Australian Government

Department of Health and Ageing

SCHEDULE OF PHARMACEUTICAL BENEFITS

SUMMARY OF CHANGES

EFFECTIVE 1 JULY 2008

PHARMACEUTICAL BENEFITS

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 July 2008. 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 July 2008 and are included, where applicable, in prices published in the Schedule—

Dispensing Fees:	Ready-prepared	$5.81
	Dangerous drug fee	$2.71
	Extemporaneously-prepared	$7.85
	Allowable additional patient charge*	$3.63
Additional Fees (for safety net prices):	Ready-prepared	$1.01
	Extemporaneously-prepared	$1.40
Patient Co-payments:	General	$31.30
	Concessional	$5.00
Safety Net Thresholds:	General	$1141.80
	Concessional	$290.00
Safety Net Card Issue Fee:		$7.86

*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

Additions — Items

9163G **Calcipotriol**, Scalp solution 50 micrograms per mL (0.005%), 30 mL (*Daivonex*)

9157Y **Cinacalcet hydrochloride**, Tablet 30 mg (base) (*Sensipar*)
9158B **Cinacalcet hydrochloride**, Tablet 60 mg (base) (*Sensipar*)
9159C **Cinacalcet hydrochloride**, Tablet 90 mg (base) (*Sensipar*)
3478C **Clonazepam**, Oral liquid 2.5 mg per mL, 10 mL (*Rivotril*) **(Doctor's Bag)**
9164H **Cystine with carbohydrate**, Sachets 4 g containing 500 mg cystine, 30 (*Cystine Amino Acid Supplement*)
3473T **Hyoscine butylbromide**, Injection 20 mg in 1 mL (*Buscopan*) **(Doctor's Bag)**
1956Y **Memantine hydrochloride**, Tablet 10 mg (*Ebixa*)
2059J **Memantine hydrochloride**, Oral drops 10 mg per g, 50 g (*Ebixa*)
9161E **Rivastigmine**, Transdermal patch 9 mg (releasing approximately 4.6 mg per 24 hours) (*Exelon Patch 5*)
9162F **Rivastigmine**, Transdermal patch 18 mg (releasing approximately 9.5 mg per 24 hours) (*Exelon Patch 10*)
9160D **Terbinafine hydrochloride**, Cream 10 mg per g (1%), 15 g (*Lamisil*)

9165J **Tyrosine with carbohydrate**, Sachets 4 g containing 1 g tyrosine, 30 (*Tyrosine Amino Acid Supplement*)

Additions — Brands

2751T *Amlodipine generichealth, GQ* — **Amlodipine**, Tablet 5 mg (as besylate)

2752W *Amlodipine generichealth, GQ* — **Amlodipine**, Tablet 10 mg (as besylate)
2265F *Fluvax Junior, CS* — **Influenza vaccine**, Injection (trivalent) 0.25 mL (containing A/Solomon Islands/3/2006, A/Brisbane/10/2007 and B/Florida/4/2006 like strains)
1638F *DBL Metronidazole Intravenous Infusion, HH* — **Metronidazole**, I.V. infusion 500 mg in 100 mL
5154G *DBL Metronidazole Intravenous Infusion, HH* — **Metronidazole**, I.V. infusion 500 mg in 100 mL **(Dental)**
3050M *Indopril 2, SI* — **Perindopril**, Tablet containing 2 mg perindopril erbumine
3051N *Indopril 4, SI* — **Perindopril**, Tablet containing 4 mg perindopril erbumine

8704D *Indopril 8, SI* — **Perindopril**, Tablet containing 8 mg perindopril erbumine

Additions — Notes

The restrictions for the following items have also been amended (see Alterations — Restrictions).

Pemetrexed disodium, Powder for I.V. infusion 100 mg (base) (*Alimta*)

Pemetrexed disodium, Powder for I.V. infusion 500 mg (base) (*Alimta*)

DELETIONS

Deletions — Items

2508B **Dexamethasone sodium phosphate**, Injection equivalent to 120 mg dexamethasone phosphate in 5 mL (*HH*)

2695W **Hydroxocobalamin acetate**, Injection 1 mg (base) in 1 mL (*Goldshield Hydroxocobalamin*)
2356B **Phenoxymethylpenicillin**, Paediatric oral suspension 125 mg per 5 mL, 100 mL (*Cilicaine V, Abbocillin-V*)
3365D **Phenoxymethylpenicillin**, Paediatric oral suspension 125 mg per 5 mL, 100 mL (*Cilicaine V, Abbocillin-V*) **(Dental)**
2354X **Phenoxymethylpenicillin**, Oral suspension 250 mg per 5 mL, 100 mL (*Cilicaine V, Abbocillin-V*)
3366E **Phenoxymethylpenicillin**, Oral suspension 250 mg per 5 mL, 100 mL (*Cilicaine V, Abbocillin-V*) **(Dental)**

Deletions — Brands

8485N *Femtran 25, IA* — **Oestradiol**, Transdermal patches 2 mg (releasing approximately 25 micrograms per 24 hours), 4

8125P *Femtran 50, IA* — **Oestradiol**, Transdermal patches 3.8 mg (releasing approximately 50 micrograms per 24 hours), 4

