



Australian Government

Department of Health and Ageing

**SCHEDULE OF PHARMACEUTICAL
BENEFITS**

SUMMARY OF CHANGES

EFFECTIVE 1 November 2011

PHARMACEUTICAL BENEFITS

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 November 2011. 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 November 2011 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	\$6.42
	Dangerous drug fee	\$2.71
	Extemporaneously-prepared	\$8.46
	Allowable additional patient charge*	\$3.92
Additional Fees (for safety net prices):	Ready-prepared	\$1.09
	Extemporaneously-prepared	\$1.44
Patient Co-payments:	General	\$34.20
	Concessional	\$5.60
Safety Net Thresholds:	General	\$1317.20
	Concessional	\$336.00
Safety Net Card Issue Fee:		\$8.58

*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 – Brand

8220P	<i>Citalopram-GA, GN</i> – Citalopram Hydrobromide , Tablet 20 mg (base)
9005Y	<i>DBL Fluorouracil Injection BP, HH</i> – Fluorouracil , Injection 1000 mg in 20 mL
8995K	<i>DBL Fluorouracil Injection BP, HH</i> – Fluorouracil , Injection 2500 mg in 50 mL
9119Y	<i>Irinotecan Actavis 500, TA</i> – Irinotecan Hydrochloride Trihydrate , I.V. injection 500 mg in 25 mL
8654L	<i>Levitaccord, RA</i> – Levetiracetam , Tablet 250 mg
8655M	<i>Levitaccord, RA</i> – Levetiracetam , Tablet 500 mg
8656N	<i>Levitaccord, RA</i> – Levetiracetam , Tablet 1 g
2349P	<i>Karicare Aptamil De-Lact, NU</i> – Milk Powder—lactose Free Formula , Lactose-predigested powder infant formula 900 g
2350Q	<i>Karicare Aptamil De-Lact, NU</i> – Milk Powder—lactose Free Formula , Lactose-predigested powder infant formula 900 g
2893G	<i>Prochlorperazine GH, GQ</i> – Prochlorperazine , Tablet containing prochlorperazine maleate 5 mg
5205Y	<i>Prochlorperazine GH, GQ</i> – Prochlorperazine , Tablet containing prochlorperazine maleate 5 mg (Dental)
8259Q	<i>Karicare Aptamil Pepti-Junior Gold, NU</i> – Protein Hydrolysate Formula with Medium Chain Triglycerides , Compound powder 450 g
1760P	<i>Roxithromycin Sandoz, SZ</i> – Roxithromycin , Tablet 150 mg
5260W	<i>Roxithromycin Sandoz, SZ</i> – Roxithromycin , Tablet 150 mg (Dental)

Addition – Equivalence Indicator

9005Y	<i>Fluorouracil Ebewe, SZ</i> – Fluorouracil , Injection 1000 mg in 20 mL
8995K	<i>Fluorouracil Ebewe, SZ</i> – Fluorouracil , Injection 2500 mg in 50 mL
2349P	<i>Karicare De-Lact, SB</i> – Milk Powder—lactose Free Formula , Lactose-predigested powder infant formula 900 g
2350Q	<i>Karicare De-Lact, SB</i> – Milk Powder—lactose Free Formula , Lactose-predigested powder infant formula 900 g
8259Q	<i>Pepti-Junior Gold, SB</i> – Protein Hydrolysate Formula with Medium Chain Triglycerides , Compound powder 450 g

Deletions

Deletion – Brand

1357K	<i>Prothiaden, AB</i> – Dothiepin Hydrochloride , Capsule 25 mg
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Deletion – Equivalence Indicator

1357K	<i>Dothep 25, AF</i> – Dothiepin Hydrochloride , Capsule 25 mg
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Alterations

Alteration – Number of Repeats

		<i>From</i>	<i>To</i>
3410L	Colchicine , Tablet 500 micrograms (<i>Colgout, Lengout</i>)	2	5
2272N	Methotrexate , Tablet 10 mg (<i>Methoblastin</i>)	1	3
2395C	Methotrexate , Injection 50 mg in 2 mL (<i>Hospira Pty Limited, Pfizer Australia Pty Ltd</i>)	0	5

Alteration – Restriction

9317J	Clopidogrel , Tablet 75 mg (as hydrogen sulfate) (<i>Iscover, Plavix, Clopidogrel Winthrop</i>)
9296G	Clopidogrel with Aspirin , Tablet 75 mg (as hydrogen sulfate)-100 mg (<i>DuoCover, CoPlavix, Clopidogrel Winthrop plus aspirin</i>)
8495D	Donepezil Hydrochloride , Tablet 5 mg (<i>Aricept</i>)
8496E	Donepezil Hydrochloride , Tablet 10 mg (<i>Aricept</i>)
3401B	Esomeprazole Magnesium Trihydrate , Tablet (enteric coated), equivalent to 40 mg esomeprazole (<i>Nexium</i>)
8770N	Galantamine Hydrobromide , Capsule 8 mg (base) (prolonged release) (<i>Reminyl, Galantyl</i>)
8771P	Galantamine Hydrobromide , Capsule 16 mg (base) (prolonged release) (<i>Reminyl, Galantyl</i>)
8772Q	Galantamine Hydrobromide , Capsule 24 mg (base) (prolonged release) (<i>Reminyl, Galantyl</i>)
1956Y	Memantine Hydrochloride , Tablet 10 mg (<i>Ebixa, Memanxa, APO-Memantine</i>)
9306T	Memantine Hydrochloride , Tablet 20 mg (<i>Ebixa</i>)
5465P	Nicotine , Transdermal patch releasing approximately 21 mg per 24 hours (<i>Nicabate P</i>)
3414Q	Nicotine , Transdermal patch releasing approximately 21 mg per 24 hours (<i>Nicotinell Step 1</i>)
9161E	Rivastigmine , Transdermal patch 9 mg (releasing approximately 4.6 mg per 24 hours) (<i>Exelon Patch 5</i>)
9162F	Rivastigmine , Transdermal patch 18 mg (releasing approximately 9.5 mg per 24 hours) (<i>Exelon Patch 10</i>)
8497F	Rivastigmine Hydrogen Tartrate , Capsule 1.5 mg (base) (<i>Exelon</i>)
8498G	Rivastigmine Hydrogen Tartrate , Capsule 3 mg (base) (<i>Exelon</i>)
8499H	Rivastigmine Hydrogen Tartrate , Capsule 4.5 mg (base) (<i>Exelon</i>)
8500J	Rivastigmine Hydrogen Tartrate , Capsule 6 mg (base) (<i>Exelon</i>)
8563Q	Rivastigmine Hydrogen Tartrate , Oral solution 2 mg (base) per mL, 120 mL (<i>Exelon</i>)
8626B	Tiotropium Bromide Monohydrate , Capsule containing powder for oral inhalation 18 micrograms (base) (for use in HandiHaler) (<i>Spiriva</i>)

Alteration – Manufacturer's Code

		<i>From</i>	<i>To</i>
2267H	<i>Bicillin L-A, PF</i> – Benzathine Benzylpenicillin , Injection 900 mg in 2.3 mL single use pre-filled syringe	AS	PF
5027N	<i>Bicillin L-A, PF</i> – Benzathine Benzylpenicillin , Injection 900 mg in 2.3 mL single use pre-filled syringe (Dental)	AS	PF
8465M	<i>Prexaton, GM</i> – Bupropion Hydrochloride , Tablet 150 mg (sustained release)	AF	GM
8710K	<i>Prexaton, GM</i> – Bupropion Hydrochloride , Tablet 150 mg (sustained release)	AF	GM
2349P	<i>Karicare De-Lact, SB</i> – Milk Powder—lactose Free Formula , Lactose-predigested powder infant formula 900 g	NU	SB
2350Q	<i>Karicare De-Lact, SB</i> – Milk Powder—lactose Free Formula , Lactose-predigested powder infant formula 900 g	NU	SB
8259Q	<i>Pepti-Junior Gold, SB</i> – Protein Hydrolysate Formula with Medium Chain Triglycerides , Compound powder 450 g	NU	SB
1760P	<i>Roxide, HX</i> – Roxithromycin , Tablet 150 mg	SZ	HX
5260W	<i>Roxide, HX</i> – Roxithromycin , Tablet 150 mg (Dental)	SZ	HX

