *Terry White Chemists Irbesartan, TW – Irbesartan*, irbesartan 300 mg tablet, 30
- 8404H *Abisart HCT 150/12.5, AF – Irbesartan + Hydrochlorothiazide*, irbesartan 150 mg + hydrochlorothiazide 12.5 mg tablet, 30
- 8404H *APO-Irbesartan HCTZ, TX – Irbesartan + Hydrochlorothiazide*, irbesartan 150 mg + hydrochlorothiazide 12.5 mg tablet, 30
- 8404H *Chem mart Irbesartan HCTZ, CH – Irbesartan + Hydrochlorothiazide*, irbesartan 150 mg + hydrochlorothiazide 12.5 mg tablet, 30
- 8404H *Irbesartan/HCT Sandoz, SZ – Irbesartan + Hydrochlorothiazide*, irbesartan 150 mg + hydrochlorothiazide 12.5 mg tablet, 30
- 8404H *Irbesartan HCT Winthrop, WA – Irbesartan + Hydrochlorothiazide*, irbesartan 150 mg + hydrochlorothiazide 12.5 mg tablet, 30
- 8404H *Irbesartan HCTZ-GA, GM – Irbesartan + Hydrochlorothiazide*, irbesartan 150 mg + hydrochlorothiazide 12.5 mg tablet, 30
- 8404H *Irbesartan/HCTZ RBX 150/12.5, RA – Irbesartan + Hydrochlorothiazide*, irbesartan 150 mg + hydrochlorothiazide 12.5 mg tablet, 30
- 8404H *Irbesatzide 150/12.5, GQ – Irbesartan + Hydrochlorothiazide*, irbesartan 150 mg + hydrochlorothiazide 12.5 mg tablet, 30
- 8404H *KSART HCT 150/12.5, QA – Irbesartan + Hydrochlorothiazide*, irbesartan 150 mg + hydrochlorothiazide 12.5 mg tablet, 30
- 8404H *STADA Irbesartan HCT 150/12.5, TD – Irbesartan + Hydrochlorothiazide*, irbesartan 150 mg + hydrochlorothiazide 12.5 mg tablet, 30
- 8404H *Terry White Chemists Irbesartan HCTZ, TW – Irbesartan + Hydrochlorothiazide*, irbesartan 150 mg + hydrochlorothiazide 12.5 mg tablet, 30
- 8405J *Abisart HCT 300/12.5, AF – Irbesartan + Hydrochlorothiazide*, irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet, 30
- 8405J *APO-Irbesartan HCTZ, TX – Irbesartan + Hydrochlorothiazide*, irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet, 30
- 8405J *Chem mart Irbesartan HCTZ, CH – Irbesartan + Hydrochlorothiazide*, irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet, 30
- 8405J *Irbesartan/HCT Sandoz, SZ – Irbesartan + Hydrochlorothiazide*, irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet, 30
- 8405J *Irbesartan HCT Winthrop, WA – Irbesartan + Hydrochlorothiazide*, irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet, 30
- 8405J *Irbesartan HCTZ-GA, GM – Irbesartan + Hydrochlorothiazide*, irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet, 30
- 8405J *Irbesartan/HCTZ RBX 300/12.5, RA – Irbesartan + Hydrochlorothiazide*, irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet, 30
- 8405J *Irbesatzide 300/12.5, GQ – Irbesartan + Hydrochlorothiazide*, irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet, 30
- 8405J *KSART HCT 300/12.5, QA – Irbesartan + Hydrochlorothiazide*, irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet, 30
- 8405J *STADA Irbesartan HCT 300/12.5, TD – Irbesartan + Hydrochlorothiazide*, irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet, 30
- 8405J *Terry White Chemists Irbesartan HCTZ, TW – Irbesartan + Hydrochlorothiazide*, irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet, 30
- 2136K *Abisart HCT 300/25, AF – Irbesartan + Hydrochlorothiazide*, irbesartan 300 mg + hydrochlorothiazide 25 mg tablet, 30
- 2136K *APO-Irbesartan HCTZ, TX – Irbesartan + Hydrochlorothiazide*, irbesartan 300 mg + hydrochlorothiazide 25 mg tablet, 30
- 2136K *Chem mart Irbesartan HCTZ, CH – Irbesartan + Hydrochlorothiazide*, irbesartan 300 mg + hydrochlorothiazide 25 mg tablet, 30
- 2136K *Irbesartan/HCT Sandoz, SZ – Irbesartan + Hydrochlorothiazide*, irbesartan 300 mg + hydrochlorothiazide 25 mg tablet, 30
- 2136K *Irbesartan HCT Winthrop, WA – Irbesartan + Hydrochlorothiazide*, irbesartan 300 mg + hydrochlorothiazide 25 mg tablet, 30
- 2136K *Irbesartan HCTZ-GA, GM – Irbesartan + Hydrochlorothiazide*, irbesartan 300 mg + hydrochlorothiazide 25 mg tablet, 30
- 2136K *Irbesartan/HCTZ RBX 300/25, RA – Irbesartan + Hydrochlorothiazide*, irbesartan 300 mg + hydrochlorothiazide 25 mg tablet, 30
- 2136K *Irbesatzide 300/25, GQ – Irbesartan + Hydrochlorothiazide*, irbesartan 300 mg + hydrochlorothiazide 25 mg tablet, 30
- 2136K *KSART HCT 300/25, QA – Irbesartan + Hydrochlorothiazide*, irbesartan 300 mg + hydrochlorothiazide 25 mg tablet, 30
- 2136K *STADA Irbesartan HCT 300/25, TD – Irbesartan + Hydrochlorothiazide*, irbesartan 300 mg + hydrochlorothiazide 25 mg tablet, 30
- 2136K *Terry White Chemists Irbesartan HCTZ, TW – Irbesartan + Hydrochlorothiazide*, irbesartan 300 mg + hydrochlorothiazide 25 mg tablet, 30
- 8534E *Lercanidipine GH, GQ – Lercanidipine*, lercanidipine hydrochloride 10 mg tablet, 28
- 8679T *Lercanidipine GH, GQ – Lercanidipine*, lercanidipine hydrochloride 20 mg tablet, 28
- 1394J *Femme-Tab ED 30/150, AE – Levonorgestrel + Ethinylloestradiol*, levonorgestrel 150 microgram + ethinylloestradiol 30 microgram tablet [84 tablets] (&) inert substance tablet [28 tablets], 112 [4 x 28 tablets]
- 8043H *Zatamil, EO – Mometasone*, mometasone furoate 0.1% (1 mg/g) lotion, 30 mL
- 1915T *Zatamil, EO – Mometasone*, mometasone furoate 0.1% (1 mg/g) ointment, 15 g
- 1596B *Ondansetron Kabi, PK – Ondansetron*, ondansetron 4 mg/2 mL injection, 1 x 2 mL ampoule

8226Y	<i>Ondansetron Kabi, PK</i> – Ondansetron , ondansetron 4 mg/2 mL injection, 1 x 2 mL ampoule
1597C	<i>Ondansetron Kabi, PK</i> – Ondansetron , ondansetron 8 mg/4 mL injection, 1 x 4 mL ampoule
8227B	<i>Ondansetron Kabi, PK</i> – Ondansetron , ondansetron 8 mg/4 mL injection, 1 x 4 mL ampoule
8462J	<i>Pamidronate Strides, YA</i> – Pamidronate Disodium , pamidronate disodium 30 mg/10 mL injection, 1 x 10 mL vial
1849H	<i>APO-Sumatriptan, TX</i> – Sumatriptan , sumatriptan 50 mg tablet, 4
1849H	<i>Chem mart Sumatriptan, CH</i> – Sumatriptan , sumatriptan 50 mg tablet, 4
1849H	<i>Terry White Chemists Sumatriptan, TW</i> – Sumatriptan , sumatriptan 50 mg tablet, 4
1070H	<i>Betavit, PP</i> – Thiamine , thiamine hydrochloride 100 mg tablet, 100
2746M	<i>Tropisetron-AFT, AE</i> – Tropisetron , tropisetron 5 mg/5 mL injection, 1 x 5 mL ampoule

Addition – Equivalence Indicator

8496E	<i>Aricept, PF</i> – Donepezil , donepezil hydrochloride 10 mg tablet, 28
8495D	<i>Aricept, PF</i> – Donepezil , donepezil hydrochloride 5 mg tablet, 28
9155W	<i>Cymbalta, LY</i> – Duloxetine , duloxetine 30 mg capsule: enteric, 28
9156X	<i>Cymbalta, LY</i> – Duloxetine , duloxetine 60 mg capsule: enteric, 28
8101J	<i>Betaferon, BN</i> – Interferon Beta-1b , interferon beta-1b 8 million international units (250 microgram) injection [15 x 250 microgram vials] (&) inert substance diluent [15 x 1.2 mL syringes], 1 pack
2746M	<i>Navoban, NV</i> – Tropisetron , tropisetron 5 mg/5 mL injection, 1 x 5 mL ampoule

Deletions

Deletion – Item

1343Q	Amlodipine , amlodipine 5 mg tablet, 30 (<i>AmlO 5</i>)
1345T	Amlodipine , amlodipine 10 mg tablet, 30 (<i>AmlO 10</i>)

Deletion – Brand

8511Y	<i>Alendronate Pfizer, FZ</i> – Alendronate , alendronate 70 mg tablet, 4
1884E	<i>Amoxycillin-PS, FZ</i> – Amoxycillin , amoxycillin 250 mg capsule, 20
3301R	<i>Amoxycillin-PS, FZ</i> – Amoxycillin , amoxycillin 250 mg capsule, 20 (Dental)
1889K	<i>Amoxycillin-PS, FZ</i> – Amoxycillin , amoxycillin 500 mg capsule, 20
3300Q	<i>Amoxycillin-PS, FZ</i> – Amoxycillin , amoxycillin 500 mg capsule, 20 (Dental)
8179L	<i>Anastrozole-PS, FZ</i> – Anastrozole , anastrozole 1 mg tablet, 30
1081X	<i>Atenolol-PS, FZ</i> – Atenolol , atenolol 50 mg tablet, 30
2687K	<i>Azathioprine-PS, FZ</i> – Azathioprine , azathioprine 50 mg tablet, 100
8604W	<i>Bisoprolol Pfizer, FZ</i> – Bisoprolol , bisoprolol fumarate 2.5 mg tablet, 28
8605X	<i>Bisoprolol Pfizer, FZ</i> – Bisoprolol , bisoprolol fumarate 5 mg tablet, 28
8606Y	<i>Bisoprolol Pfizer, FZ</i> – Bisoprolol , bisoprolol fumarate 10 mg tablet, 28
2502Q	<i>Calcitriol-PS, FZ</i> – Calcitriol , calcitriol 0.25 microgram capsule, 100
3058Y	<i>Cephalexin-PS, FZ</i> – Cephalexin , cephalexin 250 mg capsule, 20
3317N	<i>Cephalexin-PS, FZ</i> – Cephalexin , cephalexin 250 mg capsule, 20 (Dental)
3119E	<i>Cephalexin-PS, FZ</i> – Cephalexin , cephalexin 500 mg capsule, 20
3318P	<i>Cephalexin-PS, FZ</i> – Cephalexin , cephalexin 500 mg capsule, 20 (Dental)
1209P	<i>Ciprofloxacin-PS, FZ</i> – Ciprofloxacin , ciprofloxacin 500 mg tablet, 14
1210Q	<i>Ciprofloxacin-PS, FZ</i> – Ciprofloxacin , ciprofloxacin 750 mg tablet, 14
8220P	<i>Citalopram Pfizer, FZ</i> – Citalopram , citalopram 20 mg tablet, 28
8703C	<i>Citalopram Pfizer, FZ</i> – Citalopram , citalopram 40 mg tablet, 28
8318T	<i>Clarithromycin-PS, FZ</i> – Clarithromycin , clarithromycin 250 mg tablet, 14
9354H	<i>Clopidogrel-PS, FZ</i> – Clopidogrel , clopidogrel 75 mg tablet, 28
1269T	<i>Cyproterone-PS, FZ</i> – Cyproterone , cyproterone acetate 50 mg tablet, 20
1270W	<i>Cyproterone-PS, FZ</i> – Cyproterone , cyproterone acetate 50 mg tablet, 50
8019C	<i>Cyproterone-PS 100, FZ</i> – Cyproterone , cyproterone acetate 100 mg tablet, 50
1335G	<i>Diltiazem-PS, FZ</i> – Diltiazem , diltiazem hydrochloride 60 mg tablet, 90
1370D	<i>Enalapril-PS, FZ</i> – Enalapril , enalapril maleate 5 mg tablet, 30
1368B	<i>Enalapril-PS, FZ</i> – Enalapril , enalapril maleate 10 mg tablet, 30
1369C	<i>Enalapril-PS, FZ</i> – Enalapril , enalapril maleate 20 mg tablet, 30
2487X	<i>Famotidine-PS, FZ</i> – Famotidine , famotidine 20 mg tablet, 60
2488Y	<i>Famotidine-PS, FZ</i> – Famotidine , famotidine 40 mg tablet, 30
1434L	<i>Fluoxetine-PS, FZ</i> – Fluoxetine , fluoxetine 20 mg capsule, 28
1417N	<i>Eulexin, MK</i> – Flutamide , flutamide 250 mg tablet, 100
2414C	<i>Frusemide-PS, FZ</i> – Frusemide , frusemide 20 mg tablet, 100
2412Y	<i>Frusemide-PS, FZ</i> – Frusemide , frusemide 40 mg tablet, 100
2436F	<i>Indapamide-PS, FZ</i> – Indapamide , indapamide hemihydrate 2.5 mg tablet, 90
1558B	<i>Isosorbide-PS, FZ</i> – Isosorbide Mononitrate , isosorbide mononitrate 60 mg tablet: modified release, 30 tablets
2592K	<i>Isotretinoin-PS, FZ</i> – Isotretinoin , isotretinoin 20 mg capsule, 60
2848X	<i>Lamotrigine-PS, FZ</i> – Lamotrigine , lamotrigine 25 mg tablet, 56