8126Q *Femtran 100, IA* — **Oestradiol**, Transdermal patches 7.6 mg (releasing approximately 100 micrograms per 24 hours), 4

Deletions — Bioequivalence Indicator

The bioequivalence indicator ([a]) has been removed from the following brands:

8485N *Climara 25, SC* — **Oestradiol**, Transdermal patches 2 mg (releasing approximately 25 micrograms per 24 hours), 4

8125P *Climara 50, SC* — **Oestradiol**, Transdermal patches 3.8 mg (releasing approximately 50 micrograms per 24 hours), 4

8126Q *Climara 100, SC* — **Oestradiol**, Transdermal patches 7.6 mg (releasing approximately 100 micrograms per 24 hours), 4

ALTERATIONS

Alterations — Restrictions

9101B **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen (*Humira*)

9033K **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled syringe (*Humira*)

9034L **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled syringe (*Humira*) **(Diff. Max. Rpts)**

9102C **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen (*Humira*)

8495D **Donepezil hydrochloride**, Tablet 5 mg (*Aricept*)

8496E **Donepezil hydrochloride**, Tablet 10 mg (*Aricept*)

9035M **Etanercept**, Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*)

9036N **Etanercept**, Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*) **(Diff. Max. Rpts)**

9083C **Etanercept**, Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*)

9084D **Etanercept**, Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*) **(Diff. Max. Rpts)**

9087G **Etanercept**, Injections 50 mg in 1 mL single use pre-filled syringes, 4 (*Enbrel*)

9088H **Etanercept**, Injections 50 mg in 1 mL single use pre-filled syringes, 4 (*Enbrel*) **(Diff. Max. Rpts)**

8770N **Galantamine hydrobromide**, Capsule 8 mg (base) (prolonged release) (*Reminyl*)

8771P **Galantamine hydrobromide**, Capsule 16 mg (base) (prolonged release) (*Reminyl*)

8772Q **Galantamine hydrobromide**, Capsule 24 mg (base) (prolonged release) (*Reminyl*)

8769M **Gefitinib**, Tablet 250 mg (*Iressa*)

9131N **Pemetrexed disodium**, Powder for I.V. infusion 100 mg (base) (*Alimta*)

9130M **Pemetrexed disodium**, Powder for I.V. infusion 500 mg (base) (*Alimta*)

8497F **Rivastigmine hydrogen tartrate**, Capsule 1.5 mg (base) (*Exelon*)

8498G **Rivastigmine hydrogen tartrate**, Capsule 3 mg (base) (*Exelon*)

8499H **Rivastigmine hydrogen tartrate**, Capsule 4.5 mg (base) (*Exelon*)

8500J **Rivastigmine hydrogen tartrate**, Capsule 6 mg (base) (*Exelon*)

8563Q **Rivastigmine hydrogen tartrate**, Oral solution 2 mg (base) per mL, 120 mL (*Exelon*)

2142R **Sevelamer hydrochloride**, Tablet 800 mg (*Renagel*)

Alterations — Notes

Cetuximab, Solution for I.V. infusion 100 mg in 20 mL (*Erbitux*)

Cetuximab, Solution for I.V. infusion 100 mg in 50 mL (*Erbitux*)

Cetuximab, Solution for I.V. infusion 500 mg in 100 mL (*Erbitux*)

Alterations — Item Description

From:

8425K **Oestradiol and oestradiol with norethisterone acetate**, Pack containing 4 transdermal patches oestradiol 4.33 mg (releasing approximately 50 micrograms per 24 hours) and 4 transdermal patches oestradiol with norethisterone acetate 620 micrograms-2.7 mg (releasing approximately 50 micrograms- 140 micrograms per 24 hours) (*Estalis sequi 50/140*)

To:

8425K **Oestradiol and oestradiol with norethisterone acetate**, Pack containing 4 transdermal patches oestradiol 780 micrograms (releasing approximately 50 micrograms per 24 hours) and 4 transdermal patches oestradiol with norethisterone acetate 620 micrograms-2.7 mg (releasing approximately 50 micrograms-140 micrograms per 24 hours) (*Estalis sequi 50/140*)

From:

8426L **Oestradiol and oestradiol with norethisterone acetate**, Pack containing 4 transdermal patches oestradiol 4.33 mg (releasing approximately 50 micrograms per 24 hours) and 4 transdermal patches oestradiol with norethisterone acetate 510 micrograms-4.8 mg (releasing approximately 50 micrograms- 250 micrograms per 24 hours) (*Estalis sequi 50/250*)

To:

8426L **Oestradiol and oestradiol with norethisterone acetate**, Pack containing 4 transdermal patches oestradiol 780 micrograms (releasing approximately 50 micrograms per 24 hours) and 4 transdermal patches oestradiol with norethisterone acetate 510 micrograms-4.8 mg (releasing approximately 50 micrograms-250 micrograms per 24 hours) (*Estalis sequi 50/250*)

Alterations — Maximum Quantity

		From	*To*
8731M	**Mesalazine**, Tablet 500 mg (enteric coated) (*Salofalk*)	100	200
8598M	**Mesalazine**, Sachet containing granules, 500 mg per sachet (*Salofalk*)	100	200