SECTION 100 – HIGHLY SPECIALISED DRUGS PROGRAM

Additions

Addition – Item

5825N	Eltrombopag , Tablet 25 mg (as olamine) (<i>Revolade</i>) (Public)
5827Q	Eltrombopag , Tablet 25 mg (as olamine) (<i>Revolade</i>) (Private)

5826P **Eltrombopag**, Tablet 50 mg (as olamine) (*Revolade*) **(Public)**

5828R **Eltrombopag**, Tablet 50 mg (as olamine) (*Revolade*) **(Private)**

Addition – Note

9696H **Romiplostim**, Powder for injection 375 micrograms (250 micrograms in 0.5 mL when reconstituted) (*Nplate*)**(Public)**

9697J **Romiplostim**, Powder for injection 375 micrograms (250 micrograms in 0.5 mL when reconstituted) (*Nplate*)**(Private)**

9698K **Romiplostim**, Powder for injection 625 micrograms (500 micrograms in 1 mL when reconstituted) (*Nplate*)**(Public)**

9699L **Romiplostim**, Powder for injection 625 micrograms (500 micrograms in 1 mL when reconstituted) (*Nplate*)**(Private)**

Alterations

Alteration – Restriction

6450L **Adefovir Dipivoxil**, Tablet 10 mg (*Hepsera*)**(Private)**

5606C **Adefovir Dipivoxil**, Tablet 10 mg (*Hepsera*)**(Public)**

5711N **Entecavir Monohydrate**, Tablet 0.5 mg (*Baraclude*)**(Public)**

9602J **Entecavir Monohydrate**, Tablet 0.5 mg (*Baraclude*)**(Private)**

5712P **Entecavir Monohydrate**, Tablet 1 mg (*Baraclude*)**(Public)**

9603K **Entecavir Monohydrate**, Tablet 1 mg (*Baraclude*)**(Private)**

5759D **Interferon Alfa-2a**, Injection 3,000,000 i.u. in 0.5 mL single dose pre-filled syringe (*Roferon-A*)**(Public)**

6210W **Interferon Alfa-2a**, Injection 3,000,000 i.u. in 0.5 mL single dose pre-filled syringe (*Roferon-A*)**(Private)**

5760E **Interferon Alfa-2a**, Injection 4,500,000 i.u. in 0.5 mL single dose pre-filled syringe (*Roferon-A*)**(Public)**

6211X **Interferon Alfa-2a**, Injection 4,500,000 i.u. in 0.5 mL single dose pre-filled syringe (*Roferon-A*)**(Private)**

5761F **Interferon Alfa-2a**, Injection 6,000,000 i.u. in 0.5 mL single dose pre-filled syringe (*Roferon-A*)**(Public)**

6212Y **Interferon Alfa-2a**, Injection 6,000,000 i.u. in 0.5 mL single dose pre-filled syringe (*Roferon-A*)**(Private)**

5762G **Interferon Alfa-2a**, Injection 9,000,000 i.u. in 0.5 mL single dose pre-filled syringe (*Roferon-A*)**(Public)**

6213B **Interferon Alfa-2a**, Injection 9,000,000 i.u. in 0.5 mL single dose pre-filled syringe (*Roferon-A*)**(Private)**

5768N **Interferon Alfa-2b**, Solution for injection 10,000,000 i.u. in 1 mL single dose vial (*Intron A*)**(Public)**

6246R **Interferon Alfa-2b**, Solution for injection 10,000,000 i.u. in 1 mL single dose vial (*Intron A*)**(Private)**

5763H **Interferon Alfa-2b**, Solution for injection 18,000,000 i.u. in 1.2 mL multi-dose injection pen (*Intron A Redipen*)**(Public)**

6253D **Interferon Alfa-2b**, Solution for injection 18,000,000 i.u. in 1.2 mL multi-dose injection pen (*Intron A Redipen*)**(Private)**

5766L **Interferon Alfa-2b**, Solution for injection 18,000,000 i.u. in 3 mL single dose vial (*Intron A*)**(Public)**

6218G **Interferon Alfa-2b**, Solution for injection 18,000,000 i.u. in 3 mL single dose vial (*Intron A*)**(Private)**

5767M **Interferon Alfa-2b**, Solution for injection 25,000,000 i.u. in 2.5 mL single dose vial (*Intron A*)**(Public)**

6219H **Interferon Alfa-2b**, Solution for injection 25,000,000 i.u. in 2.5 mL single dose vial (*Intron A*)**(Private)**

5764J **Interferon Alfa-2b**, Solution for injection 30,000,000 i.u. in 1.2 mL multi-dose injection pen (*Intron A Redipen*)**(Public)**

6254E **Interferon Alfa-2b**, Solution for injection 30,000,000 i.u. in 1.2 mL multi-dose injection pen (*Intron A Redipen*)**(Private)**

5765K **Interferon Alfa-2b**, Solution for injection 60,000,000 i.u. in 1.2 mL multi-dose injection pen (*Intron A Redipen*)**(Public)**

6255F **Interferon Alfa-2b**, Solution for injection 60,000,000 i.u. in 1.2 mL multi-dose injection pen (*Intron A Redipen*)**(Private)**

5771R **Lamivudine**, Oral solution 5 mg per mL, 240 mL (*Zeffix*)**(Public)**

6271C **Lamivudine**, Oral solution 5 mg per mL, 240 mL (*Zeffix*)**(Private)**

5770Q **Lamivudine**, Tablet 100 mg (*Zeffix*)**(Public)**

6257H **Lamivudine**, Tablet 100 mg (*Zeffix*)**(Private)**

9515T **Peginterferon Alfa-2a**, Injection 135 micrograms in 0.5 mL single use pre-filled syringe (*Pegasys*)**(Public)**

6439X **Peginterferon Alfa-2a**, Injection 135 micrograms in 0.5 mL single use pre-filled syringe (*Pegasys*)**(Private)**

- 9516W **Peginterferon Alfa-2a**, Injection 180 micrograms in 0.5 mL single use pre-filled syringe (*Pegasys*)(**Public**)
- 6449K **Peginterferon Alfa-2a**, Injection 180 micrograms in 0.5 mL single use pre-filled syringe (*Pegasys*)(**Private**)
- 9696H **Romiplostim**, Powder for injection 375 micrograms (250 micrograms in 0.5 mL when reconstituted) (*Nplate*)(**Public**)
- 9697J **Romiplostim**, Powder for injection 375 micrograms (250 micrograms in 0.5 mL when reconstituted) (*Nplate*)(**Private**)
- 9698K **Romiplostim**, Powder for injection 625 micrograms (500 micrograms in 1 mL when reconstituted) (*Nplate*)(**Public**)
- 9699L **Romiplostim**, Powder for injection 625 micrograms (500 micrograms in 1 mL when reconstituted) (*Nplate*)(**Private**)
- 9562G **Telbivudine**, Tablet 600 mg (*Sebivo*)(**Public**)
- 9630W **Telbivudine**, Tablet 600 mg (*Sebivo*)(**Private**)
- 9563H **Tenofovir**, Tablet containing tenofovir disoproxil fumarate 300 mg (*Viread*)(**Public**)
- 6358P **Tenofovir**, Tablet containing tenofovir disoproxil fumarate 300 mg (*Viread*)(**Private**)
- 9653C **Zoledronic Acid**, Injection concentrate for I.V. infusion 4 mg (as monohydrate) in 5 mL (*Zometa*)(**Public**)
- 6371H **Zoledronic Acid**, Injection concentrate for I.V. infusion 4 mg (as monohydrate) in 5 mL (*Zometa*)(**Private**)