2849Y	<i>Lamotrigine-PS, FZ – Lamotrigine</i> , lamotrigine 50 mg tablet, 56
2850B	<i>Lamotrigine-PS, FZ – Lamotrigine</i> , lamotrigine 100 mg tablet, 56
2851C	<i>Lamotrigine-PS, FZ – Lamotrigine</i> , lamotrigine 200 mg tablet, 56
8245Y	<i>Letara, FZ – Letrozole</i> , letrozole 2.5 mg tablet, 30
8654L	<i>Levetiracetam Pfizer, FZ – Levetiracetam</i> , levetiracetam 250 mg tablet, 60
8655M	<i>Levetiracetam Pfizer, FZ – Levetiracetam</i> , levetiracetam 500 mg tablet, 60
8656N	<i>Levetiracetam Pfizer, FZ – Levetiracetam</i> , levetiracetam 1 g tablet, 60
2456G	<i>Lisinopril-PS, FZ – Lisinopril</i> , lisinopril 5 mg tablet, 30
2457H	<i>Lisinopril-PS, FZ – Lisinopril</i> , lisinopril 10 mg tablet, 30
2458J	<i>Lisinopril-PS, FZ – Lisinopril</i> , lisinopril 20 mg tablet, 30
8561N	<i>Meloxicam-PS, FZ – Meloxicam</i> , meloxicam 7.5 mg tablet, 30
8562P	<i>Meloxicam-PS, FZ – Meloxicam</i> , meloxicam 15 mg tablet, 30
2430X	<i>Metformin Pfizer, FZ – Metformin</i> , metformin hydrochloride 500 mg tablet, 100
1801T	<i>Metformin Pfizer, FZ – Metformin</i> , metformin hydrochloride 850 mg tablet, 60
8607B	<i>Metformin Pfizer, FZ – Metformin</i> , metformin hydrochloride 1 g tablet, 90
9365X	<i>Mirtazapine Pfizer, FZ – Mirtazapine</i> , mirtazapine 15 mg tablet, 30
8513C	<i>Mirtazapine Pfizer, FZ – Mirtazapine</i> , mirtazapine 30 mg tablet, 30
8883M	<i>Mirtazapine Pfizer, FZ – Mirtazapine</i> , mirtazapine 45 mg tablet, 30
8855C	<i>Mirtazapine Dispersible Pfizer, FZ – Mirtazapine</i> , MIRTAZAPINE Tablet 15 mg (orally disintegrating), 30
8856D	<i>Mirtazapine Dispersible Pfizer, FZ – Mirtazapine</i> , MIRTAZAPINE Tablet 30 mg (orally disintegrating), 30
8857E	<i>Mirtazapine Dispersible Pfizer, FZ – Mirtazapine</i> , MIRTAZAPINE Tablet 45 mg (orally disintegrating), 30
1900B	<i>Moclobemide-PS, FZ – Moclobemide</i> , moclobemide 150 mg tablet, 60
8003F	<i>Moclobemide-PS, FZ – Moclobemide</i> , moclobemide 300 mg tablet, 60
3010K	<i>Norfloxacin-PS, FZ – Norfloxacin</i> , norfloxacin 400 mg tablet, 14
8170B	<i>Olanzapine-PS, FZ – Olanzapine</i> , olanzapine 2.5 mg tablet, 28
8185T	<i>Olanzapine-PS, FZ – Olanzapine</i> , olanzapine 5 mg tablet, 28
8186W	<i>Olanzapine-PS, FZ – Olanzapine</i> , olanzapine 7.5 mg tablet, 28
8187X	<i>Olanzapine-PS, FZ – Olanzapine</i> , olanzapine 10 mg tablet, 28
3381Y	<i>PS Olanzapine ODT, FZ – Olanzapine</i> , OLANZAPINE Tablet 5 mg (orally disintegrating), 28
3382B	<i>PS Olanzapine ODT, FZ – Olanzapine</i> , OLANZAPINE Tablet 10 mg (orally disintegrating), 28
8331L	<i>Omeprazole-PS, FZ – Omeprazole</i> , omeprazole 20 mg tablet: enteric, 30 tablets
8333N	<i>Omeprazole-PS, FZ – Omeprazole</i> , omeprazole 20 mg tablet: enteric, 30 tablets
1594X	<i>Ondansetron Tabs Pfizer, FZ – Ondansetron</i> , ondansetron 4 mg tablet, 10
1595Y	<i>Ondansetron Tabs Pfizer, FZ – Ondansetron</i> , ondansetron 8 mg tablet, 10
8399C	<i>Pantoprazole-PS, FZ – Pantoprazole</i> , pantoprazole 20 mg tablet: enteric, 30 tablets
8007K	<i>Pantoprazole-PS, FZ – Pantoprazole</i> , pantoprazole 40 mg tablet: enteric, 30 tablets
8008L	<i>Pantoprazole-PS, FZ – Pantoprazole</i> , pantoprazole 40 mg tablet: enteric, 30 tablets
2242B	<i>Paroxetine-PS, FZ – Paroxetine</i> , paroxetine 20 mg tablet, 30
8694N	<i>Pioglitazone Pfizer, FZ – Pioglitazone</i> , pioglitazone 15 mg tablet, 28
8695P	<i>Pioglitazone Pfizer, FZ – Pioglitazone</i> , pioglitazone 30 mg tablet, 28
8696Q	<i>Pioglitazone Pfizer, FZ – Pioglitazone</i> , pioglitazone 45 mg tablet, 28
2833D	<i>Pravastatin-PS, FZ – Pravastatin</i> , pravastatin sodium 10 mg tablet, 30
9237E	<i>Pravastatin-PS, FZ – Pravastatin</i> , pravastatin sodium 10 mg tablet, 30
2834E	<i>Pravastatin-PS, FZ – Pravastatin</i> , pravastatin sodium 20 mg tablet, 30
9238F	<i>Pravastatin-PS, FZ – Pravastatin</i> , pravastatin sodium 20 mg tablet, 30
8197K	<i>Pravastatin-PS, FZ – Pravastatin</i> , pravastatin sodium 40 mg tablet, 30
9239G	<i>Pravastatin-PS, FZ – Pravastatin</i> , pravastatin sodium 40 mg tablet, 30
8829Q	<i>Pravastatin-PS, FZ – Pravastatin</i> , pravastatin sodium 80 mg tablet, 30
9240H	<i>Pravastatin-PS, FZ – Pravastatin</i> , pravastatin sodium 80 mg tablet, 30
2893G	<i>Prochlorperazine-PS, FZ – Prochlorperazine</i> , prochlorperazine maleate 5 mg tablet, 25
5205Y	<i>Prochlorperazine-PS, FZ – Prochlorperazine</i> , prochlorperazine maleate 5 mg tablet, 25 (Dental)
8456C	<i>Quetiapine Pfizer, FZ – Quetiapine</i> , quetiapine 25 mg tablet, 60
8457D	<i>Quetiapine Pfizer, FZ – Quetiapine</i> , quetiapine 100 mg tablet, 90
8458E	<i>Quetiapine Pfizer, FZ – Quetiapine</i> , quetiapine 200 mg tablet, 60
8580N	<i>Quetiapine Pfizer, FZ – Quetiapine</i> , quetiapine 300 mg tablet, 60
8507R	<i>Rabeprazole Pfizer, FZ – Rabeprazole</i> , rabeprazole sodium 10 mg tablet: enteric, 28 tablets
8509W	<i>Rabeprazole Pfizer, FZ – Rabeprazole</i> , rabeprazole sodium 20 mg tablet: enteric, 30 tablets
8508T	<i>Rabeprazole Pfizer, FZ – Rabeprazole</i> , rabeprazole sodium 20 mg tablet: enteric, 30 tablets
1944H	<i>Ramipril Tabs Pfizer, FZ – Ramipril</i> , ramipril 1.25 mg tablet, 30
1945J	<i>Ramipril Tabs Pfizer, FZ – Ramipril</i> , ramipril 2.5 mg tablet, 30
1946K	<i>Ramipril Tabs Pfizer, FZ – Ramipril</i> , ramipril 5 mg tablet, 30
1316G	<i>Ramipril Tabs Pfizer, FZ – Ramipril</i> , ramipril 10 mg tablet, 30
8470T	<i>Ramipril-PS, FZ – Ramipril</i> , ramipril 10 mg capsule, 30
1978D	<i>Ranitidine-PS, FZ – Ranitidine</i> , ranitidine 150 mg tablet, 60
8787L	<i>Risperidone Pfizer, FZ – Risperidone</i> , risperidone 500 microgram tablet, 60
8869T	<i>Risperidone Pfizer, FZ – Risperidone</i> , risperidone 500 microgram tablet, 60
8789N	<i>Risperidone Pfizer, FZ – Risperidone</i> , risperidone 1 mg tablet, 60