Alterations — Manufacturer's Code

		From	*To*
8511Y	**Alendronate sodium**, Tablet equivalent to 70 mg alendronic acid (*APO-Alendronate*)	GX	TX
2751T	**Amlodipine**, Tablet 5 mg (as besylate) (*APO-Amlodipine*)	GX	TX
2752W	**Amlodipine**, Tablet 10 mg (as besylate) (*APO-Amlodipine*)	GX	TX
1968N	**Quinapril hydrochloride**, Tablet 5 mg (base) (*APO-Quinapril*)	GX	TX
1969P	**Quinapril hydrochloride**, Tablet 10 mg (base) (*APO-Quinapril*)	GX	TX
1970Q	**Quinapril hydrochloride**, Tablet 20 mg (base) (*APO-Quinapril*)	GX	TX

SECTION 100 — HIGHLY SPECIALISED DRUGS PROGRAM

ADDITIONS

Additions — Items

9625N **Cinacalcet hydrochloride**, Tablet 30 mg (base) (*Sensipar*)

9626P **Cinacalcet hydrochloride**, Tablet 60 mg (base) (*Sensipar*)

9627Q **Cinacalcet hydrochloride**, Tablet 90 mg (base) (*Sensipar*)

9624M **Natalizumab**, Solution concentrate for I.V. infusion 300 mg in 15 mL (*Tysabri*)

9629T **Raltegravir potassium**, Tablet 400 mg (base) (*Isentress*)

ALTERATIONS

Alterations - Restrictions

6450L **Adefovir dipivoxil**, Tablet 10 mg (*Hepsera*)

9602J **Entecavir monohydrate**, Tablet 0.5 mg (*Baraclude*)
9603K **Entecavir monohydrate**, Tablet 1 mg (*Baraclude*)
6291D **Filgrastim**, Injection 300 micrograms in 0.5 mL single use pre-filled syringe (*Neupogen*)
6126K **Filgrastim**, Injection 300 micrograms in 1 mL (*Neupogen*)
6292E **Filgrastim**, Injection 480 micrograms in 0.5 mL single use pre-filled syringe (*Neupogen*)
6127L **Filgrastim**, Injection 480 micrograms in 1.6 mL (*Neupogen*)
6456T **Iloprost trometamol**, Solution for inhalation 20 micrograms (base) in 2 mL (*Ventavis*)
6496X **Infliximab**, Powder for I.V. infusion 100 mg (*Remicade*)
6210W **Interferon alfa-2a**, Injection 3,000,000 i.u. in 0.5 mL single dose pre-filled syringe (*Roferon-A*)
6211X **Interferon alfa-2a**, Injection 4,500,000 i.u. in 0.5 mL single dose pre-filled syringe (*Roferon-A*)
6212Y **Interferon alfa-2a**, Injection 6,000,000 i.u. in 0.5 mL single dose pre-filled syringe (*Roferon-A*)
6213B **Interferon alfa-2a**, Injection 9,000,000 i.u. in 0.5 mL single dose pre-filled syringe (*Roferon-A*)
6246R **Interferon alfa-2b**, Solution for injection 10,000,000 i.u. in 1 mL single dose vial (*Intron A*)
6253D **Interferon alfa-2b**, Solution for injection 18,000,000 i.u. in 1.2 mL multi-dose injection pen (*Intron A Redipen*)
6218G **Interferon alfa-2b**, Solution for injection 18,000,000 i.u. in 3 mL single dose vial (*Intron A*)
6219H **Interferon alfa-2b**, Solution for injection 25,000,000 i.u. in 2.5 mL single dose vial (*Intron A*)
6254E **Interferon alfa-2b**, Solution for injection 30,000,000 i.u. in 1.2 mL multi-dose injection pen (*Intron A Redipen*)
6255F **Interferon alfa-2b**, Solution for injection 60,000,000 i.u. in 1.2 mL multi-dose injection pen (*Intron A Redipen*)
6271C **Lamivudine**, Oral solution 5 mg per mL, 240 mL (*Zeffix*)
6257H **Lamivudine**, Tablet 100 mg (*Zeffix*)
6363X **Pegfilgrastim**, Injection 6 mg in 0.6 mL single use pre-filled syringe (*Neulasta*)
6439X **Peginterferon alfa-2a**, Injection 135 micrograms in 0.5 mL single use pre-filled syringe (*Pegasys*)
6449K **Peginterferon alfa-2a**, Injection 180 micrograms in 0.5 mL single use pre-filled syringe (*Pegasys*)

9620H **Sevelamer hydrochloride**, Tablet 800 mg (*Renagel*)

Alterations — Notes

Bosentan monohydrate, Tablet 62.5 mg (base) (*Tracleer*)

Bosentan monohydrate, Tablet 125 mg (base) (*Tracleer*)
Epoprostenol sodium, Powder for I.V. infusion 500 micrograms (base) with 1 vial diluent 50 mL (*Flolan*)
Epoprostenol sodium, Powder for I.V. infusion 1.5 mg (base) with 2 vials diluent 50 mL (*Flolan*)
Iloprost trometamol, Solution for inhalation 20 micrograms (base) in 2 mL (*Ventavis*)
Sildenafil citrate, Tablet 20 mg (base) (*Revatio*)

Sitaxentan sodium, Tablet 100 mg (*Thelin*)