Alteration – Note

- 5606C **Adefovir Dipivoxil**, Tablet 10 mg (*Hepsera*)(**Public**)
- 6450L **Adefovir Dipivoxil**, Tablet 10 mg (*Hepsera*)(**Private**)
- 5711N **Entecavir Monohydrate**, Tablet 0.5 mg (*Baraclude*)(**Public**)
- 9602J **Entecavir Monohydrate**, Tablet 0.5 mg (*Baraclude*)(**Private**)
- 5712P **Entecavir Monohydrate**, Tablet 1 mg (*Baraclude*)(**Public**)
- 9603K **Entecavir Monohydrate**, Tablet 1 mg (*Baraclude*)(**Private**)
- 9563H **Tenofovir**, Tablet containing tenofovir disoproxil fumarate 300 mg (*Viread*)(**Public**)
- 6358P **Tenofovir**, Tablet containing tenofovir disoproxil fumarate 300 mg (*Viread*)(**Private**)

Advance Notices

Advance Notices – Deletion of Item

The following item will be deleted from the Schedule of Pharmaceutical Benefits on 1 December 2011:
Item discontinued by the manufacturer—

- 3176E **Norethisterone with Mestranol**, Tablets 1 mg-50 micrograms, 21 (*Norinyl-1*)

Advance Notices – Deletion of Brand

The following brands will be deleted from the Schedule of Pharmaceutical Benefits on 1 December 2011:
Brand discontinued by the manufacturer—

- 2776D *Synphasic, PF* – **Norethisterone with Ethinyloestradiol**, Pack containing 12 tablets 500 micrograms-35 micrograms, 9 tablets 1 mg-35 micrograms and 7 inert tablets
- 1215Y *Dolaforte, CO* – **Codeine Phosphate with Paracetamol**, Tablet 30 mg-500 mg
- 8785J *Dolaforte, CO* – **Codeine Phosphate with Paracetamol**, Tablet 30 mg-500 mg
- 3316M *Dolaforte, CO* – **Codeine Phosphate with Paracetamol**, Tablet 30 mg-500 mg (**Dental**)

The following brands will be deleted from the Schedule of Pharmaceutical Benefits on 1 March 2012:
Brand discontinued by the manufacturer—

- 1760P *Roxide, HX* – **Roxithromycin**, Tablet 150 mg
- 5260W *Roxide, HX* – **Roxithromycin**, Tablet 150 mg (**Dental**)
- 2350Q *Karicare De-Lact, SB* – **Milk Powder—lactose Free Formula**, Lactose-predigested powder infant formula 900 g
- 2349P *Karicare De-Lact, SB* – **Milk Powder—lactose Free Formula**, Lactose-predigested powder infant formula 900 g
- 8259Q *Pepti-Junior Gold, SB* – **Protein Hydrolysate Formula with Medium Chain Triglycerides**, Compound powder 450 g

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					for Max. Qty \$	Recordable Value for Safety Net \$		
CLOPIDOGREL								
<u>Authority required (STREAMLINED)</u>								
3879								
Treatment of acute coronary syndrome (myocardial infarction or unstable angina) in combination with aspirin;								
3146								
Treatment in combination with aspirin following cardiac stent insertion.								
Note								
Not for prophylaxis of DVT or peripheral arterial disease.								
Note								
Shared Care Model:								
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
9317J NP	Tablet 75 mg (as hydrogen sulfate)	28	5	..	70.30	34.20 ^a	Clopidogrel Winthrop ^a Iscover ^a Plavix	WA BQ SW

CLOPIDOGREL with ASPIRIN

Authority required (STREAMLINED)

3880

Treatment of acute coronary syndrome (myocardial infarction or unstable angina);

3219

Treatment following cardiac stent insertion;

1722

Prevention of recurrence of myocardial infarction or unstable angina in patients with a history of symptomatic cardiac ischaemic events while on therapy with low-dose aspirin.

Note

Not for prophylaxis of DVT or peripheral arterial disease.

Note

Shared Care Model:

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

9296G NP	Tablet 75 mg (as hydrogen sulfate)-100 mg	30	5	..	74.87	34.20 ^a	Clopidogrel Winthrop plus aspirin ^a CoPlavix ^a DuoCover	WA SW BQ
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DONEPEZIL HYDROCHLORIDE

Authority required

INITIAL APPLICATION FOR THE TREATMENT OF MILD TO MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients with an (S)MMSE of 10 or more. Initial treatment, as the sole PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease. Confirmation of this diagnosis must be made by or in consultation with a specialist/consultant physician (including a psychiatrist).

The authority application must include the result of the baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE). This baseline (S)MMSE must be a score of 10 or more. If this score is 25 - 30 points, the result of a baseline Alzheimer's Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

If an ADAS-Cog score is not supplied with the initial application, this scale cannot be used for the purpose of fulfilling the criteria for continued PBS supply.

This application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment. For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised;

CONTINUING TREATMENT — (S)MMSE or ADAS-Cog improvement.

Continuing treatment, as the sole PBS-subsidised therapy, following initial PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease in patients with demonstrated improvement in cognitive function as measured by:

(a) for patients with a baseline (S)MMSE score of 10 or more and less than 25, an increase of at least 2 points from baseline on the Mini-Mental

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State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE);
(b) for patients with a baseline (S)MMSE score of at least 25 points, a decrease of at least 4 points from baseline on the Alzheimer's Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) or an increase of at least 2 points from baseline on the Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE).

The initial authority application for continuing treatment must include the relevant result from the (S)MMSE or the ADAS-Cog and must be in writing.

Subsequent applications for continuing treatment can be made by telephone.

Authority required

INITIAL APPLICATION FOR THE TREATMENT OF MILD TO MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients with an (S)MMSE of 9 or less who require a clinician's assessment.

Initial treatment, as the sole PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease of patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, who are unable to register a score of 10 or more for reasons other than their Alzheimer's disease, as specified below. Confirmation of this diagnosis must be made by or in consultation with a specialist/consultant physician (including a psychiatrist).

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

This application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment. For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

Patients who qualify under this criterion are from 1 or more of the following groups:

- (1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;
- (2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;
- (3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;
- (4) Intellectual (developmental or acquired) disability, eg Down's syndrome;
- (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;
- (6) Prominent dysphasia, out of proportion to other cognitive and functional impairment;

CONTINUING TREATMENT — Clinician assessed improvement.

Continuing treatment, as the sole PBS-subsidised therapy, following initial PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease in patients with demonstrated improvement in function, based on a rating of "very much improved" or "much improved" on the Clinicians Interview Based Impression of Change (CIBIC) scale, which must be assessed by the same clinician who initiated treatment.

The initial authority application for continuing treatment must state the improvement achieved on the CIBIC scale and must be in writing.

Subsequent applications for continuing treatment can be made by telephone.

Note

Continuing Therapy Only:

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

8495D NP	Tablet 5 mg	28	5	..	155.45	34.20	Aricept	PF
8496E NP	Tablet 10 mg	28	5	..	155.45	34.20	Aricept	PF

ESOMEPRAZOLE MAGNESIUM TRIHYDRATE

Authority required

Pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion;

Scleroderma oesophagus.

Note

Continuing Therapy Only:

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

3401B NP	Tablet (enteric coated), equivalent to 40 mg esomeprazole	30	5	..	45.69	34.20	Nexium	AP
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GALANTAMINE HYDROBROMIDE

Authority required

INITIAL APPLICATION FOR THE TREATMENT OF MILD TO MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients with an (S)MMSE of 10 or more.

Initial treatment, as the sole PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease. Confirmation of this diagnosis must be made

GENERAL PHARMACEUTICAL BENEFITS

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by or in consultation with a specialist/consultant physician (including a psychiatrist).