3169T	<i>Risperidone Pfizer, FZ – Risperidone</i> , risperidone 1 mg tablet, 60
9079W	<i>Risperidone Pfizer, FZ – Risperidone</i> , risperidone 2 mg tablet, 60
3170W	<i>Risperidone Pfizer, FZ – Risperidone</i> , risperidone 2 mg tablet, 60
3171X	<i>Risperidone Pfizer, FZ – Risperidone</i> , risperidone 3 mg tablet, 60
3172Y	<i>Risperidone Pfizer, FZ – Risperidone</i> , risperidone 4 mg tablet, 60
1760P	<i>Roxithromycin-PS, FZ – Roxithromycin</i> , roxithromycin 150 mg tablet, 10
5260W	<i>Roxithromycin-PS, FZ – Roxithromycin</i> , roxithromycin 150 mg tablet, 10 (Dental)
8016X	<i>Roxithromycin-PS, FZ – Roxithromycin</i> , roxithromycin 300 mg tablet, 5
5261X	<i>Roxithromycin-PS, FZ – Roxithromycin</i> , roxithromycin 300 mg tablet, 5 (Dental)
2011W	<i>Simvastatin Pfizer, FZ – Simvastatin</i> , simvastatin 10 mg tablet, 30
9242K	<i>Simvastatin Pfizer, FZ – Simvastatin</i> , simvastatin 10 mg tablet, 30
2012X	<i>Simvastatin Pfizer, FZ – Simvastatin</i> , simvastatin 20 mg tablet, 30
9243L	<i>Simvastatin Pfizer, FZ – Simvastatin</i> , simvastatin 20 mg tablet, 30
8173E	<i>Simvastatin Pfizer, FZ – Simvastatin</i> , simvastatin 40 mg tablet, 30
9244M	<i>Simvastatin Pfizer, FZ – Simvastatin</i> , simvastatin 40 mg tablet, 30
8313M	<i>Simvastatin Pfizer, FZ – Simvastatin</i> , simvastatin 80 mg tablet, 30
9245N	<i>Simvastatin Pfizer, FZ – Simvastatin</i> , simvastatin 80 mg tablet, 30
1849H	<i>Sumatriptan-PS, FZ – Sumatriptan</i> , sumatriptan 50 mg tablet, 4
1070H	<i>Betamin, SW – Thiamine</i> , thiamine hydrochloride 100 mg tablet, 100
8133C	<i>Valaciclovir Pfizer, FZ – Valaciclovir</i> , valaciclovir 500 mg tablet, 10
8133C	<i>Valvala, NV – Valaciclovir</i> , valaciclovir 500 mg tablet, 10
8134D	<i>Valaciclovir Pfizer, FZ – Valaciclovir</i> , valaciclovir 500 mg tablet, 30
8134D	<i>Valvala, NV – Valaciclovir</i> , valaciclovir 500 mg tablet, 30
5480K	<i>Valaciclovir Pfizer, FZ – Valaciclovir</i> , valaciclovir 500 mg tablet, 30
8064K	<i>Valaciclovir Pfizer, FZ – Valaciclovir</i> , valaciclovir 500 mg tablet, 42
8064K	<i>Valvala, NV – Valaciclovir</i> , valaciclovir 500 mg tablet, 42

Deletion – Equivalence Indicator

1417N *Flutamin, AF – Flutamide*, flutamide 250 mg tablet, 100

Alterations

Alteration – Restriction

1217C	Ciprofloxacin , ciprofloxacin 0.3% (3 mg/mL) eye drops, 5 mL (<i>CiloQuin, Ciloxan</i>)
5564W	Ciprofloxacin , ciprofloxacin 0.3% (3 mg/mL) eye drops, 5 mL (<i>CiloQuin, Ciloxan</i>)(Optometrical)
8383F	Ofloxacin , ofloxacin 0.3% (3 mg/mL) eye drops, 5 mL (<i>Ocuflox</i>)
5567B	Ofloxacin , ofloxacin 0.3% (3 mg/mL) eye drops, 5 mL (<i>Ocuflox</i>)(Optometrical)
3036T	Strontium , strontium ranelate 2 g granules, 28 x 2 g sachets (<i>Protos 2 g</i>)

Alteration – Item Description

The following item description required amending to include 1.2 mL syringes instead of 2 mL vials.

From:

8101J **Interferon Beta-1b**, interferon beta-1b 8 million international units (250 microgram) injection [15 x 250 microgram vials] (&) inert substance diluent [15 x 2 mL vials], 1 pack (*Betaferon, Extavia*)

To:

8101J **Interferon Beta-1b**, interferon beta-1b 8 million international units (250 microgram) injection [15 x 250 microgram vials] (&) inert substance diluent [15 x 1.2 mL syringes], 1 pack (*Betaferon, Extavia*)

Alteration – Manufacturer's Code

		From	To
8503M	<i>Zentel, AS – Albendazole</i> , albendazole 200 mg tablet: chewable, 6	GK	AS
9047E	<i>Zentel, AS – Albendazole</i> , albendazole 200 mg tablet: chewable, 6	GK	AS
8459F	<i>Eskazole, AS – Albendazole</i> , albendazole 400 mg tablet: chewable, 60	GK	AS
3310F	<i>Amoxil, AS – Amoxicillin</i> , amoxicillin 100 mg/mL oral liquid: powder for, 20 mL (Dental)	GK	AS
1888J	<i>Amoxil, AS – Amoxicillin</i> , amoxicillin 100 mg/mL oral liquid: powder for, 20 mL	GK	AS
9714G	<i>Amoxil, AS – Amoxicillin</i> , amoxicillin 100 mg/mL oral liquid: powder for, 20 mL	GK	AS
1886G	<i>Amoxil, AS – Amoxicillin</i> , amoxicillin 125 mg/5 mL oral liquid: powder for, 100 mL	GK	AS
3302T	<i>Amoxil, AS – Amoxicillin</i> , amoxicillin 125 mg/5 mL oral liquid: powder for, 100 mL (Dental)	GK	AS
1884E	<i>Amoxil, AS – Amoxicillin</i> , amoxicillin 250 mg capsule, 20	GK	AS
3301R	<i>Amoxil, AS – Amoxicillin</i> , amoxicillin 250 mg capsule, 20 (Dental)	GK	AS
1887H	<i>Amoxil Forte, AS – Amoxicillin</i> , amoxicillin 250 mg/5 mL oral liquid: powder for, 100 mL	GK	AS
3393N	<i>Amoxil Forte, AS – Amoxicillin</i> , amoxicillin 250 mg/5 mL oral liquid: powder for, 100 mL (Dental)	GK	AS
1889K	<i>Amoxil, AS – Amoxicillin</i> , amoxicillin 500 mg capsule, 20	GK	AS
3300Q	<i>Amoxil, AS – Amoxicillin</i> , amoxicillin 500 mg capsule, 20 (Dental)	GK	AS
1892N	<i>Augmentin, AS – Amoxicillin + Clavulanic Acid</i> , amoxicillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL oral liquid:	GK	AS

		From	To
	powder for, 75 mL		
5009P	<i>Augmentin</i> , AS – Amoxicillin + Clavulanic Acid , amoxicillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL oral liquid: powder for, 75 mL (Dental)	GK	AS
5011R	<i>Augmentin Duo 400</i> , AS – Amoxicillin + Clavulanic Acid , amoxicillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL oral liquid: powder for, 60 mL (Dental)	GK	AS
8319W	<i>Augmentin Duo 400</i> , AS – Amoxicillin + Clavulanic Acid , amoxicillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL oral liquid: powder for, 60 mL	GK	AS
1891M	<i>Augmentin Duo</i> , AS – Amoxicillin + Clavulanic Acid , amoxicillin 500 mg + clavulanic acid 125 mg tablet, 10	GK	AS
5008N	<i>Augmentin Duo</i> , AS – Amoxicillin + Clavulanic Acid , amoxicillin 500 mg + clavulanic acid 125 mg tablet, 10 (Dental)	GK	AS
5006L	<i>Augmentin Duo forte</i> , AS – Amoxicillin + Clavulanic Acid , amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10 (Dental)	GK	AS
8254K	<i>Augmentin Duo forte</i> , AS – Amoxicillin + Clavulanic Acid , amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10	GK	AS
8300W	<i>Wellvone</i> , AS – Atovaquone , atovaquone 750 mg/5 mL oral liquid, 210 mL	GK	AS
8465M	<i>Zyban</i> , AS – Bupropion , bupropion hydrochloride 150 mg tablet: modified release, 30 tablets	GK	AS
8710K	<i>Zyban</i> , AS – Bupropion , bupropion hydrochloride 150 mg tablet: modified release, 90 tablets	GK	AS
8292K	<i>Zinnat</i> , AS – Cefuroxime , cefuroxime 250 mg tablet, 14	GK	AS
5052X	<i>Zinnat</i> , AS – Cefuroxime , cefuroxime 250 mg tablet, 14 (Dental)	GK	AS
2850B	<i>Lamictal</i> , AS – Lamotrigine , lamotrigine 100 mg tablet, 56	GK	AS
2851C	<i>Lamictal</i> , AS – Lamotrigine , lamotrigine 200 mg tablet, 56	GK	AS
2848X	<i>Lamictal</i> , AS – Lamotrigine , lamotrigine 25 mg tablet, 56	GK	AS
8063J	<i>Lamictal</i> , AS – Lamotrigine , lamotrigine 5 mg tablet, 56	GK	AS
2849Y	<i>Lamictal</i> , AS – Lamotrigine , lamotrigine 50 mg tablet, 56	GK	AS
8290H	<i>Quilonum SR</i> , AS – Lithium Carbonate , lithium carbonate 450 mg tablet: modified release, 100 tablets	GK	AS
1611T	<i>Mesasal</i> , AS – Mesalazine , mesalazine 250 mg tablet: enteric, 100 tablets	GK	AS
8298R	<i>Naramig</i> , AS – Naratriptan , naratriptan 2.5 mg tablet, 2	GK	AS
9734H	<i>Naramig</i> , AS – Naratriptan , naratriptan 2.5 mg tablet, 2	GK	AS
1594X	<i>Zofran</i> , AS – Ondansetron , ondansetron 4 mg tablet, 10	GK	AS
8224W	<i>Zofran</i> , AS – Ondansetron , ondansetron 4 mg tablet, 4	GK	AS
8412R	<i>Zofran Zydis</i> , AS – Ondansetron , ondansetron 4 mg wafer, 10	GK	AS
8410P	<i>Zofran Zydis</i> , AS – Ondansetron , ondansetron 4 mg wafer, 4	GK	AS
1596B	<i>Zofran</i> , AS – Ondansetron , ondansetron 4 mg/2 mL injection, 1 x 2 mL ampoule	GK	AS
8226Y	<i>Zofran</i> , AS – Ondansetron , ondansetron 4 mg/2 mL injection, 1 x 2 mL ampoule	GK	AS
8233H	<i>Zofran syrup 50 mL</i> , AS – Ondansetron , ondansetron 4 mg/5 mL oral liquid, 50 mL	GK	AS
9441X	<i>Zofran syrup 50 mL</i> , AS – Ondansetron , ondansetron 4 mg/5 mL oral liquid, 50 mL	GK	AS
1595Y	<i>Zofran</i> , AS – Ondansetron , ondansetron 8 mg tablet, 10	GK	AS
8225X	<i>Zofran</i> , AS – Ondansetron , ondansetron 8 mg tablet, 4	GK	AS
8413T	<i>Zofran Zydis</i> , AS – Ondansetron , ondansetron 8 mg wafer, 10	GK	AS
8411Q	<i>Zofran Zydis</i> , AS – Ondansetron , ondansetron 8 mg wafer, 4	GK	AS
1597C	<i>Zofran</i> , AS – Ondansetron , ondansetron 8 mg/4 mL injection, 1 x 4 mL ampoule	GK	AS
8227B	<i>Zofran</i> , AS – Ondansetron , ondansetron 8 mg/4 mL injection, 1 x 4 mL ampoule	GK	AS
2242B	<i>Aropax</i> , AS – Paroxetine , paroxetine 20 mg tablet, 30	GK	AS
1966L	<i>Daraprim</i> , AS – Pyrimethamine , pyrimethamine 25 mg tablet, 50	GK	AS
1937Y	<i>Zantac</i> , AS – Ranitidine , ranitidine 150 mg tablet: effervescent, 30	GK	AS
8903N	<i>Zantac</i> , AS – Ranitidine , ranitidine 150 mg tablet: effervescent, 30	GK	AS
1978D	<i>Zantac</i> , AS – Ranitidine , ranitidine 150 mg tablet, 60	GK	AS
8162N	<i>Zantac Syrup</i> , AS – Ranitidine , ranitidine 150 mg/10 mL oral liquid, 300 mL	GK	AS
8905Q	<i>Zantac Syrup</i> , AS – Ranitidine , ranitidine 150 mg/10 mL oral liquid, 300 mL	GK	AS
1977C	<i>Zantac</i> , AS – Ranitidine , ranitidine 300 mg tablet, 30	GK	AS
8341B	<i>Imigran</i> , AS – Sumatriptan , sumatriptan 20 mg/actuation nasal spray, 2 actuations	GK	AS
8885P	<i>Imigran FDT</i> , AS – Sumatriptan , SUMATRIPTAN Tablet (fast disintegrating) 50 mg (as succinate), 2	GK	AS
8144P	<i>Imigran</i> , LN – Sumatriptan , SUMATRIPTAN Tablet 50 mg (as succinate), 2	GK	LN
5230G	<i>Timentin</i> , AS – Ticarcillin + Clavulanic Acid , ticarcillin 3 g + clavulanic acid 100 mg injection, 10 x 3.1 g vials (Dental)	GK	AS
2179Q	<i>Timentin</i> , AS – Ticarcillin + Clavulanic Acid , ticarcillin 3 g + clavulanic acid 100 mg injection, 10 x 3.1 g vials	GK	AS
8064K	<i>Valtrex</i> , AS – Valaciclovir , valaciclovir 500 mg tablet, 42	GK	AS
8134D	<i>Valtrex</i> , AS – Valaciclovir , valaciclovir 500 mg tablet, 30	GK	AS
5480K	<i>Valtrex</i> , AS – Valaciclovir , valaciclovir 500 mg tablet, 30	GK	AS
8133C	<i>Valtrex</i> , AS – Valaciclovir , valaciclovir 500 mg tablet, 10	GK	AS