SECTION 100 — HUMAN GROWTH HORMONE PROGRAM

ADDITIONS

Additions — Item

9628R **Somatropin (recombinant human growth hormone)**, Injection 0.6 mg (1.8 i.u.) with diluent in single use syringe (without preservative) (*Genotropin MiniQuick*)

ADVANCE NOTICES

Advance Notices - Deletion of Items

The following items will be deleted from the Schedule of Pharmaceutical Benefits on 1 **August** 2008:
Items discontinued by the manufacturer —

9002T **Benzathine penicillin**, Powder for injection 900 mg (1,200,000 i.u.) (*Pan Benzathine Benzylpenicillin*)

5252K **Benzathine penicillin**, Powder for injection 900 mg (1,200,000 i.u.) (*Pan Benzathine Benzylpenicillin*) **(Dental)**

9003W **Benzathine penicillin**, Powder for injection 900 mg (1,200,000 i.u.) (*Pan Benzathine Benzylpenicillin*)

The following item will be deleted from the **Highly Specialised Drugs Program** on 1 **August** 2008:
Item discontinued by the manufacturer —

6199G **Saquinavir mesylate**, Capsule 200 mg (base) (*Invirase*)

The following item will be deleted from the Schedule of Pharmaceutical Benefits on 1 **September** 2008:
Item discontinued by the manufacturer —

1351D **Dipivefrine hydrochloride**, Eye drops 1 mg per mL (0.1%), 10 mL (*Propine*)

Advance Notices — Deletion of Brand

The following **brand** will be deleted from the Schedule of Pharmaceutical Benefits on 1 **August** 2008:
Brand discontinued by the manufacturer —

9607P *APO-go, FA* — **Apomorphine hydrochloride**, Injection 20 mg in 2 mL

RESTRICTIONS

The text of restrictions mentioned above:

Adalimumab

NOTE:

Any queries concerning the arrangements to prescribe adalimumab 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 adalimumab 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.

NOTE:

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents (adalimumab, etanercept and infliximab) for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept and infliximab.

From 1 August 2006, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial adalimumab, etanercept or infliximab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The 5-year break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis after 1 August 2006.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for all agents except for infliximab, for which a maximum of 22 weeks will be authorised. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients.

Applications for patients who commenced treatment with etanercept prior to 17 March 2005 or adalimumab and infliximab prior to 16 March 2006, may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or

(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a treatment Cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate or sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

NOTE:

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

Applications for treatment with adalimumab where the dosing frequency exceeds 40 mg per fortnight will not be approved.

9101B **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen (*Humira*)
9033K **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled syringe (*Humira*)

Authority required

Initial 1
Initial PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:
(1) have severe active psoriatic arthritis; and
(2) have received no prior PBS-subsidised biological treatment for this condition in this Treatment Cycle; and
(3) have failed to achieve an adequate response to:
(a) methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; and
(b) sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or
(c) leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months.

Patients must have had the psoriatic component of their disease confirmed by a dermatologist or by biopsy at any time.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities, including severity, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
(i) an active joint count of at least 20 active (swollen and tender) joints; or
(ii) at least 4 active joints from the following list of major joints:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes details of the patient's ESR and CRP measurements and the patient's active joint count which must have been assessed no earlier than 1 month prior to the date of application; and
(3) a copy of the signed patient acknowledgement form which is included in the Supporting Information Form. Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients who fail to demonstrate a response to treatment with adalimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle

Authority required

Initial 2
Initial PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:
(1) have a documented history of severe active psoriatic arthritis; and
(2) have received prior PBS-subsidised biological treatment for this condition in this Treatment Cycle and are eligible to receive further biological therapy; and
(3) have not failed treatment with adalimumab during the current Treatment Cycle.

Applications for patients who have demonstrated a response to PBS-subsidised adalimumab treatment within this Treatment Cycle and who wish to re-commence adalimumab treatment within the same Cycle following a break in therapy, will only be approved where evidence of a response to the patient's most recent course of PBS-subsidised adalimumab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), patients must

have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients who fail to demonstrate a response to treatment with adalimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle.

Once patients fail to respond to treatment with 3 biological agents, they are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

9102C **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen (*Humira*)
9034L **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled syringe (*Humira*)

Authority required

Initial 3
Initial PBS-subsidised supply for continuing treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:
(1) have a documented history of severe active psoriatic arthritis; and
(2) were receiving treatment with adalimumab prior to 16 March 2006; and
(3) have demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with adalimumab.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(3) a copy of the signed patient acknowledgement form which is included in the Supporting Information Form. Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated.

A maximum of 24 weeks of treatment with adalimumab will be authorised under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients who fail to demonstrate a response to treatment with adalimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle.

Patients may qualify for PBS-subsidised treatment under this restriction once only

Authority required

Continuing treatment

Continuing PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults:
(1) who have a documented history of severe active psoriatic arthritis; and
(2) whose most recent course of PBS-subsidised biological agent for this condition in the current Treatment Cycle was with adalimumab; and
(3) who, at the time of application, demonstrate an adequate response to treatment with adalimumab.

An adequate response to treatment with adalimumab is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following:
(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

All applications for continuing treatment with adalimumab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients who fail to demonstrate a response to treatment with adalimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle.