The authority application must include the result of the baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE). This baseline (S)MMSE must be a score of 10 or more. If this score is 25 - 30 points, the result of a baseline Alzheimer's Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

If an ADAS-Cog score is not supplied with the initial application, this scale cannot be used for the purpose of fulfilling the criteria for continued PBS supply.

This application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment. For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised;

CONTINUING TREATMENT — (S)MMSE or ADAS-Cog improvement.

Continuing treatment, as the sole PBS-subsidised therapy, following initial PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease in patients with demonstrated improvement in cognitive function as measured by:

- (a) for patients with a baseline (S)MMSE score of 10 or more and less than 25, an increase of at least 2 points from baseline on the Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE);
- (b) for patients with a baseline (S)MMSE score of at least 25 points, a decrease of at least 4 points from baseline on the Alzheimer's Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) or an increase of at least 2 points from baseline on the Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE).

The initial authority application for continuing treatment must include the relevant result from the (S)MMSE or the ADAS-Cog and must be in writing.

Subsequent applications for continuing treatment can be made by telephone.

Authority required

INITIAL APPLICATION FOR THE TREATMENT OF MILD TO MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients with an (S)MMSE of 9 or less who require a clinician's assessment.

Initial treatment, as the sole PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease of patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, who are unable to register a score of 10 or more for reasons other than their Alzheimer's disease, as specified below. Confirmation of this diagnosis must be made by or in consultation with a specialist/consultant physician (including a psychiatrist).

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

This application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment. For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

Patients who qualify under this criterion are from 1 or more of the following groups:

- (1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;
- (2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;
- (3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;
- (4) Intellectual (developmental or acquired) disability, eg Down's syndrome;
- (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;
- (6) Prominent dysphasia, out of proportion to other cognitive and functional impairment;

CONTINUING TREATMENT — Clinician assessed improvement.

Continuing treatment, as the sole PBS-subsidised therapy, following initial PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease in patients with demonstrated improvement in function, based on a rating of "very much improved" or "much improved" on the Clinicians Interview Based Impression of Change (CIBIC) scale, which must be assessed by the same clinician who initiated treatment.

The initial authority application for continuing treatment must state the improvement achieved on the CIBIC scale and must be in writing.

Subsequent applications for continuing treatment can be made by telephone.

Note

Continuing Therapy Only:

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

8770N NP	Capsule 8 mg (base) (prolonged release)	28	5	..	113.09	34.20	^a	Galantyl	AF
							^a	Reminyl	JC
8771P	Capsule 16 mg (base) (prolonged release)	28	5	..	136.91	34.20	^a	Galantyl	AF

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price	Maximum	Brand Name and Manufacturer
					for Max. Qty \$	Recordable Value for Safety Net \$	
NP							
						^a	Reminyl JC
8772Q	Capsule 24 mg (base) (prolonged release)	28	5	..	161.93	34.20	^a Galantyl AF
NP						^a	Reminyl JC

MEMANTINE HYDROCHLORIDE

Authority required

INITIAL APPLICATION FOR THE TREATMENT OF MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients with an (S)MMSE of 10 to 14.

Initial treatment, as the sole PBS-subsidised therapy, of moderately severe Alzheimer's disease. Confirmation of this diagnosis must be made by or in consultation with a specialist/consultant physician (including a psychiatrist).

The authority application must include the result of the baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE). This baseline (S)MMSE must be a score of 10 to 14.

This application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment. For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised;

CONTINUING TREATMENT — (S)MMSE improvement.

Continuing treatment, as the sole PBS-subsidised therapy, following initial PBS-subsidised therapy, of moderately severe Alzheimer's disease in patients with demonstrated improvement in cognitive function as measured by an increase of at least 2 points from baseline on the Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE).

The initial authority application for continuing treatment must include the relevant result from the (S)MMSE and must be in writing.

Subsequent applications for continuing treatment can be made by telephone.

Authority required

INITIAL APPLICATION FOR THE TREATMENT OF MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients with an (S)MMSE of 9 or less who require a clinician's assessment.

Initial treatment, as the sole PBS-subsidised therapy, of moderately severe Alzheimer's disease of patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, who are unable to register a score of 10 to 14 for reasons other than their Alzheimer's disease, as specified below. Confirmation of this diagnosis must be made by or in consultation with a specialist/consultant physician (including a psychiatrist).

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

This application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment. For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

Patients who qualify under this criterion are from 1 or more of the following groups:

- (1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;
- (2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;
- (3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;
- (4) Intellectual (developmental or acquired) disability, eg Down's syndrome;
- (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;
- (6) Prominent dysphasia, out of proportion to other cognitive and functional impairment;

CONTINUING TREATMENT — Clinician assessed improvement.

Continuing treatment, as the sole PBS-subsidised therapy, following initial PBS-subsidised therapy, of moderately severe Alzheimer's disease in patients with demonstrated improvement in function, based on a rating of "very much improved" or "much improved" on the Clinicians Interview Based Impression of Change (CIBIC) scale, which must be assessed by the same clinician who initiated treatment.

The initial authority application for continuing treatment must state the improvement achieved on the CIBIC scale and must be in writing.

Subsequent applications for continuing treatment can be made by telephone.

Note

Continuing Therapy Only:

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

1956Y	Tablet 10 mg	56	5	..	106.95	34.20	^a APO-Memantine TX
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GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
NP							
							^a Ebixa LU
							^a Memanxa QA
9306T	Tablet 20 mg	28	5	..	106.95	34.20	Ebixa LU
NP							

NICOTINE

Authority required

Short-term sole PBS-subsidised therapy as an aid to achieving abstinence in a patient who has indicated they are ready to cease smoking and who has entered a comprehensive support and counselling program.

Details of the program must be specified in the initial authority application;

Short-term sole PBS-subsidised therapy as an aid to achieving abstinence in a patient who has indicated they are ready to cease smoking and who is entering a comprehensive support and counselling program during the consultation at which this authority is requested.

Details of the program must be specified in the initial authority application.

Note

A maximum of 12 weeks of PBS-subsidised nicotine replacement therapy will be authorised per year. No applications for increased maximum quantities and/or repeats will be authorised.

Authority required

Nicotine dependence in an Aboriginal or a Torres Strait Islander person as the sole PBS-subsidised therapy.

Note

Only 2 courses of PBS-subsidised nicotine replacement therapy will be authorised per year.

No applications for increased maximum quantities and/or repeats will be authorised.

Benefit is improved if used in conjunction with a comprehensive support and counselling program.

5465P	Transdermal patch releasing approximately	28	2	..	55.22	34.20	Nicabate P	GC
NP	21 mg per 24 hours							
3414Q	Transdermal patch releasing approximately	28	2	..	55.22	34.20	Nicotinell Step 1	NC
NP	21 mg per 24 hours							

RIVASTIGMINE

Authority required

INITIAL APPLICATION FOR THE TREATMENT OF MILD TO MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients with an (S)MMSE of 10 or more.

Initial treatment, as the sole PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease. Confirmation of this diagnosis must be made by or in consultation with a specialist/consultant physician (including a psychiatrist).

The authority application must include the result of the baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE). This baseline (S)MMSE must be a score of 10 or more. If this score is 25 - 30 points, the result of a baseline Alzheimer's Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

If an ADAS-Cog score is not supplied with the initial application, this scale cannot be used for the purpose of fulfilling the criteria for continued PBS supply.

This application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment. For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised;

CONTINUING TREATMENT — (S)MMSE or ADAS-Cog improvement.

Continuing treatment, as the sole PBS-subsidised therapy, following initial PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease in patients with demonstrated improvement in cognitive function as measured by:

(a) for patients with a baseline (S)MMSE score of 10 or more and less than 25, an increase of at least 2 points from baseline on the Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE);

(b) for patients with a baseline (S)MMSE score of at least 25 points, a decrease of at least 4 points from baseline on the Alzheimer's Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) or an increase of at least 2 points from baseline on the Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE).