Advance Notices

Advance Notices – Deletion of Brand

The following brand will be deleted from the Schedule of Pharmaceutical Benefits on 1 May 2013:

8511Y *Fosamax Once Weekly*, MK – **Alendronate**, alendronate 70 mg tablet, 4

SECTION 100 – HIGHLY SPECIALISED DRUGS PROGRAM

Additions

Addition – Item

- 2433C **Boceprevir**, Boceprevir 200 mg capsule, 336 capsules (*Victrelis*) (**Public**)
 2435E **Boceprevir**, Boceprevir 200 mg capsule, 336 capsules (*Victrelis*) (**Private**)
 2437G **Telaprevir**, telaprevir 375 mg tablet, 42 (*Incivo*) (**Public**)
 2378E **Telaprevir**, telaprevir 375 mg tablet, 42 (*Incivo*) (**Private**)

Addition – Brand

- 6287X *Pamidronate Strides, YA* – **Pamidronate Disodium**, pamidronate disodium 30 mg/10 mL injection, 1 x 10 mL vial (**Private**)
 5668H *Pamidronate Strides, YA* – **Pamidronate Disodium**, pamidronate disodium 30 mg/10 mL injection, 1 x 10 mL vial (**Public**)
 6289B *Pamidronate Strides, YA* – **Pamidronate Disodium**, pamidronate disodium 90 mg/10 mL injection, 1 x 10 mL vial (**Private**)
 5670K *Pamidronate Strides, YA* – **Pamidronate Disodium**, pamidronate disodium 90 mg/10 mL injection, 1 x 10 mL vial (**Public**)

Deletions

Deletion – Brand

- 6280M *Valvala, NV* – **Valaciclovir**, valaciclovir 500 mg tablet, 100 (**Private**)
 9568N *Valvala, NV* – **Valaciclovir**, valaciclovir 500 mg tablet, 100 (**Public**)

Alterations

Alteration – Restriction

- 9524G **Peginterferon Alfa-2a (& Ribavirin)**, peginterferon alfa-2a 135 microgram/0.5 mL injection [4 x 0.5 mL syringes] (& ribavirin 200 mg tablet [168 tablets], 1 pack (*Pegasys RBV*)) (**Public**)
 6392K **Peginterferon Alfa-2a (& Ribavirin)**, peginterferon alfa-2a 135 microgram/0.5 mL injection [4 x 0.5 mL syringes] (& ribavirin 200 mg tablet [168 tablets], 1 pack (*Pegasys RBV*)) (**Private**)
 6394M **Peginterferon Alfa-2a (& Ribavirin)**, peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (& ribavirin 200 mg tablet [112 tablets], 1 pack (*Pegasys RBV*)) (**Private**)
 9525H **Peginterferon Alfa-2a (& Ribavirin)**, peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (& ribavirin 200 mg tablet [112 tablets], 1 pack (*Pegasys RBV*)) (**Public**)
 6395N **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*)) (**Private**)
 9526J **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*)) (**Public**)
 6396P **Peginterferon Alfa-2a (& Ribavirin)**, peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (& ribavirin 200 mg tablet [168 tablets], 1 pack (*Pegasys RBV*)) (**Private**)
 9527K **Peginterferon Alfa-2a (& Ribavirin)**, peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (& ribavirin 200 mg tablet [168 tablets], 1 pack (*Pegasys RBV*)) (**Public**)
 9534T **Peginterferon Alfa-2b (& Ribavirin)**, peginterferon alfa-2b 100 microgram injection [4 x 100 microgram cartridges] (& ribavirin 200 mg capsule [112 capsules] (& inert substance diluent [4 x 0.5 mL cartridges], 1 pack (*Pegatron*)) (**Public**)
 6405D **Peginterferon Alfa-2b (& Ribavirin)**, peginterferon alfa-2b 100 microgram injection [4 x 100 microgram cartridges] (& ribavirin 200 mg capsule [112 capsules] (& inert substance diluent [4 x 0.5 mL cartridges], 1 pack (*Pegatron*)) (**Private**)
 9536X **Peginterferon Alfa-2b (& Ribavirin)**, peginterferon alfa-2b 120 microgram injection [4 x 120 microgram cartridges] (& ribavirin 200 mg capsule [140 capsules] (& inert substance diluent [4 x 0.5 mL cartridges], 1 pack (*Pegatron*)) (**Public**)
 6407F **Peginterferon Alfa-2b (& Ribavirin)**, peginterferon alfa-2b 120 microgram injection [4 x 120 microgram cartridges] (& ribavirin 200 mg capsule [140 capsules] (& inert substance diluent [4 x 0.5 mL cartridges], 1 pack (*Pegatron*)) (**Private**)
 9538B **Peginterferon Alfa-2b (& Ribavirin)**, peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] (& ribavirin 200 mg capsule [140 capsules] (& inert substance diluent [4 x 0.5 mL cartridges], 1 pack (*Pegatron*)) (**Public**)
 6409H **Peginterferon Alfa-2b (& Ribavirin)**, peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] (& ribavirin 200 mg capsule [140 capsules] (& inert substance diluent [4 x 0.5 mL cartridges], 1 pack (*Pegatron*)) (**Private**)
 9539C **Peginterferon Alfa-2b (& Ribavirin)**, peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] (& ribavirin 200 mg capsule [168 capsules] (& inert substance diluent [4 x 0.5 mL cartridges], 1 pack (*Pegatron*)) (**Public**)
 6410J **Peginterferon Alfa-2b (& Ribavirin)**, peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] (& ribavirin 200 mg capsule [168 capsules] (& inert substance diluent [4 x 0.5 mL cartridges], 1 pack (*Pegatron*)) (**Private**)
 9634C **Peginterferon Alfa-2b (& Ribavirin)**, peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] (& ribavirin 200 mg capsule [196 capsules] (& inert substance diluent [4 x 0.5 mL cartridges], 1 pack (*Pegatron*)) (**Private**)
 9540D **Peginterferon Alfa-2b (& Ribavirin)**, peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] (& ribavirin 200 mg capsule [196 capsules] (& inert substance diluent [4 x 0.5 mL cartridges], 1 pack (*Pegatron*)) (**Public**)
 9529M **Peginterferon Alfa-2b (& Ribavirin)**, peginterferon alfa-2b 50 microgram injection [4 x 50 microgram cartridges] (& ribavirin 200 mg capsule [112 capsules] (& inert substance diluent [4 x 0.5 mL cartridges], 1 pack (*Pegatron*)) (**Public**)

6400W	Peginterferon Alfa-2b (& Ribavirin , peginterferon alfa-2b 50 microgram injection [4 x 50 microgram cartridges] (&) ribavirin 200 mg capsule [112 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack (<i>Pegatron</i>) (Private)
9531P	Peginterferon Alfa-2b (& Ribavirin , peginterferon alfa-2b 80 microgram injection [4 x 80 microgram cartridges] (&) ribavirin 200 mg capsule [140 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack (<i>Pegatron</i>) (Public)
6402Y	Peginterferon Alfa-2b (& Ribavirin , peginterferon alfa-2b 80 microgram injection [4 x 80 microgram cartridges] (&) ribavirin 200 mg capsule [140 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack (<i>Pegatron</i>) (Private)
9530N	Peginterferon Alfa-2b (& Ribavirin , peginterferon alfa-2b 80 microgram injection [4 x 80 microgram cartridges] (&) ribavirin 200 mg capsule [84 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack (<i>Pegatron</i>) (Public)
6401X	Peginterferon Alfa-2b (& Ribavirin , peginterferon alfa-2b 80 microgram injection [4 x 80 microgram cartridges] (&) ribavirin 200 mg capsule [84 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack (<i>Pegatron</i>) (Private)

Alteration – Manufacturer's Code

		<i>From</i>	<i>To</i>
5770Q	<i>Zeffix, AS – Lamivudine</i> , lamivudine 100 mg tablet, 28 (Public)	GK	AS
6257H	<i>Zeffix, AS – Lamivudine</i> , lamivudine 100 mg tablet, 28 (Private)	GK	AS
5771R	<i>Zeffix, AS – Lamivudine</i> , lamivudine 5 mg/mL oral liquid, 240 mL (Public)	GK	AS
6271C	<i>Zeffix, AS – Lamivudine</i> , lamivudine 5 mg/mL oral liquid, 240 mL (Private)	GK	AS
6280M	<i>Valtrex, AS – Valaciclovir</i> , valaciclovir 500 mg tablet, 100 (Private)	GK	AS
9568N	<i>Valtrex, AS – Valaciclovir</i> , valaciclovir 500 mg tablet, 100 (Public)	GK	AS

Advance Notices

Advance Notices – Deletion of Item

The following item will be deleted from the Schedule of Pharmaceutical Benefits on 1 June 2013

5730N	Epoetin Beta , epoetin beta 20 000 international units/0.6 mL injection, 6 x 0.6 mL syringes (NeoRecormon) (Public)
6486J	Epoetin Beta , epoetin beta 20 000 international units/0.6 mL injection, 6 x 0.6 mL syringes (NeoRecormon) (Private)