Once patients fail to respond to treatment with 3 biological agents, they are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

6450L **Adefovir dipivoxil**, Tablet 10 mg (*Hepsera*)

Private hospital authority required

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

(1)(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;

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

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 should have undergone a liver biopsy at some point since initial diagnosis to obtain histological evidence of chronic hepatitis.

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

9163G **Calcipotriol**, Scalp solution 50 micrograms per mL (0.005%), 30 mL (*Daivonex*)

Restricted benefit

Chronic stable plaque type psoriasis vulgaris of the scalp

9157Y **Cinacalcet hydrochloride**, Tablet 30 mg (base) (*Sensipar*)
9158B **Cinacalcet hydrochloride**, Tablet 60 mg (base) (*Sensipar*)
9159C **Cinacalcet hydrochloride**, Tablet 90 mg (base) (*Sensipar*)

Authority required

Maintenance therapy, following initiation and stabilisation of treatment with cinacalcet, of a patient with chronic kidney disease on dialysis who has a decrease of at least 30% in iPTH concentrations after 6 months treatment.

NOTE:

During the titration phase, intact PTH should be monitored 4 weekly (measured at least 12 hours post dose) and dose titrated until an appropriate iPTH concentration is achieved. During the titration phase, approval will be limited to sufficient supply for 4 weeks treatment at a time, with doses between 30 and 180 mg per day according to the patient's response and tolerability.

During the maintenance phase, approval will be limited to provide sufficient quantity for 4 weeks treatment up to a maximum of 6 months supply for doses between 30 and 180 mg per day according to the patient's response and tolerability. Intact PTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration.

9625N **Cinacalcet hydrochloride**, Tablet 30 mg (base) (*Sensipar*)
9626P **Cinacalcet hydrochloride**, Tablet 60 mg (base) (*Sensipar*)
9627Q **Cinacalcet hydrochloride**, Tablet 90 mg (base) (*Sensipar*)

Private hospital authority required

Management, including initiation and stabilisation, by a nephrologist, of a patient with chronic kidney disease on dialysis who has sustained secondary hyperparathyroidism with iPTH of at least 50 pmol per L, not responding to conventional therapy.

NOTE:

During the titration phase, intact PTH should be monitored 4 weekly (measured at least 12 hours post dose) and dose titrated until an appropriate iPTH concentration is achieved. During the titration phase, approval will be limited to sufficient supply for 4 weeks treatment at a time, with doses between 30 and 180 mg per day according to the patient's response and tolerability.

During the maintenance phase, approval will be limited to provide sufficient quantity for 4 weeks treatment up to a maximum of 6 months supply for doses between 30 and 180 mg per day according to the patient's response and tolerability. Intact PTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration.

"Sustained" means the abnormality was detected on at least 2 blood samples collected over a period of 2 to 4 months.

Private hospital authority required

Management, including initiation and stabilisation, by a nephrologist, of a patient with chronic kidney disease on dialysis who has sustained secondary hyperparathyroidism with iPTH of at least 15 pmol per L

and less than 50 pmol per L AND an (adjusted) serum calcium concentration at least 2.6 mmol per L, not responding to conventional treatment.

NOTE:

During the titration phase, intact PTH should be monitored 4 weekly (measured at least 12 hours post dose) and dose titrated until an appropriate iPTH concentration is achieved. During the titration phase, approval will be limited to sufficient supply for 4 weeks treatment at a time, with doses between 30 and 180 mg per day according to the patient's response and tolerability.

During the maintenance phase, approval will be limited to provide sufficient quantity for 4 weeks treatment up to a maximum of 6 months supply for doses between 30 and 180 mg per day according to the patient's response and tolerability. Intact PTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration.

"Sustained" means the abnormality was detected on at least 2 blood samples collected over a period of 2 to 4 months.

9164H **Cystine with carbohydrate**, Sachets 4 g containing 500 mg cystine, 30 (*Cystine Amino Acid Supplement*)

Restricted benefit

Pyridoxine non-responsive homocystinuria

9602J **Entecavir monohydrate**, Tablet 0.5 mg (*Baraclude*)

Private hospital authority required

Patients with chronic hepatitis B who satisfy all of the following criteria:

(1) Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy);

(2)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection; or

(b) Elevated HBV DNA levels in conjunction with documented chronic hepatitis B infection;

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

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 **Entecavir monohydrate**, Tablet 1 mg (*Baraclude*)

Private hospital authority required

Patients with chronic hepatitis B who have failed lamivudine therapy and who satisfy all of the following criteria:

(1)(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;

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

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 should have undergone a liver biopsy at some point since initial diagnosis to obtain histological evidence of chronic hepatitis. PBS-subsidised entecavir monohydrate must be used as monotherapy.

Etanercept

NOTE:

Any queries concerning the arrangements to prescribe etanercept 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 etanercept 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.

NOTE:

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents (adalimumab, etanercept and infliximab) for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept and infliximab.

From 1 August 2006, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial adalimumab, etanercept or infliximab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The 5-year break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis after 1 August 2006.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for all agents except for infliximab, for which a maximum of 22 weeks will be authorised. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients.