The initial authority application for continuing treatment must include the relevant result from the (S)MMSE or the ADAS-Cog and must be in writing.

Subsequent applications for continuing treatment can be made by telephone.

Authority required

INITIAL APPLICATION FOR THE TREATMENT OF MILD TO MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients with an (S)MMSE of 9 or less who require a clinician's assessment.

Initial treatment, as the sole PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease of patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, who are unable to register a score of 10 or more

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price	Maximum	Brand Name and Manufacturer
					for Max. Qty \$	Recordable Value for Safety Net \$	

for reasons other than their Alzheimer's disease, as specified below. Confirmation of this diagnosis must be made by or in consultation with a specialist/consultant physician (including a psychiatrist).

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

This application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment. For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

Patients who qualify under this criterion are from 1 or more of the following groups:

- (1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;
- (2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;
- (3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;
- (4) Intellectual (developmental or acquired) disability, eg Down's syndrome;
- (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;
- (6) Prominent dysphasia, out of proportion to other cognitive and functional impairment;

CONTINUING TREATMENT — Clinician assessed improvement.

Continuing treatment, as the sole PBS-subsidised therapy, following initial PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease in patients with demonstrated improvement in function, based on a rating of "very much improved" or "much improved" on the Clinicians Interview Based Impression of Change (CIBIC) scale, which must be assessed by the same clinician who initiated treatment.

The initial authority application for continuing treatment must state the improvement achieved on the CIBIC scale and must be in writing.

Subsequent applications for continuing treatment can be made by telephone.

Note

Continuing Therapy Only:

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

9161E NP	Transdermal patch 9 mg (releasing approximately 4.6 mg per 24 hours)	30	5	..	166.09	34.20	Exelon Patch 5	NV
9162F NP	Transdermal patch 18 mg (releasing approximately 9.5 mg per 24 hours)	30	5	..	166.09	34.20	Exelon Patch 10	NV

RIVASTIGMINE HYDROGEN TARTRATE

Authority required

INITIAL APPLICATION FOR THE TREATMENT OF MILD TO MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients with an (S)MMSE of 10 or more.

Initial treatment, as the sole PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease. Confirmation of this diagnosis must be made by or in consultation with a specialist/consultant physician (including a psychiatrist).

The authority application must include the result of the baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE). This baseline (S)MMSE must be a score of 10 or more. If this score is 25 - 30 points, the result of a baseline Alzheimer's Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

If an ADAS-Cog score is not supplied with the initial application, this scale cannot be used for the purpose of fulfilling the criteria for continued PBS supply.

This application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment. For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised;

CONTINUING TREATMENT — (S)MMSE or ADAS-Cog improvement.

Continuing treatment, as the sole PBS-subsidised therapy, following initial PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease in patients with demonstrated improvement in cognitive function as measured by:

- (a) for patients with a baseline (S)MMSE score of 10 or more and less than 25, an increase of at least 2 points from baseline on the Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE);
- (b) for patients with a baseline (S)MMSE score of at least 25 points, a decrease of at least 4 points from baseline on the Alzheimer's Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) or an increase of at least 2 points from baseline on the Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE).

The initial authority application for continuing treatment must include the relevant result from the (S)MMSE or the ADAS-Cog and must be in writing.

Subsequent applications for continuing treatment can be made by telephone.

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price	Maximum	Brand Name and Manufacturer
					for Max. Qty \$	Recordable Value for Safety Net \$	

Authority required

INITIAL APPLICATION FOR THE TREATMENT OF MILD TO MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients with an (S)MMSE of 9 or less who require a clinician's assessment.

Initial treatment, as the sole PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease of patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, who are unable to register a score of 10 or more for reasons other than their Alzheimer's disease, as specified below. Confirmation of this diagnosis must be made by or in consultation with a specialist/consultant physician (including a psychiatrist).

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

This application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment. For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

Patients who qualify under this criterion are from 1 or more of the following groups:

- (1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;
- (2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;
- (3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;
- (4) Intellectual (developmental or acquired) disability, eg Down's syndrome;
- (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;
- (6) Prominent dysphasia, out of proportion to other cognitive and functional impairment;

CONTINUING TREATMENT — Clinician assessed improvement.

Continuing treatment, as the sole PBS-subsidised therapy, following initial PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease in patients with demonstrated improvement in function, based on a rating of "very much improved" or "much improved" on the Clinicians Interview Based Impression of Change (CIBIC) scale, which must be assessed by the same clinician who initiated treatment.

The initial authority application for continuing treatment must state the improvement achieved on the CIBIC scale and must be in writing.

Subsequent applications for continuing treatment can be made by telephone.

Note

Continuing Therapy Only:

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

8497F NP	Capsule 1.5 mg (base)	56	5	..	155.45	34.20	Exelon	NV
8498G NP	Capsule 3 mg (base)	56	5	..	155.45	34.20	Exelon	NV
8499H NP	Capsule 4.5 mg (base)	56	5	..	155.45	34.20	Exelon	NV
8500J NP	Capsule 6 mg (base)	56	5	..	155.45	34.20	Exelon	NV
8563Q NP	Oral solution 2 mg (base) per mL, 120 mL	¥1	5	..	155.45	34.20	Exelon	NV

TIOTROPIUM BROMIDE MONOHYDRATE

Restricted benefit

Chronic obstructive pulmonary disease.

8626B NP	Capsule containing powder for oral inhalation 18 micrograms (base) (for use in HandiHaler)	30	5	..	76.89	34.20	Spiriva	BY
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HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
ADEFOVIR DIPIVOXIL						
Authority required						
Chronic hepatitis B in a patient who has failed antihepadnaviral therapy and who satisfies all of the following criteria:						
(a) Repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or						
(b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antihepadnaviral therapy except in patients with evidence of poor compliance.						
Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.						
Note						
Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.						
6450L	Tablet 10 mg	60	5	..	*1296.42	Hepsera GI

ELTROMBOPAG

Note

Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

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

Written applications for authority to prescribe eltrombopag should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

Authority required

Initial (new patients)

Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who is:

(1) Splenectomised and:

(a) has had an inadequate response to, or is intolerant to, corticosteroid therapy post splenectomy; and

(b) has had an inadequate response to, or is intolerant to, immunoglobulin therapy post splenectomy;

OR

(2) Not splenectomised and:

(a) has had an inadequate response, or is intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks; and

(b) has had an inadequate response, or is intolerant to, immunoglobulin therapy; and

(c) in whom splenectomy is contraindicated for medical reasons.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of initial application:

(a) a platelet count of less than or equal to 20,000 million per L;

OR

(b) a platelet count of 20-30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

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

(1) a completed authority prescription form,

(2) a signed patient acknowledgement,

(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)],

(4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and

(5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

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

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion.

Note

Patients will be able to trial either eltrombopag and/or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with either eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
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treatment with either of these drugs.

No applications for increased repeats will be authorised.

Authority required

Initial (grandfather patients)

Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who was receiving treatment with eltrombopag prior to 1 November 2011 and in whom the criteria for initial treatment can be demonstrated to have been met at the time eltrombopag was commenced.

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

- (1) a completed authority prescription form,
- (2) a signed patient acknowledgement,
- (3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and
- (4) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion.

Note

No applications for increased repeats will be authorised.

Authority required

Continuing therapy or re-initiation after a break in therapy

First period of PBS-subsidised continuing treatment or re-initiation of interrupted PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has displayed a sustained platelet response to treatment with eltrombopag during the initial period of PBS-subsidised treatment.

For the purposes of this restriction, a sustained platelet response is defined as:

- (a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised eltrombopag,
- AND either of the following:
- (b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart;
 - OR
 - (c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart.

Applications for the first period of continuing PBS-subsidised treatment or re-initiation of interrupted treatment must be made in writing and must include:

- (1) a completed authority prescription form, and
- (2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and
- (3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy).

The most recent platelet count must be no more than one month old at the time of application.

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be made by telephone.