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
CIPROFLOXACIN								
<u>Authority required</u>								
Bacterial keratitis								
The Treatment criteria is:								
Must be treated by an ophthalmologist or in consultation with an ophthalmologist.								
1217C	ciprofloxacin 0.3% (3 mg/mL) eye drops, 5 mL	2	*28.58	29.69	^a CiloQuin	IQ
				^b 2.06	*30.64	29.69	^a Ciloxan	AQ
CIPROFLOXACIN								
<u>Authority required</u>								
Bacterial keratitis								
The Treatment criteria is:								
Must be treated by an ophthalmologist or in consultation with an ophthalmologist.								
5564W OP	ciprofloxacin 0.3% (3 mg/mL) eye drops, 5 mL	2	*28.58	29.69	^a CiloQuin	IQ
				^b 2.06	*30.64	29.69	^a Ciloxan	AQ
INTERFERON BETA-1B								
<u>Authority required</u>								
Initial treatment of clinically definite relapsing-remitting multiple sclerosis in ambulatory (without assistance or support) patients who have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years. The diagnosis must be confirmed by magnetic resonance imaging of the brain and/or spinal cord and the date of the scan included in the authority application, unless the authority application is accompanied by written certification provided by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient. The authority will be limited to the maximum quantity and number of repeats indicated in the schedule								
<u>Authority required</u>								
Continuing treatment of clinically definite relapsing-remitting multiple sclerosis in patients previously issued with an authority prescription for this drug who do not show continuing progression of disability while on treatment with this drug and who have demonstrated compliance with, and an ability to tolerate, this therapy. Authorities will be limited to the maximum quantity and number of repeats indicated in the schedule								
8101J	interferon beta-1b 8 million international units (250 microgram) injection [15 x 250 microgram vials] (&) inert substance diluent [15 x 1.2 mL syringes], 1 pack	1	5	..	1000.91	36.10	^a Betaferon	BN
							^a Extavia	NV
LEVONORGESTREL + ETHINYLOESTRADIOL								
2416E NP	levonorgestrel 100 microgram + ethinyloestradiol 20 microgram tablet [84 tablets] (&) inert substance tablet [28 tablets], 112 [4 x 28 tablets]	1	2	..	15.40	16.51	Femme-Tab ED 20/100	AE
OFLOXACIN								
<u>Authority required</u>								
Bacterial keratitis								
The Treatment criteria is:								
Must be treated by an ophthalmologist or in consultation with an ophthalmologist.								
8383F	ofloxacin 0.3% (3 mg/mL) eye drops, 5 mL	2	*32.24	33.35	Ocuflox	AG
OFLOXACIN								
<u>Authority required</u>								
Bacterial keratitis								
The Treatment criteria is:								
Must be treated by an ophthalmologist or in consultation with an ophthalmologist.								
5567B OP	ofloxacin 0.3% (3 mg/mL) eye drops, 5 mL	2	*32.24	33.35	Ocuflox	AG
ROTIGOTINE								
<u>Restricted benefit</u>								
Parkinson disease								

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
The Clinical criteria is:								
The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.								
2385M	rotigotine 2 mg/24 hours patch, 28	1	5	..	77.35	36.10	Neupro	UC
ROTIGOTINE								
<u>Restricted benefit</u>								
Parkinson disease								
The Clinical criteria is:								
The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.								
2384L	rotigotine 4 mg/24 hours patch, 28	1	5	..	100.96	36.10	Neupro	UC
2410W	rotigotine 6 mg/24 hours patch, 28	1	5	..	113.68	36.10	Neupro	UC
SIMVASTATIN + SITAGLIPTIN								
<u>Authority required (STREAMLINED)</u>								
4183								
Diabetes mellitus type 2 and hypercholesterolaemia								
The Clinical criteria is:								
Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs,								
AND the Clinical criteria is:								
The treatment must be in combination with metformin; OR								
The treatment must be in combination with a sulfonylurea,								
AND the Clinical criteria is:								
Patient must have a contraindication to a combination of metformin and a sulfonylurea; OR								
Patient must not have tolerated a combination of metformin and a sulfonylurea,								
AND the Clinical criteria is:								
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) or a glucagon-like peptide-1 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 prior to initiation with a gliptin, a glitazone or a glucagon-like peptide-1 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 gliptin, a glitazone or a glucagon-like peptide-1 is initiated.								
The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is or 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 or a glucagon-like peptide-1, must be documented in the patient's medical records.								
Note								
The treatment must not be in combination with a thiazolidinedione (glitazone) or glucagon-like peptide-1.								
2391W	simvastatin 10 mg + sitagliptin 100 mg	1	5	..	97.72	36.10	Juvicor	MK
NP	tablet: film-coated, 28							
2377D	simvastatin 20 mg + sitagliptin 100 mg	1	5	..	100.79	36.10	Juvicor	MK
NP	tablet: film-coated, 28							
2383K	simvastatin 40 mg + sitagliptin 100 mg	1	5	..	105.22	36.10	Juvicor	MK
NP	tablet: film-coated, 28							
STRONTIUM								
<u>Authority required (STREAMLINED)</u>								
4117								
Osteoporosis								
The Population criteria is:								
Patient must be aged 70 years or older,								
AND the Clinical criteria is:								
Patient must have a Bone Mineral Density (BMD) T-score of -3.0 or less,								
AND the Clinical criteria is:								
Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.								

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.						
	<u>Authority required (STREAMLINED)</u>						
	4123						
	Established osteoporosis						
	The Clinical criteria is:						
	Patient must have fracture due to minimal trauma,						
	AND the Clinical criteria is:						
	Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.						
	The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.						
	A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.						
	Note						
	Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.						
3036T NP	strontium ranelate 2 g granules, 28 x 2 g sachets	1	5	..	51.76	36.10	Protos 2 g SE

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	<p>BOCEPREVIR <u>Authority required (STREAMLINED)</u> 4182 Chronic genotype 1 hepatitis C infection</p> <p>The Treatment criteria is: Must be treated in an accredited treatment centre,</p> <p>AND the Clinical criteria is: Patient must have compensated liver disease,</p> <p>AND the Clinical criteria is: Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,</p> <p>AND the Clinical criteria is: The treatment must be in combination with peginterferon alfa and ribavirin,</p> <p>AND the Clinical criteria is: The treatment must be limited to a maximum duration of 32 weeks in patients without hepatic cirrhosis who were partial responders or relapsers to the prior course of interferon based therapy for hepatitis C; OR The treatment must be limited to a maximum duration of 44 weeks in patients without hepatic cirrhosis who were null responders to the prior course of interferon based therapy for hepatitis C; OR The treatment must be limited to a maximum duration of 44 weeks for all patients with hepatic cirrhosis,</p> <p>AND the Clinical criteria is: The treatment must cease after the first 8 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 12,</p> <p>AND the Clinical criteria is: The treatment must cease after the first 20 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 24,</p> <p>AND the Population criteria is: Patient must be 18 years or older,</p> <p>AND the Population criteria is: 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.</p> <p>Chronic genotype 1 hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.</p> <p>Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised boceprevir, 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.</p> <p>For patients without hepatic cirrhosis who were partial responders or relapsers to the prior course of interferon based therapy, a maximum of 7 repeats may be prescribed.</p> <p>For patients without hepatic cirrhosis who were null responders to the prior course of interferon based therapy, a maximum of 10 repeats may be prescribed.</p> <p>For patients with hepatic cirrhosis, a maximum of 10 repeats may be prescribed.</p>					
	<p><u>Authority required (STREAMLINED)</u> 4202 Chronic genotype 1 hepatitis C infection</p> <p>The Treatment criteria is: Must be treated in an accredited treatment centre,</p> <p>AND the Clinical criteria is: Patient must have compensated liver disease,</p> <p>AND the Clinical criteria is: Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,</p> <p>AND the Clinical criteria is: The treatment must be in combination with peginterferon alfa and ribavirin,</p> <p>AND the Clinical criteria is: The treatment must be limited to a maximum duration of 24 weeks in patients without hepatic cirrhosis; OR The treatment must be limited to a maximum duration of 44 weeks in patients with hepatic cirrhosis,</p> <p>AND the Clinical criteria is: The treatment must cease after the first 20 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at</p>					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty	\$	
	treatment week 24, AND the Population criteria is: Patient must be 18 years or older, AND the Population criteria is: 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. Evidence of chronic genotype 1 hepatitis C infection (repeated 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 boceprevir, 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. For patients without hepatic cirrhosis, a maximum of 5 repeats may be prescribed. For patients with hepatic cirrhosis, a maximum of 10 repeats may be prescribed. Note No increase in the maximum quantity or number of units 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.						
2433C	Boceprevir 200 mg capsule, 336 capsules	1	10	..	3920.00		Victrelis MK

PEGINTERFERON ALFA-2A (&) RIBAVIRIN

Authority required (STREAMLINED)

4184

Chronic genotype 1 hepatitis C infection

The Treatment criteria is:

Must be treated in an accredited treatment centre,

AND the Clinical criteria is:

Patient must have compensated liver disease,

AND the Clinical criteria is:

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

AND the Clinical criteria is:

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir; OR

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir,

AND the Clinical criteria is:

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who were prior treatment partial responders or relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 12; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapsers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 12; or (iii) have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis,

AND the Clinical criteria is:

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	AND the Clinical criteria is:					
	The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,					
	AND the Clinical criteria is:					
	The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,					
	AND the Clinical criteria is:					
	The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,					
	AND the Clinical criteria is:					
	The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,					
	AND the Clinical criteria is:					
	The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,					
	AND the Population criteria is:					
	Patient must be aged 18 years or older,					
	AND the Population criteria is:					
	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.					
	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.					
	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.					
	Authority required (STREAMLINED)					
	4197					
	Chronic genotype 1 hepatitis C infection					
	The Treatment criteria is:					
	Must be treated in an accredited treatment centre,					
	AND the Clinical criteria is:					
	Patient must have compensated liver disease,					
	AND the Clinical criteria is:					
	Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,					
	AND the Clinical criteria is:					
	The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR					
	The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR					
	The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR					
	The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis; OR					
	The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis,					
	AND the Clinical criteria is:					
	The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,					
	AND the Clinical criteria is:					
	The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,					
	AND the Clinical criteria is:					
	The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,					
	AND the Clinical criteria is:					
	The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,					
	AND the Clinical criteria is:					
	The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,					
	AND the Population criteria is:					
	Patient must be aged 18 years or older,					
	AND the Population criteria is:					
	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.					
	Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.					
	For patients using peginterferon and ribavirin without an NS3 protease inhibitor who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.					
	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.					
	Authority required (STREAMLINED)					
	4206					
	Chronic non-genotype 1 hepatitis C infection					
	The Treatment criteria is:					
	Must be treated in an accredited treatment centre,					
	AND the Clinical criteria is:					
	The treatment must be the sole PBS-subsidised treatment for hepatitis C,					
	AND the Clinical criteria is:					
	Patient must have compensated liver disease,					
	AND the Clinical criteria is:					
	The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,					
	AND the Clinical criteria is:					
	Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),					
	AND the Clinical criteria is:					
	Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,					
	AND the Clinical criteria is:					
	The treatment must be limited to a maximum duration of 48 weeks,					
	AND the Clinical criteria is:					
	The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,					
	AND the Population criteria is:					
	Patient must be aged 18 years or older,					
	AND the Population criteria is:					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	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.					
	Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.					
	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.					
	Authority required (STREAMLINED)					
	4187					
	Chronic non-genotype 1 hepatitis C infection					
	The Treatment criteria is:					
	Must be treated in an accredited treatment centre,					
	AND the Clinical criteria is:					
	The treatment must be the sole PBS-subsidised treatment for hepatitis C,					
	AND the Clinical criteria is:					
	Patient must have compensated liver disease,					
	AND the Clinical criteria is:					
	Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,					
	AND the Clinical criteria is:					
	The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,					
	AND the Clinical criteria is:					
	The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR					
	The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR					
	The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis,					
	AND the Clinical criteria is:					
	The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,					
	AND the Clinical criteria is:					
	The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,					
	AND the Population criteria is:					
	Patient must be aged 18 years or older,					
	AND the Population criteria is:					
	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.					
	Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.					
	For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.					
	For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12.					
	For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed.					
	For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed.					
	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.					
	Caution					
	Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max. Qty \$		
	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.						
9524G	peginterferon alfa-2a 135 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [168 tablets], 1 pack	2	5	..	*3072.84		Pegasys RBV RO
9525H	peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [112 tablets], 1 pack	2	5	..	*3085.28		Pegasys RBV RO
9526J	peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [140 tablets], 1 pack	2	5	..	*3245.82		Pegasys RBV RO
9527K	peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [168 tablets], 1 pack	2	5	..	*3406.36		Pegasys RBV RO

PEGINTERFERON ALFA-2B (&) RIBAVIRIN

Authority required (STREAMLINED)

4189

Chronic genotype 1 hepatitis C infection

The Treatment criteria is:

Must be treated in an accredited treatment centre,

AND the Clinical criteria is:

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

AND the Clinical criteria is:

Patient must have compensated liver disease,

AND the Clinical criteria is:

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

AND the Clinical criteria is:

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

AND the Clinical criteria is:

The treatment must be limited to a maximum duration of 48 weeks,

AND the Clinical criteria is:

The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND the Population criteria is:

Patient must weigh at least 27 kg,

AND the Population criteria is:

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.