Applications for patients who commenced treatment with etanercept prior to 17 March 2005 or adalimumab and infliximab prior to 16 March 2006, may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or

(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a treatment Cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate or sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

9087G **Etanercept**, Injections 50 mg in 1 mL single use pre-filled syringes, 4 (*Enbrel*)

9035M **Etanercept**, Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*)

9083C **Etanercept**, Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*)

Authority required

Initial 1

Initial PBS-subsidised treatment with etanercept, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:

(1) have severe active psoriatic arthritis; and

(2) have received no prior PBS-subsidised biological treatment for this condition in this Treatment Cycle; and

(3) have failed to achieve an adequate response to:

(a) methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; and

(b) sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or

(c) leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months.

Patients must have had the psoriatic component of their disease confirmed by a dermatologist or by biopsy at any time.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities, including severity, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
(i) an active joint count of at least 20 active (swollen and tender) joints; or
(ii) at least 4 active joints from the following list of major joints:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes details of the patient's ESR and CRP measurements and the patient's active joint count which must have been assessed no earlier than 1 month prior to the date of application; and
(3) a copy of the signed patient acknowledgement form which is included in the Supporting Information Form. Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle

Authority required

Initial 2
Initial PBS-subsidised treatment with etanercept, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:
(1) have a documented history of severe active psoriatic arthritis; and
(2) have received prior PBS-subsidised biological treatment for this condition in this Treatment Cycle and are eligible to receive further biological therapy; and
(3) have not failed treatment with etanercept during the current Treatment Cycle.

Applications for patients who have demonstrated a response to PBS-subsidised etanercept treatment within this Treatment Cycle and who wish to re-commence etanercept treatment within the same Cycle following a break in therapy, will only be approved where evidence of a response to the patient's most recent course of PBS-subsidised etanercept treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

Where the most recent course of PBS-subsidised etanercept treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised etanercept treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

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

(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle.

Once patients fail to respond to treatment with 3 biological agents, they are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

NOTE:

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

9088H **Etanercept**, Injections 50 mg in 1 mL single use pre-filled syringes, 4 (*Enbrel*)
9036N **Etanercept**, Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*)
9084D **Etanercept**, Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*)

Authority required

Initial 3
Initial PBS-subsidised supply for continuing treatment with etanercept, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:
(1) have a documented history of severe active psoriatic arthritis; and
(2) were receiving treatment with etanercept prior to 17 March 2005; and
(3) have demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with etanercept.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(3) a copy of the signed patient acknowledgement form which is included in the Supporting Information Form. Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated.

A maximum of 24 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle.

Patients may qualify for PBS-subsidised treatment under this restriction once only

Authority required

Continuing treatment

Continuing PBS-subsidised treatment with etanercept, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults:
(1) who have a documented history of severe active psoriatic arthritis; and
(2) whose most recent course of PBS-subsidised biological agent for this condition in the current Treatment Cycle was with etanercept; and
(3) who, at the time of application, demonstrate an adequate response to treatment with etanercept.

An adequate response to treatment with etanercept is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following:
(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle.

Once patients fail to respond to treatment with 3 biological agents, they are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

NOTE:

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

6291D **Filgrastim**, Injection 300 micrograms in 0.5 mL single use pre-filled syringe (*Neupogen*)
6126K **Filgrastim**, Injection 300 micrograms in 1 mL (*Neupogen*)
6292E **Filgrastim**, Injection 480 micrograms in 0.5 mL single use pre-filled syringe (*Neupogen*)
6127L **Filgrastim**, Injection 480 micrograms in 1.6 mL (*Neupogen*)

Private hospital authority required

For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia

Private hospital authority required

Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy

Private hospital authority required

Mobilisation of peripheral blood progenitor cells, in a normal volunteer, for use in allogeneic transplantation

Private hospital authority required

A patient receiving marrow-ablative chemotherapy and subsequent bone marrow transplantation

Private hospital authority required

A patient with a non-myeloid malignancy receiving marrow-ablative chemotherapy and subsequent autologous peripheral blood progenitor cell transplantation

Private hospital authority required

A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Private hospital authority required

A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Private hospital authority required

A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Private hospital authority required

A patient with severe congenital neutropenia (absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, and in whom a bone marrow examination has shown evidence of maturational arrest of the neutrophil lineage)

Private hospital authority required

A patient with severe chronic neutropenia (absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, or evidence of neutrophil dysfunction, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months))

Private hospital authority required

A patient with chronic cyclic neutropenia (absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months))

Private hospital authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in

acute lymphoblastic leukaemia

Private hospital authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in

breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide)

Private hospital authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in

germ cell tumours

Private hospital authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in

infants and children with CNS tumours

Private hospital authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in

neuroblastoma

Private hospital authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in

non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen)

Private hospital authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in

relapsed Hodgkin disease

Private hospital authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in

sarcoma

Gefitinib

NOTE:

Any queries concerning the arrangements to prescribe gefitinib may be directed to Medicare Australia on 1800 700 270.

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

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826 HOBART TAS 7001

8769M **Gefitinib**, Tablet 250 mg (*Iressa*)

Authority required

Initial PBS-subsidised treatment, as monotherapy, of locally advanced or metastatic non-small cell lung cancer in patients with a WHO performance status of 2 or less, where:
(1) disease progression has occurred following treatment with at least 1 chemotherapy agent; and
(2) there is evidence that the patient has an activating mutation(s) of the epidermal growth factor receptor (EGFR) gene in tumour material. The mutation(s) must be demonstrated by analysis of the DNA sequence of the EGFR gene.