Note

No applications for increased repeats will be authorised.

Authority required

Second and subsequent applications for continuing therapy

Continuing treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has previously received PBS-subsidised therapy with eltrombopag and who continues to display a response to treatment with eltrombopag.

For the purposes of this restriction, a continuing response to treatment with eltrombopag is defined as:

- (a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with eltrombopag,
- AND either of the following:
- (b) a platelet count greater than or equal to 50,000 million per L
 - OR
 - (c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count.

Platelet counts must be no more than 1 month old at the time of application.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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

Authority applications for second and subsequent periods of continuing therapy may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note

No applications for increased repeats will be authorised.

5827Q	Tablet 25 mg (as olamine)	28	5	..	1558.42	Revolade	GK
5828R	Tablet 50 mg (as olamine)	28	5	..	3070.42	Revolade	GK

ENTECAVIR MONOHYDRATE

Authority required

Chronic hepatitis B in a patient who satisfies all of the following criteria:

(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;

(2) Evidence of chronic liver injury as determined by:

- (a) Confirmed elevated serum ALT; or
- (b) Liver biopsy.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

Note

PBS-subsidised entecavir monohydrate must be used as monotherapy.

9602J	Tablet 0.5 mg	60	5	..	*805.76	Baraclude	BQ
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ENTECAVIR MONOHYDRATE

Authority required

Chronic hepatitis B in a patient who has failed lamivudine therapy and who satisfies all of the following criteria:

(a) Repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or

(b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antihepadnaviral therapy except in patients with evidence of poor compliance.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

Note

PBS-subsidised entecavir monohydrate must be used as monotherapy.

9603K	Tablet 1 mg	60	5	..	*1296.42	Baraclude	BQ
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INTERFERON ALFA-2a

Caution

Treatment with interferon 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.

Authority required

Use in the treatment of Philadelphia chromosome positive myelogenous leukaemia in the chronic phase;

Chronic hepatitis B in a patient who satisfies all of the following criteria:

(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;

(2) Evidence of chronic liver injury as determined by:

- (a) Confirmed elevated serum ALT; or
- (b) Liver biopsy;

(3) Is not a person with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L).

6210W	Injection 3,000,000 i.u. in 0.5 mL single dose pre-filled syringe	30	5	..	*936.12	Roferon-A	RO
6211X	Injection 4,500,000 i.u. in 0.5 mL single dose pre-filled syringe	30	5	..	*1387.32	Roferon-A	RO
6212Y	Injection 6,000,000 i.u. in 0.5 mL single dose pre-filled syringe	30	5	..	*1833.72	Roferon-A	RO
6213B	Injection 9,000,000 i.u. in 0.5 mL single dose pre-filled syringe	30	5	..	*2727.72	Roferon-A	RO

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer	
INTERFERON ALFA-2b							
Caution							
Treatment with interferon 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.							
Authority required							
Adjunctive therapy of malignant melanoma following surgery in patients with nodal involvement;							
Use in the treatment of Philadelphia chromosome positive myelogenous leukaemia in the chronic phase;							
Chronic hepatitis B in a patient who satisfies all of the following criteria:							
(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;							
(2) Evidence of chronic liver injury as determined by:							
(a) Confirmed elevated serum ALT; or							
(b) Liver biopsy;							
(3) Is not a person with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L).							
6246R	Solution for injection 10,000,000 i.u. in 1 mL single dose vial	15	5	..	*1535.91	Intron A	MK
6253D	Solution for injection 18,000,000 i.u. in 1.2 mL multi-dose injection pen	2	5	..	*378.20	Intron A Redipen	MK
6218G	Solution for injection 18,000,000 i.u. in 3 mL single dose vial	15	5	..	*2727.57	Intron A	MK
6219H	Solution for injection 25,000,000 i.u. in 2.5 mL single dose vial	15	5	..	*3770.22	Intron A	MK
6254E	Solution for injection 30,000,000 i.u. in 1.2 mL multi-dose injection pen	2	5	..	*626.06	Intron A Redipen	MK
6255F	Solution for injection 60,000,000 i.u. in 1.2 mL multi-dose injection pen	2	5	..	*1238.02	Intron A Redipen	MK

LAMIVUDINE

Authority required

Chronic hepatitis B in a patient who satisfies all of the following criteria:

(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;

(2) Evidence of chronic liver injury as determined by:

(a) Confirmed elevated serum ALT; or

(b) Liver biopsy.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

6271C	Oral solution 5 mg per mL, 240 mL	5	5	..	*369.97	Zeffix	GK
6257H	Tablet 100 mg	56	5	..	*317.08	Zeffix	GK

PEGINTERFERON ALFA-2a

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.

Authority required

Monotherapy in a patient with chronic hepatitis B and compensated liver disease who satisfies all of the following criteria:

(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;

(2) Evidence of chronic liver injury as determined by:

(a) Confirmed elevated serum ALT; or

(b) Liver biopsy;

(3) Have received no prior peginterferon alfa therapy for the treatment of hepatitis B;

(4) Is not a person with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L).

Treatment is limited to 1 course of treatment for a duration of up to 48 weeks;

Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no prior interferon alfa or peginterferon alfa treatment for hepatitis C and have a contraindication to ribavirin, who satisfy all of the following criteria:

(1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive);

(2) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.

The treatment course is limited to up to 48 weeks.

Patients may only continue treatment after the first 12 weeks if the result of an HCV RNA quantitative assay (performed at the same laboratory using the same test) shows that the plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
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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; and
- (d) facilities for safe liver biopsy.

6439X	Injection 135 micrograms in 0.5 mL single use pre-filled syringe	8	5	..	*2378.22	Pegasys	RO
6449K	Injection 180 micrograms in 0.5 mL single use pre-filled syringe	8	5	..	*2746.88	Pegasys	RO

ROMIPILOSTIM

Note

Romiplostim is not PBS-subsidised as an alternative to splenectomy.

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

Written applications for authority to prescribe romiplostim should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

Authority required

Initial (new patients)

Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who is:

- (1) Splenectomised and:
 - (a) has had an inadequate response to, or is intolerant to, corticosteroid therapy post splenectomy; and
 - (b) has had an inadequate response to, or is intolerant to, immunoglobulin therapy post splenectomy;
- OR
- (2) Not splenectomised and:
 - (a) has had an inadequate response, or is intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks; and
 - (b) has had an inadequate response, or is intolerant to, immunoglobulin therapy; and
 - (c) in whom splenectomy is contraindicated for medical reasons.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of initial application:

- (a) a platelet count of less than or equal to 20,000 million per L;
- OR
- (b) a platelet count of 20-30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

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

- (1) a completed authority prescription form,
- (2) a signed patient acknowledgement,
- (3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)],
- (4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and
- (5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

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

At the time of the written authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The dose (microgram/kg/week) must be provided at the time of application.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
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treatment authorised under this restriction does not exceed 24 weeks.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week.

Note

Patients will be able to trial either eltrombopag and/or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with either eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

Authority required

Initial (grandfather patients)

Initial PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who was receiving treatment with romiplostim prior to 1 April 2011 and in whom the criteria for initial treatment can be demonstrated to have been met at the time romiplostim was commenced.

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

- (1) a completed authority prescription form,
- (2) a signed patient acknowledgement,
- (3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and
- (4) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

For patients whose dose of romiplostim had been stable for at least 4 weeks at the time of the initial application for PBS-subsidy, the medical practitioner should request sufficient number of vials based on the weight of the patient and dose (microgram/kg/week) to provide up to 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Where the patient is in the titration phase of treatment with romiplostim, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The dose (microgram/kg/week) must be provided at the time of application.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week.

Authority required

Continuing therapy or re-initiation after a break in therapy

First period of PBS-subsidised continuing treatment or re-initiation of interrupted PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has displayed a sustained platelet response to treatment with romiplostim during the initial period of PBS-subsidised treatment.