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.

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.

Authority required (STREAMLINED)

4198

Chronic genotype 1 hepatitis C infection

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	<p>The Treatment criteria is: Must be treated in an accredited treatment centre,</p> <p>AND the Clinical criteria is: The treatment must be the sole PBS-subsidised treatment for hepatitis C,</p> <p>AND the Clinical criteria is: Patient must have compensated liver disease,</p> <p>AND the Clinical criteria is: Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,</p> <p>AND the Clinical criteria is: The treatment must be limited to a maximum duration of 48 weeks,</p> <p>AND the Clinical criteria is: The treatment must cease unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,</p> <p>AND the Population criteria is: Patient must weigh at least 27 kg,</p> <p>AND the Population criteria is: 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. Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records. For patients who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.</p> <p>Note No increase in the maximum quantity or number of units may be authorised.</p> <p>Note No increase in the maximum number of repeats may be authorised.</p> <p>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.</p> <p>Authority required (STREAMLINED) 4199 Chronic non-genotype 1 hepatitis C infection</p> <p>The Treatment criteria is: Must be treated in an accredited treatment centre,</p> <p>AND the Clinical criteria is: The treatment must be the sole PBS-subsidised treatment for hepatitis C,</p> <p>AND the Clinical criteria is: Patient must have compensated liver disease,</p> <p>AND the Clinical criteria is: The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,</p> <p>AND the Clinical criteria is: Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),</p> <p>AND the Clinical criteria is: Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,</p> <p>AND the Clinical criteria is: The treatment must be limited to a maximum duration of 48 weeks,</p> <p>AND the Clinical criteria is: The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,</p> <p>AND the Population criteria is: Patient must weigh at least 27 kg,</p> <p>AND the Population criteria is: Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be</p>					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
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using an effective form of contraception if of child-bearing age.

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

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.

Authority required (STREAMLINED)

4192

Chronic non-genotype 1 hepatitis C infection

The Treatment criteria is:

Must be treated in an accredited treatment centre,

AND the Clinical criteria is:

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

AND the Clinical criteria is:

Patient must have compensated liver disease,

AND the Clinical criteria is:

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

AND the Clinical criteria is:

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,

AND the Clinical criteria is:

The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis,

AND the Clinical criteria is:

The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,

AND the Clinical criteria is:

The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

AND the Population criteria is:

Patient must weigh at least 27 kg,

AND the Population criteria is:

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.

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

For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12.

For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed.

For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed.

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.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	Authority required (STREAMLINED)					
	4184					
	Chronic genotype 1 hepatitis C infection					
	The Treatment criteria is:					
	Must be treated in an accredited treatment centre,					
	AND the Clinical criteria is:					
	Patient must have compensated liver disease,					
	AND the Clinical criteria is:					
	Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),					
	AND the Clinical criteria is:					
	Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir; OR					
	Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir,					
	AND the Clinical criteria is:					
	The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR					
	The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who were prior treatment partial responders or relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 12; OR					
	The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR					
	The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapsers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 12; or (iii) have hepatic cirrhosis; OR					
	The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis,					
	AND the Clinical criteria is:					
	The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,					
	AND the Clinical criteria is:					
	The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,					
	AND the Clinical criteria is:					
	The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,					
	AND the Clinical criteria is:					
	The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,					
	AND the Clinical criteria is:					
	The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,					
	AND the Clinical criteria is:					
	The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,					
	AND the Population criteria is:					
	Patient must be aged 18 years or older,					
	AND the Population criteria is:					
	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.					
	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.					
	Note					
	No increase in the maximum quantity or number of units may be authorised.					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
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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.

Authority required (STREAMLINED)

4197

Chronic genotype 1 hepatitis C infection

The Treatment criteria is:

Must be treated in an accredited treatment centre,

AND the Clinical criteria is:

Patient must have compensated liver disease,

AND the Clinical criteria is:

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

AND the Clinical criteria is:

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis,

AND the Clinical criteria is:

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,

AND the Clinical criteria is:

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

AND the Clinical criteria is:

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,

AND the Clinical criteria is:

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND the Clinical criteria is:

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

AND the Population criteria is:

Patient must be aged 18 years or older,

AND the Population criteria is:

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.

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

For patients using peginterferon and ribavirin without an NS3 protease inhibitor who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

Note

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

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
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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.

Authority required (STREAMLINED)**4206**

Chronic non-genotype 1 hepatitis C infection

The Treatment criteria is:

Must be treated in an accredited treatment centre,

AND the Clinical criteria is:

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

AND the Clinical criteria is:

Patient must have compensated liver disease,

AND the Clinical criteria is:

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,

AND the Clinical criteria is:

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

AND the Clinical criteria is:

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

AND the Clinical criteria is:

The treatment must be limited to a maximum duration of 48 weeks,

AND the Clinical criteria is:

The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND the Population criteria is:

Patient must be aged 18 years or older,

AND the Population criteria is:

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.

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

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.

Authority required (STREAMLINED)**4187**

Chronic non-genotype 1 hepatitis C infection

The Treatment criteria is:

Must be treated in an accredited treatment centre,

AND the Clinical criteria is:

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

AND the Clinical criteria is:

Patient must have compensated liver disease,

AND the Clinical criteria is:

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer	
	Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,						
	AND the Clinical criteria is:						
	The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,						
	AND the Clinical criteria is:						
	The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR						
	The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR						
	The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis,						
	AND the Clinical criteria is:						
	The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,						
	AND the Clinical criteria is:						
	The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,						
	AND the Population criteria is:						
	Patient must be aged 18 years or older,						
	AND the Population criteria is:						
	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.						
	Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.						
	For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.						
	For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12.						
	For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed.						
	For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed.						
	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.						
	Caution						
	Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.						
	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.						
9534T	peginterferon alfa-2b 100 microgram injection [4 x 100 microgram cartridges] (&) ribavirin 200 mg capsule [112 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack	2	5	..	*3099.62	Pegatron	MK
9529M	peginterferon alfa-2b 50 microgram injection [4 x 50 microgram cartridges] (&) ribavirin 200 mg capsule [112 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack	2	5	..	*2119.74	Pegatron	MK
9530N	peginterferon alfa-2b 80 microgram injection [4 x 80 microgram cartridges] (&) ribavirin 200 mg capsule [84 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack	2	5	..	*2422.72	Pegatron	MK

PEGINTERFERON ALFA-2B (&) RIBAVIRIN

Authority required (STREAMLINED)

4184

Chronic genotype 1 hepatitis C infection

The Treatment criteria is:

Must be treated in an accredited treatment centre,

AND the Clinical criteria is:

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	<p>Patient must have compensated liver disease,</p> <p>AND the Clinical criteria is:</p> <p>Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),</p> <p>AND the Clinical criteria is:</p> <p>Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir; OR</p> <p>Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir,</p> <p>AND the Clinical criteria is:</p> <p>The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR</p> <p>The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who were prior treatment partial responders or relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 12; OR</p> <p>The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR</p> <p>The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapsers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 12; or (iii) have hepatic cirrhosis; OR</p> <p>The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis,</p> <p>AND the Clinical criteria is:</p> <p>The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,</p> <p>AND the Clinical criteria is:</p> <p>The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,</p> <p>AND the Clinical criteria is:</p> <p>The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,</p> <p>AND the Clinical criteria is:</p> <p>The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,</p> <p>AND the Clinical criteria is:</p> <p>The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,</p> <p>AND the Clinical criteria is:</p> <p>The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,</p> <p>AND the Population criteria is:</p> <p>Patient must be aged 18 years or older,</p> <p>AND the Population criteria is:</p> <p>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.</p> <p>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.</p> <p>Note</p> <p>No increase in the maximum quantity or number of units may be authorised.</p> <p>Note</p> <p>No increase in the maximum number of repeats may be authorised.</p> <p>Note</p> <p>Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:</p> <p>(a) a nurse educator/counsellor for patients; and</p>					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	(b) 24-hour access by patients to medical advice; and (c) an established liver clinic.					
	<u>Authority required (STREAMLINED)</u> 4197 Chronic genotype 1 hepatitis C infection					
	The Treatment criteria is: Must be treated in an accredited treatment centre,					
	AND the Clinical criteria is: Patient must have compensated liver disease,					
	AND the Clinical criteria is: Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,					
	AND the Clinical criteria is: The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis; OR The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis,					
	AND the Clinical criteria is: The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,					
	AND the Clinical criteria is: The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,					
	AND the Clinical criteria is: The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,					
	AND the Clinical criteria is: The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,					
	AND the Clinical criteria is: The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,					
	AND the Population criteria is: Patient must be aged 18 years or older,					
	AND the Population criteria is: 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. Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records. For patients using peginterferon and ribavirin without an NS3 protease inhibitor who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.					
	<u>Note</u> No increase in the maximum quantity or number of units may be authorised.					
	<u>Note</u> No increase in the maximum number of repeats may be authorised.					
	<u>Note</u> 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					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	(b) 24-hour access by patients to medical advice; and (c) an established liver clinic.					
	<u>Authority required (STREAMLINED)</u>					
	4206 Chronic non-genotype 1 hepatitis C infection					
	The Treatment criteria is: Must be treated in an accredited treatment centre,					
	AND the Clinical criteria is: The treatment must be the sole PBS-subsidised treatment for hepatitis C,					
	AND the Clinical criteria is: Patient must have compensated liver disease,					
	AND the Clinical criteria is: The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,					
	AND the Clinical criteria is: Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),					
	AND the Clinical criteria is: Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,					
	AND the Clinical criteria is: The treatment must be limited to a maximum duration of 48 weeks,					
	AND the Clinical criteria is: The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,					
	AND the Population criteria is: Patient must be aged 18 years or older,					
	AND the Population criteria is: 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. Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.					
	<u>Note</u> No increase in the maximum quantity or number of units may be authorised.					
	<u>Note</u> No increase in the maximum number of repeats may be authorised.					
	<u>Note</u> 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.					
	<u>Authority required (STREAMLINED)</u>					
	4187 Chronic non-genotype 1 hepatitis C infection					
	The Treatment criteria is: Must be treated in an accredited treatment centre,					
	AND the Clinical criteria is: The treatment must be the sole PBS-subsidised treatment for hepatitis C,					
	AND the Clinical criteria is: Patient must have compensated liver disease,					
	AND the Clinical criteria is: Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,					
	AND the Clinical criteria is: The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,					
	AND the Clinical criteria is: The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer	
	The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR						
	The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis,						
	AND the Clinical criteria is:						
	The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,						
	AND the Clinical criteria is:						
	The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,						
	AND the Population criteria is:						
	Patient must be aged 18 years or older,						
	AND the Population criteria is:						
	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.						
	Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.						
	For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.						
	For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12.						
	For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed.						
	For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed.						
	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.						
	Caution						
	Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.						
	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.						
9536X	peginterferon alfa-2b 120 microgram injection [4 x 120 microgram cartridges] (&) ribavirin 200 mg capsule [140 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack	2	5	..	*3491.58	Pegatron	MK
9538B	peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] (&) ribavirin 200 mg capsule [140 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack	2	5	..	*4079.52	Pegatron	MK
9539C	peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] (&) ribavirin 200 mg capsule [168 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack	2	5	..	*4079.52	Pegatron	MK
9540D	peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] (&) ribavirin 200 mg capsule [196 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack	2	5	..	*4364.48	Pegatron	MK
9531P	peginterferon alfa-2b 80 microgram injection [4 x 80 microgram cartridges] (&) ribavirin 200 mg capsule [140 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack	2	5	..	*2707.66	Pegatron	MK