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

(1) a completed authority prescription form; and
(2) a completed Gefitinib (Iressa) PBS Authority Application for Use in the Treatment of Locally Advanced or Metastatic Non-Small Cell Lung Cancer - Supporting Information Form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm and click on 'Medical Practitioners')]; and
(3) details of the prior chemotherapy including the name(s) of drug(s) and date of the most recent treatment cycle; and
(4) details of the patient's WHO performance status; and
(5) a copy of the pathology report providing evidence of the presence of activating mutation(s) of the EGFR gene from an Approved Pathology Authority

Authority required

Continuing PBS-subsidised treatment, as monotherapy, of locally advanced or metastatic non-small cell lung cancer in patients with a WHO performance status of 2 or less, where the patient has previously been issued with an authority prescription for gefitinib.

Applications for continuing treatment may be made in writing or on the telephone by contacting Medicare Australia on 1800 700 270

NOTE:

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

Iloprost trometamol

NOTE:

Any queries concerning the arrangements to prescribe iloprost trometamol 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 iloprost trometamol should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

6456T **Iloprost trometamol**, Solution for inhalation 20 micrograms (base) in 2 mL (*Ventavis*)

Public and private hospital authority required

Initial (new patients)
Application for initial PBS-subsidised treatment with iloprost trometamol of patients who have not received prior PBS-subsidised treatment with bosentan monohydrate, epoprostenol sodium, sildenafil citrate or sitaxentan sodium and who have been assessed by a physician from a designated hospital to have:
(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, unless a RHC is contraindicated on clinical grounds; OR
(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, unless a RHC is contraindicated on clinical grounds; OR
(c) WHO Functional Class III drug-induced pulmonary arterial hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, unless a RHC is contraindicated on clinical grounds.

Patients must have failed to respond [see Note for definition of response] to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the test results of the ECHO composite assessment plus 6MWT or the ECHO composite assessment only.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form [see Note for authority approval requirements]; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) a signed patient acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with iloprost trometamol for primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with bosentan monohydrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, OR with epoprostenol sodium for primary pulmonary hypertension, OR with sildenafil citrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with sitaxentan sodium for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

Public and private hospital authority required

Initial (new patients)
Application for initial PBS-subsidised treatment with iloprost trometamol of patients who have not received prior PBS-subsidised treatment with bosentan monohydrate, epoprostenol sodium, sildenafil citrate or sitaxentan sodium and who have been assessed by a physician from a designated hospital to have:
(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, unless a RHC is contraindicated on clinical grounds; OR
(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, unless a RHC is contraindicated on clinical grounds; OR
(c) WHO Functional Class III drug-induced pulmonary arterial hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, unless a RHC is contraindicated on clinical grounds; OR
(d) WHO Functional Class IV primary pulmonary hypertension; OR
(e) WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR

(f) WHO Functional Class IV drug-induced pulmonary arterial hypertension.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the test results of the ECHO composite assessment plus 6MWT or the ECHO composite assessment only.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form [see Note for authority approval requirements]; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) a signed patient acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with iloprost trometamol for primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with bosentan monohydrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, OR with epoprostenol sodium for primary pulmonary hypertension, OR with sildenafil citrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with sitaxentan sodium for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

Public and private hospital authority required

Initial (change or re-commencement for all patients)
Application for initial PBS-subsidised treatment with iloprost trometamol of patients with either of the following:
(a) primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease who wish to re-commence PBS-subsidised iloprost trometamol after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with iloprost trometamol; OR
(b) primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma and whose most recent course of PBS-subsidised treatment was with bosentan monohydrate; OR
(c) primary pulmonary hypertension and whose most recent course of PBS-subsidised treatment was with epoprostenol sodium; OR
(d) primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with sildenafil citrate; OR
(e) primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with sitaxentan sodium.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form [see Note for authority approval requirements]; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised iloprost trometamol, bosentan monohydrate, epoprostenol sodium, sildenafil citrate or sitaxentan sodium, whichever was initiated first, was granted; and

(3) the date of the first application for PBS-subsidised treatment with iloprost trometamol, bosentan monohydrate, epoprostenol sodium, sildenafil citrate or sitaxentan sodium, whichever was initiated first; and
(4) the results of the patient's response to treatment with their last course of PBS-subsidised iloprost trometamol, bosentan monohydrate, epoprostenol sodium, sildenafil citrate or sitaxentan sodium.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

Public and private hospital authority required

Continuing treatment (all patients)
Continuing PBS-subsidised treatment with iloprost trometamol of patients who have received approval for initial PBS-subsidised treatment with iloprost trometamol, and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of iloprost trometamol treatment [see Note for definition of response].

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

Infliximab

NOTE:

Any queries concerning the arrangements to prescribe infliximab 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 infliximab 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.

NOTE:

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents (adalimumab, etanercept and infliximab) for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept and infliximab.

From 1 August 2006, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial adalimumab, etanercept or infliximab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The 5-year break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis after 1 August 2006.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for all agents except for infliximab, for which a maximum of 22 weeks will be authorised. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to

Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients.