For the purposes of this restriction, a sustained platelet response is defined as:

- (a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised romiplostim,
- AND either of the following:
- (b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart;
- OR
- (c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart.

Applications for the first period of continuing PBS-subsidised treatment or re-initiation of interrupted treatment must be made in writing and must include:

- (1) a completed authority prescription form, and
- (2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and
- (3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy).

The most recent platelet count must be no more than one month old at the time of application.

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be made by telephone.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
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Authority approval will not be given for doses of higher than 10 micrograms/kg/week.

Authority required

Second and subsequent applications for continuing therapy

Continuing treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has previously received PBS-subsidised therapy with romiplostim and who continues to display a response to treatment with romiplostim.

For the purposes of this restriction, a continuing response to treatment with romiplostim is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with romiplostim,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count.

Platelet counts must be no more than 1 month old at the time of application.

Authority applications for second and subsequent periods of continuing therapy may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week.

Note

Special Pricing Arrangements apply.

9697J	Powder for injection 375 micrograms (250 micrograms in 0.5 mL when reconstituted)	1	1023.02	Nplate	AN
9699L	Powder for injection 625 micrograms (500 micrograms in 1 mL when reconstituted)	1	2001.42	Nplate	AN

TELBIVUDINE

Authority required

Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B who is nucleoside analogue naive and satisfies all of the following criteria:

(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented hepatitis B infection;

(2) Evidence of chronic liver injury as determined by:

(a) Confirmed elevated serum; or

(b) Liver biopsy.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

9630W	Tablet 600 mg	56	5	..	*528.26	Sebivo	NV
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TENOFOVIR

Authority required

Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;

Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.

Authority required

Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B who is nucleoside analogue naive and satisfies all of the following criteria:

(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented hepatitis B infection;

(2) Evidence of chronic liver injury as determined by:

(a) Confirmed elevated serum; or

(b) Liver biopsy.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy;

Chronic hepatitis B in a patient who has failed antihepadnaviral therapy and who satisfies all of the following criteria:

(a) Repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	with documented chronic hepatitis B infection; or (b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antihepadnaviral therapy except in patients with evidence of poor compliance. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.					
	Note Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.					
6358P	Tablet containing tenofovir disoproxil fumarate 300 mg	60	5	..	*1011.26	Viread GI
	ZOLEDRONIC ACID Authority required Multiple myeloma; Bone metastases from breast cancer; Bone metastases from hormone-resistant prostate cancer; Treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy.					
	Note Special Pricing Arrangements apply.					
6371H	Injection concentrate for I.V. infusion 4 mg (as monohydrate) in 5 mL	1	11	..	474.42	Zometa NV

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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

Authority required (STREAMLINED)

3864

Chronic hepatitis B in a patient who has failed antihepadnaviral therapy and who satisfies all of the following criteria:

(a) Repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or

(b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antihepadnaviral therapy except in patients with evidence of poor compliance.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

Note

Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

5606C	Tablet 10 mg	60	5	..	*1250.00	Hepsera	GI
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ELTROMBOPAG

Note

Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

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

Written applications for authority to prescribe eltrombopag should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

Authority required

Initial (new patients)

Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who is:

(1) Splenectomised and:

(a) has had an inadequate response to, or is intolerant to, corticosteroid therapy post splenectomy; and

(b) has had an inadequate response to, or is intolerant to, immunoglobulin therapy post splenectomy;

OR

(2) Not splenectomised and:

(a) has had an inadequate response, or is intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks; and

(b) has had an inadequate response, or is intolerant to, immunoglobulin therapy; and

(c) in whom splenectomy is contraindicated for medical reasons.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of initial application:

(a) a platelet count of less than or equal to 20,000 million per L;

OR

(b) a platelet count of 20-30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

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

(1) a completed authority prescription form,

(2) a signed patient acknowledgement,

(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)],

(4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and

(5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

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

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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

Patients will be able to trial either eltrombopag and/or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with either eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

No applications for increased repeats will be authorised.

Authority required

Initial (grandfather patients)

Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who was receiving treatment with eltrombopag prior to 1 November 2011 and in whom the criteria for initial treatment can be demonstrated to have been met at the time eltrombopag was commenced.

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

- (1) a completed authority prescription form,
- (2) a signed patient acknowledgement,
- (3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and
- (4) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion.

Note

No applications for increased repeats will be authorised.

Authority required

Continuing therapy or re-initiation after a break in therapy

First period of PBS-subsidised continuing treatment or re-initiation of interrupted PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has displayed a sustained platelet response to treatment with eltrombopag during the initial period of PBS-subsidised treatment.

For the purposes of this restriction, a sustained platelet response is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised eltrombopag,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart;

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart.

Applications for the first period of continuing PBS-subsidised treatment or re-initiation of interrupted treatment must be made in writing and must include:

- (1) a completed authority prescription form, and
- (2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and
- (3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy).

The most recent platelet count must be no more than one month old at the time of application.

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be made by telephone.

Note

No applications for increased repeats will be authorised.

Authority required

Second and subsequent applications for continuing therapy

Continuing treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has previously received PBS-subsidised therapy with eltrombopag and who continues to display a response to treatment with eltrombopag.

For the purposes of this restriction, a continuing response to treatment with eltrombopag is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with eltrombopag,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
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Platelet counts must be no more than 1 month old at the time of application.

Authority applications for second and subsequent periods of continuing therapy may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note

No applications for increased repeats will be authorised.

5825N	Tablet 25 mg (as olamine)	28	5	..	1512.00	Revolade	GK
5826P	Tablet 50 mg (as olamine)	28	5	..	3024.00	Revolade	GK

ENTECAVIR MONOHYDRATE

Authority required (STREAMLINED)

3872

Chronic hepatitis B in a patient who satisfies all of the following criteria:

(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAG positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAG negative - in conjunction with documented chronic hepatitis B infection;

(2) Evidence of chronic liver injury as determined by:

(a) Confirmed elevated serum ALT; or

(b) Liver biopsy.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

Note

PBS-subsidised entecavir monohydrate must be used as monotherapy.

5711N	Tablet 0.5 mg	60	5	..	*768.60	Baraclude	BQ
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ENTECAVIR MONOHYDRATE

Authority required (STREAMLINED)

3874

Chronic hepatitis B in a patient who has failed lamivudine therapy and who satisfies all of the following criteria:

(a) Repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or

(b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antihepadnaviral therapy except in patients with evidence of poor compliance.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

Note

PBS-subsidised entecavir monohydrate must be used as monotherapy.

5712P	Tablet 1 mg	60	5	..	*1250.00	Baraclude	BQ
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INTERFERON ALFA-2a

Caution

Treatment with interferon 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.

Authority required (STREAMLINED)

3382

Use in the treatment of Philadelphia chromosome positive myelogenous leukaemia in the chronic phase;

3870

Chronic hepatitis B in a patient who satisfies all of the following criteria:

(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAG positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAG negative - in conjunction with documented chronic hepatitis B infection;

(2) Evidence of chronic liver injury as determined by:

(a) Confirmed elevated serum ALT; or

(b) Liver biopsy;

(3) Is not a persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L).

5759D	Injection 3,000,000 i.u. in 0.5 mL single dose pre-filled syringe	30	5	..	*894.00	Roferon-A	RO
5760E	Injection 4,500,000 i.u. in 0.5 mL single dose pre-filled syringe	30	5	..	*1341.00	Roferon-A	RO

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer	
5761F	Injection 6,000,000 i.u. in 0.5 mL single dose pre-filled syringe	30	5	..	*1787.40	Roferon-A	RO
5762G	Injection 9,000,000 i.u. in 0.5 mL single dose pre-filled syringe	30	5	..	*2681.40	Roferon-A	RO

INTERFERON ALFA-2b

Caution

Treatment with interferon 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.