TELAPREVIR

Authority required (STREAMLINED)

4186

Chronic genotype 1 hepatitis C infection

The Treatment criteria is:

Must be treated in an accredited treatment centre,

AND the Clinical criteria is:

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	<p>Patient must have compensated liver disease,</p> <p>AND the Clinical criteria is:</p> <p>Patient must not have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C,</p> <p>AND the Clinical criteria is:</p> <p>The treatment must be in combination with peginterferon alfa and ribavirin,</p> <p>AND the Clinical criteria is:</p> <p>The treatment must be limited to a maximum duration of 12 weeks,</p> <p>AND the Clinical criteria is:</p> <p>The treatment must cease if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,</p> <p>AND the Population criteria is:</p> <p>Patient must be 18 years or older,</p> <p>AND the Population criteria is:</p> <p>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.</p> <p>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.</p> <p>Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised telaprevir, 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.</p> <p><u>Authority required (STREAMLINED)</u></p> <p>4191</p> <p>Chronic genotype 1 hepatitis C infection</p> <p>The Treatment criteria is:</p> <p>Must be treated in an accredited treatment centre,</p> <p>AND the Clinical criteria is:</p> <p>Patient must have compensated liver disease,</p> <p>AND the Clinical criteria is:</p> <p>Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C,</p> <p>AND the Clinical criteria is:</p> <p>The treatment must be in combination with peginterferon alfa and ribavirin,</p> <p>AND the Clinical criteria is:</p> <p>The treatment must be limited to a maximum duration of 12 weeks,</p> <p>AND the Clinical criteria is:</p> <p>The treatment must cease if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,</p> <p>AND the Population criteria is:</p> <p>Patient must be 18 years or older,</p> <p>AND the Population criteria is:</p> <p>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.</p> <p>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.</p> <p>Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised telaprevir, 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.</p> <p><u>Note</u></p> <p>No increase in the maximum quantity or number of units may be authorised.</p> <p><u>Note</u></p> <p>No increase in the maximum number of repeats may be authorised.</p> <p><u>Note</u></p> <p>Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:</p> <p>(a) a nurse educator/counsellor for patients; and</p> <p>(b) 24-hour access by patients to medical advice; and</p> <p>(c) an established liver clinic.</p>					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					Price for Max.	Qty \$		
2437G	telaprevir 375 mg tablet, 42	6	*14865.72		Incivo	JC

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
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BOCEPREVIR

Authority required

Chronic genotype 1 hepatitis C infection

The Treatment criteria is:

Must be treated in an accredited treatment centre,

AND the Clinical criteria is:

Patient must have compensated liver disease,

AND the Clinical criteria is:

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

AND the Clinical criteria is:

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

AND the Clinical criteria is:

The treatment must be limited to a maximum duration of 32 weeks in patients without hepatic cirrhosis who were partial responders or relapsers to the prior course of interferon based therapy for hepatitis C; OR

The treatment must be limited to a maximum duration of 44 weeks in patients without hepatic cirrhosis who were null responders to the prior course of interferon based therapy for hepatitis C; OR

The treatment must be limited to a maximum duration of 44 weeks for all patients with hepatic cirrhosis,

AND the Clinical criteria is:

The treatment must cease after the first 8 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 12,

AND the Clinical criteria is:

The treatment must cease after the first 20 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 24,

AND the Population criteria is:

Patient must be 18 years or older,

AND the Population criteria is:

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.

Chronic genotype 1 hepatitis C infection (repeated 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 boceprevir, 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.

For patients without hepatic cirrhosis who were partial responders or relapsers to the prior course of interferon based therapy, a maximum of 7 repeats may be prescribed.

For patients without hepatic cirrhosis who were null responders to the prior course of interferon based therapy, a maximum of 10 repeats may be prescribed.

For patients with hepatic cirrhosis, a maximum of 10 repeats may be prescribed.

Authority required

Chronic genotype 1 hepatitis C infection

The Treatment criteria is:

Must be treated in an accredited treatment centre,

AND the Clinical criteria is:

Patient must have compensated liver disease,

AND the Clinical criteria is:

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

AND the Clinical criteria is:

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

AND the Clinical criteria is:

The treatment must be limited to a maximum duration of 24 weeks in patients without hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 44 weeks in patients with hepatic cirrhosis,

AND the Clinical criteria is:

The treatment must cease after the first 20 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 24,

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max. Qty \$		
	AND the Population criteria is:						
	Patient must be 18 years or older,						
	AND the Population criteria is:						
	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.						
	Evidence of chronic genotype 1 hepatitis C infection (repeated 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 boceprevir, 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.						
	For patients without hepatic cirrhosis, a maximum of 5 repeats may be prescribed.						
	For patients with hepatic cirrhosis, a maximum of 10 repeats may be prescribed.						
	Note						
	No increase in the maximum quantity or number of units 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.						
2435E	Boceprevir 200 mg capsule, 336 capsules	1	10	..	3966.52	Victrelis	MK

PEGINTERFERON ALFA-2A (&) RIBAVIRIN

Authority required

Chronic genotype 1 hepatitis C infection

The Treatment criteria is:

Must be treated in an accredited treatment centre,

AND the Clinical criteria is:

Patient must have compensated liver disease,

AND the Clinical criteria is:

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

AND the Clinical criteria is:

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir; OR

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir,

AND the Clinical criteria is:

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who were prior treatment partial responders or relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 12; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapsers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 12; or (iii) have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis,

AND the Clinical criteria is:

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND the Clinical criteria is:

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	<p>qualitative assay at week 12,</p> <p>AND the Clinical criteria is:</p> <p>The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,</p> <p>AND the Clinical criteria is:</p> <p>The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,</p> <p>AND the Clinical criteria is:</p> <p>The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,</p> <p>AND the Clinical criteria is:</p> <p>The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,</p> <p>AND the Population criteria is:</p> <p>Patient must be aged 18 years or older,</p> <p>AND the Population criteria is:</p> <p>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.</p> <p>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.</p> <p>Note</p> <p>No increase in the maximum quantity or number of units may be authorised.</p> <p>Note</p> <p>No increase in the maximum number of repeats may be authorised.</p> <p>Note</p> <p>Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:</p> <p>(a) a nurse educator/counsellor for patients; and</p> <p>(b) 24-hour access by patients to medical advice; and</p> <p>(c) an established liver clinic.</p> <p>Authority required</p> <p>Chronic genotype 1 hepatitis C infection</p> <p>The Treatment criteria is:</p> <p>Must be treated in an accredited treatment centre,</p> <p>AND the Clinical criteria is:</p> <p>Patient must have compensated liver disease,</p> <p>AND the Clinical criteria is:</p> <p>Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,</p> <p>AND the Clinical criteria is:</p> <p>The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR</p> <p>The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR</p> <p>The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR</p> <p>The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis; OR</p> <p>The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis,</p> <p>AND the Clinical criteria is:</p> <p>The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,</p> <p>AND the Clinical criteria is:</p>					

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	<p>The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,</p> <p>AND the Clinical criteria is:</p> <p>The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,</p> <p>AND the Clinical criteria is:</p> <p>The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,</p> <p>AND the Clinical criteria is:</p> <p>The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,</p> <p>AND the Population criteria is:</p> <p>Patient must be aged 18 years or older,</p> <p>AND the Population criteria is:</p> <p>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.</p> <p>Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.</p> <p>For patients using peginterferon and ribavirin without an NS3 protease inhibitor who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.</p> <p>Note</p> <p>No increase in the maximum quantity or number of units may be authorised.</p> <p>Note</p> <p>No increase in the maximum number of repeats may be authorised.</p> <p>Note</p> <p>Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:</p> <p>(a) a nurse educator/counsellor for patients; and</p> <p>(b) 24-hour access by patients to medical advice; and</p> <p>(c) an established liver clinic.</p> <p>Authority required</p> <p>Chronic non-genotype 1 hepatitis C infection</p> <p>The Treatment criteria is:</p> <p>Must be treated in an accredited treatment centre,</p> <p>AND the Clinical criteria is:</p> <p>The treatment must be the sole PBS-subsidised treatment for hepatitis C,</p> <p>AND the Clinical criteria is:</p> <p>Patient must have compensated liver disease,</p> <p>AND the Clinical criteria is:</p> <p>The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,</p> <p>AND the Clinical criteria is:</p> <p>Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),</p> <p>AND the Clinical criteria is:</p> <p>Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,</p> <p>AND the Clinical criteria is:</p> <p>The treatment must be limited to a maximum duration of 48 weeks,</p> <p>AND the Clinical criteria is:</p> <p>The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,</p> <p>AND the Population criteria is:</p> <p>Patient must be aged 18 years or older,</p> <p>AND the Population criteria is:</p> <p>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.</p> <p>Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.</p> <p>Note</p>					

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
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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.

Authority required

Chronic non-genotype 1 hepatitis C infection

The Treatment criteria is:

Must be treated in an accredited treatment centre,

AND the Clinical criteria is:

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

AND the Clinical criteria is:

Patient must have compensated liver disease,

AND the Clinical criteria is:

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

AND the Clinical criteria is:

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,

AND the Clinical criteria is:

The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis,

AND the Clinical criteria is:

The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,

AND the Clinical criteria is:

The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

AND the Population criteria is:

Patient must be aged 18 years or older,

AND the Population criteria is:

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.

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

For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12.

For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed.

For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed.

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.

Caution

Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

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

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer	
					Price for Max. Qty \$		
	(c) an established liver clinic.						
6392K	peginterferon alfa-2a 135 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [168 tablets], 1 pack	2	5	..	*3119.36	Pegasys RBV	RO
6394M	peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [112 tablets], 1 pack	2	5	..	*3131.80	Pegasys RBV	RO
6395N	peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [140 tablets], 1 pack	2	5	..	*3292.34	Pegasys RBV	RO
6396P	peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [168 tablets], 1 pack	2	5	..	*3452.88	Pegasys RBV	RO

PEGINTERFERON ALFA-2B (&) RIBAVIRIN

Authority required

Chronic genotype 1 hepatitis C infection

The Treatment criteria is:

Must be treated in an accredited treatment centre,

AND the Clinical criteria is:

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

AND the Clinical criteria is:

Patient must have compensated liver disease,

AND the Clinical criteria is:

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

AND the Clinical criteria is:

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

AND the Clinical criteria is:

The treatment must be limited to a maximum duration of 48 weeks,

AND the Clinical criteria is:

The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND the Population criteria is:

Patient must weigh at least 27 kg,

AND the Population criteria is:

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.

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.

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.