Authority required (STREAMLINED)

3384

Adjunctive therapy of malignant melanoma following surgery in patients with nodal involvement;

3382

Use in the treatment of Philadelphia chromosome positive myelogenous leukaemia in the chronic phase;

3870

Chronic hepatitis B in a patient who satisfies all of the following criteria:

- (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAG positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAG negative - in conjunction with documented chronic hepatitis B infection;
- (2) Evidence of chronic liver injury as determined by:
 - (a) Confirmed elevated serum ALT; or
 - (b) Liver biopsy;
- (3) Is not a persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L).

5768N	Solution for injection 10,000,000 i.u. in 1 mL single dose vial	15	5	..	*1489.50	Intron A	MK
5763H	Solution for injection 18,000,000 i.u. in 1.2 mL multi-dose injection pen	2	5	..	*357.48	Intron A Redipen	MK
5766L	Solution for injection 18,000,000 i.u. in 3 mL single dose vial	15	5	..	*2681.10	Intron A	MK
5767M	Solution for injection 25,000,000 i.u. in 2.5 mL single dose vial	15	5	..	*3723.75	Intron A	MK
5764J	Solution for injection 30,000,000 i.u. in 1.2 mL multi-dose injection pen	2	5	..	*595.80	Intron A Redipen	MK
5765K	Solution for injection 60,000,000 i.u. in 1.2 mL multi-dose injection pen	2	5	..	*1191.60	Intron A Redipen	MK

LAMIVUDINE

Authority required (STREAMLINED)

3872

Chronic hepatitis B in a patient who satisfies all of the following criteria:

- (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAG positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAG negative - in conjunction with documented chronic hepatitis B infection;
 - (2) Evidence of chronic liver injury as determined by:
 - (a) Confirmed elevated serum ALT; or
 - (b) Liver biopsy.
- Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

5771R	Oral solution 5 mg per mL, 240 mL	5	5	..	*349.55	Zeffix	GK
5770Q	Tablet 100 mg	56	5	..	*298.72	Zeffix	GK

PEGINTERFERON ALFA-2a

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.

Authority required (STREAMLINED)

3868

Monotherapy in a patient with chronic hepatitis B and compensated liver disease who satisfies all of the following criteria:

- (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAG positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAG negative - in conjunction with documented chronic hepatitis B infection;
- (2) Evidence of chronic liver injury as determined by:
 - (a) Confirmed elevated serum ALT; or
 - (b) Liver biopsy;
- (3) Have received no prior peginterferon alfa therapy for the treatment of hepatitis B;
- (4) Is not a person with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than

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	30 micromoles per L). Treatment is limited to 1 course of treatment for a duration of up to 48 weeks;					
	3412 Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no prior interferon alfa or peginterferon alfa treatment for hepatitis C and have a contraindication to ribavirin, who satisfy all of the following criteria: (1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive); (2) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception. The treatment course is limited to up to 48 weeks. Patients may only continue treatment after the first 12 weeks if the result of an HCV RNA quantitative assay (performed at the same laboratory using the same test) shows that the plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop.					
	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; and (d) facilities for safe liver biopsy.					
9515T	Injection 135 micrograms in 0.5 mL single use pre-filled syringe	8	5	..	*2331.80	Pegasys RO
9516W	Injection 180 micrograms in 0.5 mL single use pre-filled syringe	8	5	..	*2700.46	Pegasys RO

ROMIPILOSTIM

Note

Romiplostim is not PBS-subsidised as an alternative to splenectomy.

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

Written applications for authority to prescribe romiplostim should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

Authority required

Initial (new patients)

Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who is:

(1) Splenectomised and:

- (a) has had an inadequate response to, or is intolerant to, corticosteroid therapy post splenectomy; and
- (b) has had an inadequate response to, or is intolerant to, immunoglobulin therapy post splenectomy;

OR

(2) Not splenectomised and:

- (a) has had an inadequate response, or is intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks; and
- (b) has had an inadequate response, or is intolerant to, immunoglobulin therapy; and
- (c) in whom splenectomy is contraindicated for medical reasons.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of initial application:

- (a) a platelet count of less than or equal to 20,000 million per L;

OR

- (b) a platelet count of 20-30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

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

- (1) a completed authority prescription form,
- (2) a signed patient acknowledgement,
- (3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)],
- (4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and
- (5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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

At the time of the written authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The dose (microgram/kg/week) must be provided at the time of application.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week.

Note

Patients will be able to trial either eltrombopag and/or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with either eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

Authority required

Initial (grandfather patients)

Initial PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who was receiving treatment with romiplostim prior to 1 April 2011 and in whom the criteria for initial treatment can be demonstrated to have been met at the time romiplostim was commenced.

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

- (1) a completed authority prescription form,
- (2) a signed patient acknowledgement,
- (3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and
- (4) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

For patients whose dose of romiplostim had been stable for at least 4 weeks at the time of the initial application for PBS-subsidy, the medical practitioner should request sufficient number of vials based on the weight of the patient and dose (microgram/kg/week) to provide up to 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Where the patient is in the titration phase of treatment with romiplostim, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The dose (microgram/kg/week) must be provided at the time of application.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week.

Authority required

Continuing therapy or re-initiation after a break in therapy

First period of PBS-subsidised continuing treatment or re-initiation of interrupted PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has displayed a sustained platelet response to treatment with romiplostim during the initial period of PBS-subsidised treatment.

For the purposes of this restriction, a sustained platelet response is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised romiplostim,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart;

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart.

Applications for the first period of continuing PBS-subsidised treatment or re-initiation of interrupted treatment must be made in writing and must include:

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- (1) a completed authority prescription form, and
 (2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and
 (3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy).

The most recent platelet count must be no more than one month old at the time of application.

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be made by telephone.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week.

Authority required

Second and subsequent applications for continuing therapy

Continuing treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has previously received PBS-subsidised therapy with romiplostim and who continues to display a response to treatment with romiplostim.

For the purposes of this restriction, a continuing response to treatment with romiplostim is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with romiplostim,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count.

Platelet counts must be no more than 1 month old at the time of application.

Authority applications for second and subsequent periods of continuing therapy may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week.

Note

Special Pricing Arrangements apply.

9696H	Powder for injection 375 micrograms (250 micrograms in 0.5 mL when reconstituted)	1	977.50	Nplate	AN
9698K	Powder for injection 625 micrograms (500 micrograms in 1 mL when reconstituted)	1	1955.00	Nplate	AN

TELBIVUDINE

Authority required (STREAMLINED)

3866

Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B who is nucleoside analogue naive and satisfies all of the following criteria:

(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAG positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAG negative - in conjunction with documented hepatitis B infection;

(2) Evidence of chronic liver injury as determined by:

(a) Confirmed elevated serum; or

(b) Liver biopsy.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

9562G	Tablet 600 mg	56	5	..	*501.76	Sebivo	NV
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TENOFOVIR

Authority required (STREAMLINED)

3588

Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
3589						
Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.						
Authority required (STREAMLINED)						
3866						
Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B who is nucleoside analogue naive and satisfies all of the following criteria:						
(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAG positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAG negative - in conjunction with documented hepatitis B infection;						
(2) Evidence of chronic liver injury as determined by:						
(a) Confirmed elevated serum; or						
(b) Liver biopsy.						
Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy;						
3864						
Chronic hepatitis B in a patient who has failed antihepadnaviral therapy and who satisfies all of the following criteria:						
(a) Repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or						
(b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antihepadnaviral therapy except in patients with evidence of poor compliance.						
Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.						
Note						
Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.						
9563H	Tablet containing tenofovir disoproxil fumarate 300 mg	60	5	..	*966.20	Viread GI
ZOLEDRONIC ACID						
Authority required (STREAMLINED)						
3342						
Multiple myeloma;						
3343						
Bone metastases from breast cancer;						
3882						
Bone metastases from hormone-resistant prostate cancer;						
3341						
Treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy.						
Note						
Special Pricing Arrangements apply.						
9653C	Injection concentrate for I.V. infusion 4 mg (as monohydrate) in 5 mL	1	11	..	450.00	Zometa NV