Authority required

Chronic genotype 1 hepatitis C infection

The Treatment criteria is:

Must be treated in an accredited treatment centre,

AND the Clinical criteria is:

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

AND the Clinical criteria is:

Patient must have compensated liver disease,

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	AND the Clinical criteria is:					
	Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,					
	AND the Clinical criteria is:					
	The treatment must be limited to a maximum duration of 48 weeks,					
	AND the Clinical criteria is:					
	The treatment must cease unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,					
	AND the Population criteria is:					
	Patient must weigh at least 27 kg,					
	AND the Population criteria is:					
	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.					
	Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records. For patients who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.					
	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.					
	Authority required					
	Chronic non-genotype 1 hepatitis C infection					
	The Treatment criteria is:					
	Must be treated in an accredited treatment centre,					
	AND the Clinical criteria is:					
	The treatment must be the sole PBS-subsidised treatment for hepatitis C,					
	AND the Clinical criteria is:					
	Patient must have compensated liver disease,					
	AND the Clinical criteria is:					
	The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,					
	AND the Clinical criteria is:					
	Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),					
	AND the Clinical criteria is:					
	Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,					
	AND the Clinical criteria is:					
	The treatment must be limited to a maximum duration of 48 weeks,					
	AND the Clinical criteria is:					
	The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,					
	AND the Population criteria is:					
	Patient must weigh at least 27 kg,					
	AND the Population criteria is:					
	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.					
	Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.					
	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					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	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.					
	<u>Authority required</u>					
	Chronic non-genotype 1 hepatitis C infection					
	The Treatment criteria is:					
	Must be treated in an accredited treatment centre,					
	AND the Clinical criteria is:					
	The treatment must be the sole PBS-subsidised treatment for hepatitis C,					
	AND the Clinical criteria is:					
	Patient must have compensated liver disease,					
	AND the Clinical criteria is:					
	Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,					
	AND the Clinical criteria is:					
	The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,					
	AND the Clinical criteria is:					
	The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR					
	The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR					
	The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis,					
	AND the Clinical criteria is:					
	The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,					
	AND the Clinical criteria is:					
	The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,					
	AND the Population criteria is:					
	Patient must weigh at least 27 kg,					
	AND the Population criteria is:					
	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.					
	Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.					
	For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.					
	For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12.					
	For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed.					
	For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed.					
	<u>Note</u>					
	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.					
	<u>Authority required</u>					
	Chronic genotype 1 hepatitis C infection					
	The Treatment criteria is:					
	Must be treated in an accredited treatment centre,					
	AND the Clinical criteria is:					
	Patient must have compensated liver disease,					
	AND the Clinical criteria is:					

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),					
	AND the Clinical criteria is:					
	Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir; OR					
	Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir,					
	AND the Clinical criteria is:					
	The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR					
	The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who were prior treatment partial responders or relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 12; OR					
	The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR					
	The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapsers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 12; or (iii) have hepatic cirrhosis; OR					
	The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis,					
	AND the Clinical criteria is:					
	The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,					
	AND the Clinical criteria is:					
	The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,					
	AND the Clinical criteria is:					
	The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,					
	AND the Clinical criteria is:					
	The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,					
	AND the Clinical criteria is:					
	The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,					
	AND the Clinical criteria is:					
	The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,					
	AND the Population criteria is:					
	Patient must be aged 18 years or older,					
	AND the Population criteria is:					
	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.					
	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.					
	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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Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	<p><u>Authority required</u> Chronic genotype 1 hepatitis C infection</p> <p>The Treatment criteria is: Must be treated in an accredited treatment centre,</p> <p>AND the Clinical criteria is: Patient must have compensated liver disease,</p> <p>AND the Clinical criteria is: Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,</p> <p>AND the Clinical criteria is: The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis; OR The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis,</p> <p>AND the Clinical criteria is: The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,</p> <p>AND the Clinical criteria is: The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,</p> <p>AND the Clinical criteria is: The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,</p> <p>AND the Clinical criteria is: The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,</p> <p>AND the Clinical criteria is: The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,</p> <p>AND the Population criteria is: Patient must be aged 18 years or older,</p> <p>AND the Population criteria is: 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. Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records. For patients using peginterferon and ribavirin without an NS3 protease inhibitor who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.</p> <p><u>Note</u> No increase in the maximum quantity or number of units may be authorised.</p> <p><u>Note</u> No increase in the maximum number of repeats may be authorised.</p> <p><u>Note</u> 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.</p> <p><u>Authority required</u></p>					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	Chronic non-genotype 1 hepatitis C infection					
	<p>The Treatment criteria is: Must be treated in an accredited treatment centre,</p> <p>AND the Clinical criteria is: The treatment must be the sole PBS-subsidised treatment for hepatitis C,</p> <p>AND the Clinical criteria is: Patient must have compensated liver disease,</p> <p>AND the Clinical criteria is: The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,</p> <p>AND the Clinical criteria is: Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),</p> <p>AND the Clinical criteria is: Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,</p> <p>AND the Clinical criteria is: The treatment must be limited to a maximum duration of 48 weeks,</p> <p>AND the Clinical criteria is: The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,</p> <p>AND the Population criteria is: Patient must be aged 18 years or older,</p> <p>AND the Population criteria is: 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. Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.</p> <p>Note No increase in the maximum quantity or number of units may be authorised.</p> <p>Note No increase in the maximum number of repeats may be authorised.</p> <p>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.</p> <p>Authority required Chronic non-genotype 1 hepatitis C infection</p> <p>The Treatment criteria is: Must be treated in an accredited treatment centre,</p> <p>AND the Clinical criteria is: The treatment must be the sole PBS-subsidised treatment for hepatitis C,</p> <p>AND the Clinical criteria is: Patient must have compensated liver disease,</p> <p>AND the Clinical criteria is: Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,</p> <p>AND the Clinical criteria is: The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,</p> <p>AND the Clinical criteria is: The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis,</p> <p>AND the Clinical criteria is: The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed</p>					

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty	\$	
	at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,						
	AND the Clinical criteria is:						
	The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,						
	AND the Population criteria is:						
	Patient must be aged 18 years or older,						
	AND the Population criteria is:						
	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.						
	Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.						
	For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.						
	For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12.						
	For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed.						
	For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed.						
	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.						
	Caution						
	Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.						
	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.						
6405D	peginterferon alfa-2b 100 microgram injection [4 x 100 microgram cartridges] (&) ribavirin 200 mg capsule [112 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack	2	5	..	*3146.14	Pegatron	MK
6400W	peginterferon alfa-2b 50 microgram injection [4 x 50 microgram cartridges] (&) ribavirin 200 mg capsule [112 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack	2	5	..	*2166.26	Pegatron	MK
6401X	peginterferon alfa-2b 80 microgram injection [4 x 80 microgram cartridges] (&) ribavirin 200 mg capsule [84 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack	2	5	..	*2469.24	Pegatron	MK

PEGINTERFERON ALFA-2B (&) RIBAVIRIN

Authority required

Chronic genotype 1 hepatitis C infection

The Treatment criteria is:

Must be treated in an accredited treatment centre,

AND the Clinical criteria is:

Patient must have compensated liver disease,

AND the Clinical criteria is:

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

AND the Clinical criteria is:

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir; OR

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir,

AND the Clinical criteria is:

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max. Qty \$		
	boceprevir who were prior treatment partial responders or relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 12; OR						
	The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR						
	The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapsers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 12; or (iii) have hepatic cirrhosis; OR						
	The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis,						
	AND the Clinical criteria is:						
	The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,						
	AND the Clinical criteria is:						
	The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,						
	AND the Clinical criteria is:						
	The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,						
	AND the Clinical criteria is:						
	The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,						
	AND the Clinical criteria is:						
	The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,						
	AND the Clinical criteria is:						
	The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,						
	AND the Population criteria is:						
	Patient must be aged 18 years or older,						
	AND the Population criteria is:						
	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.						
	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.						
	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.						
	Authority required						
	Chronic genotype 1 hepatitis C infection						
	The Treatment criteria is:						
	Must be treated in an accredited treatment centre,						
	AND the Clinical criteria is:						
	Patient must have compensated liver disease,						
	AND the Clinical criteria is:						
	Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,						
	AND the Clinical criteria is:						
	The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with						

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty \$		
	telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis; OR The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis, AND the Clinical criteria is: The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop, AND the Clinical criteria is: The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND the Clinical criteria is: The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL, AND the Clinical criteria is: The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND the Clinical criteria is: The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND the Population criteria is: Patient must be aged 18 years or older, AND the Population criteria is: 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. Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records. For patients using peginterferon and ribavirin without an NS3 protease inhibitor who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary. 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. Authority required Chronic non-genotype 1 hepatitis C infection The Treatment criteria is: Must be treated in an accredited treatment centre, AND the Clinical criteria is: The treatment must be the sole PBS-subsidised treatment for hepatitis C, AND the Clinical criteria is: Patient must have compensated liver disease, AND the Clinical criteria is: The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C, AND the Clinical criteria is:						

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),					
	AND the Clinical criteria is:					
	Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,					
	AND the Clinical criteria is:					
	The treatment must be limited to a maximum duration of 48 weeks,					
	AND the Clinical criteria is:					
	The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,					
	AND the Population criteria is:					
	Patient must be aged 18 years or older,					
	AND the Population criteria is:					
	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.					
	Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.					
	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.					
	Authority required					
	Chronic non-genotype 1 hepatitis C infection					
	The Treatment criteria is:					
	Must be treated in an accredited treatment centre,					
	AND the Clinical criteria is:					
	The treatment must be the sole PBS-subsidised treatment for hepatitis C,					
	AND the Clinical criteria is:					
	Patient must have compensated liver disease,					
	AND the Clinical criteria is:					
	Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,					
	AND the Clinical criteria is:					
	The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,					
	AND the Clinical criteria is:					
	The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR					
	The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR					
	The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis,					
	AND the Clinical criteria is:					
	The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,					
	AND the Clinical criteria is:					
	The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,					
	AND the Population criteria is:					
	Patient must be aged 18 years or older,					
	AND the Population criteria is:					
	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.					
	Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					Qty	\$	
	For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.						
	For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12.						
	For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed.						
	For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed.						
	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.						
	Caution Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.						
	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.						
6407F	peginterferon alfa-2b 120 microgram injection [4 x 120 microgram cartridges] (&) ribavirin 200 mg capsule [140 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack	2	5	..	*3538.10	Pegatron	MK
6409H	peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] (&) ribavirin 200 mg capsule [140 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack	2	5	..	*4126.04	Pegatron	MK
6410J	peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] (&) ribavirin 200 mg capsule [168 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack	2	5	..	*4126.04	Pegatron	MK
9634C	peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] (&) ribavirin 200 mg capsule [196 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack	2	5	..	*4411.00	Pegatron	MK
6402Y	peginterferon alfa-2b 80 microgram injection [4 x 80 microgram cartridges] (&) ribavirin 200 mg capsule [140 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack	2	5	..	*2754.18	Pegatron	MK

TELAPREVIR

Authority required

Chronic genotype 1 hepatitis C infection

The Treatment criteria is:

Must be treated in an accredited treatment centre,

AND the Clinical criteria is:

Patient must have compensated liver disease,

AND the Clinical criteria is:

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

AND the Clinical criteria is:

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

AND the Clinical criteria is:

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

AND the Clinical criteria is:

The treatment must cease if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,

AND the Population criteria is:

Patient must be 18 years or older,

AND the Population criteria is:

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.

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

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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	<p>medical records.</p> <p>Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised telaprevir, 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.</p> <p><u>Authority required</u> Chronic genotype 1 hepatitis C infection</p> <p>The Treatment criteria is: Must be treated in an accredited treatment centre,</p> <p>AND the Clinical criteria is: Patient must have compensated liver disease,</p> <p>AND the Clinical criteria is: Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C,</p> <p>AND the Clinical criteria is: The treatment must be in combination with peginterferon alfa and ribavirin,</p> <p>AND the Clinical criteria is: The treatment must be limited to a maximum duration of 12 weeks,</p> <p>AND the Clinical criteria is: The treatment must cease if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,</p> <p>AND the Population criteria is: Patient must be 18 years or older,</p> <p>AND the Population criteria is: 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.</p> <p>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.</p> <p>Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised telaprevir, 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.</p> <p><u>Note</u> No increase in the maximum quantity or number of units may be authorised.</p> <p><u>Note</u> No increase in the maximum number of repeats may be authorised.</p> <p><u>Note</u> Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:</p> <p>(a) a nurse educator/counsellor for patients; and</p> <p>(b) 24-hour access by patients to medical advice; and</p> <p>(c) an established liver clinic.</p>						
2378E	telaprevir 375 mg tablet, 42	6	*14912.26	Incivo	JC