Applications for patients who commenced treatment with etanercept prior to 17 March 2005 or adalimumab and infliximab prior to 16 March 2006, may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or

(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a treatment Cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate or sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

6496X **Infliximab**, Powder for I.V. infusion 100 mg (*Remicade*)

Public and private hospital authority required

Initial 1

Initial PBS-subsidised treatment with infliximab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:
(1) have severe active psoriatic arthritis; and
(2) have received no prior PBS-subsidised biological treatment for this condition in this Treatment Cycle; and
(3) have failed to achieve an adequate response to:
(a) methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; and
(b) sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or
(c) leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months.

Patients must have had the psoriatic component of their disease confirmed by a dermatologist or by biopsy at any time.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities, including severity, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
(i) an active joint count of at least 20 active (swollen and tender) joints; or
(ii) at least 4 active joints from the following list of major joints:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes details of the patient's ESR and CRP measurements and the patient's active joint count which must have been assessed no earlier than 1 month prior to the date of application; and
(3) a copy of the signed patient acknowledgement form which is included in the Supporting Information Form. Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle

Public and private hospital authority required

Initial 2
Initial PBS-subsidised treatment with infliximab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:
(1) have a documented history of severe active psoriatic arthritis; and
(2) have received prior PBS-subsidised biological treatment for this condition in this Treatment Cycle and are eligible to receive further biological therapy; and
(3) have not failed treatment with infliximab during the current Treatment Cycle.

Applications for patients who have demonstrated a response to PBS-subsidised infliximab treatment within this Treatment Cycle and who wish to re-commence infliximab treatment within the same Cycle following a break in therapy, will only be approved where evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle.

Once patients fail to respond to treatment with 3 biological agents, they are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

Public and private hospital authority required

Initial 3

Initial PBS-subsidised supply for continuing treatment with infliximab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:
(1) have a documented history of severe active psoriatic arthritis; and
(2) were receiving treatment with infliximab prior to 16 March 2006; and
(3) have demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with infliximab.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(3) a copy of the signed patient acknowledgement form which is included in the Supporting Information Form. Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated.

A maximum of 24 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle.

Patients may qualify for PBS-subsidised treatment under this restriction once only

Public and private hospital authority required

Continuing treatment
Continuing PBS-subsidised treatment with infliximab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults:
(1) who have a documented history of severe active psoriatic arthritis; and
(2) whose most recent course of PBS-subsidised biological agent for this condition in the current Treatment Cycle was with infliximab; and
(3) who, at the time of application, demonstrate an adequate response to treatment with infliximab.

An adequate response to treatment with infliximab is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following:
(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

All applications for continuing treatment with infliximab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing

treatment with infliximab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle.

Once patients fail to respond to treatment with 3 biological agents, they are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

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.

6210W **Interferon alfa-2a**, Injection 3,000,000 i.u. in 0.5 mL single dose pre-filled syringe (*Roferon-A*)
6211X **Interferon alfa-2a**, Injection 4,500,000 i.u. in 0.5 mL single dose pre-filled syringe (*Roferon-A*)
6212Y **Interferon alfa-2a**, Injection 6,000,000 i.u. in 0.5 mL single dose pre-filled syringe (*Roferon-A*)
6213B **Interferon alfa-2a**, Injection 9,000,000 i.u. in 0.5 mL single dose pre-filled syringe (*Roferon-A*)

Private hospital authority required

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

Private hospital authority required

Patients with chronic hepatitis B who satisfy all of the following criteria:

(1) Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy);

(2)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection; or

(b) Elevated HBV DNA levels in conjunction with documented chronic hepatitis B infection;(3) Are not 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);

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

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.

6246R **Interferon alfa-2b**, Solution for injection 10,000,000 i.u. in 1 mL single dose vial (*Intron A*)
6253D **Interferon alfa-2b**, Solution for injection 18,000,000 i.u. in 1.2 mL multi-dose injection pen (*Intron A Redipen*)
6218G **Interferon alfa-2b**, Solution for injection 18,000,000 i.u. in 3 mL single dose vial (*Intron A*)

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

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

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

Private hospital authority required

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

Private hospital authority required

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

Private hospital authority required

Patients with chronic hepatitis B who satisfy all of the following criteria:

(1) Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy);

(2)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection; or

(b) Elevated HBV DNA levels in conjunction with documented chronic hepatitis B infection;

(3) Are not 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);

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

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

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

Private hospital authority required

Patients with chronic hepatitis B who satisfy all of the following criteria:

(1) Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy);

(2)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection; or

(b) Elevated HBV DNA levels in conjunction with documented chronic hepatitis B infection;

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

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

2059J **Memantine hydrochloride**, Oral drops 10 mg per g, 50 g (*Ebixa*)

1956Y **Memantine hydrochloride**, Tablet 10 mg (*Ebixa*)

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 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

Authority required

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 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

Authority required

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

Authority required

APPLICATION FOR THE TREATMENT OF MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients who commenced treatment prior to 1 March 2008.
Continuing treatment, as the sole PBS-subsidised therapy, of a patient commenced on memantine prior to 1 March 2008.

Applications for continuing treatment can be made by telephone

Natalizumab

CAUTION:

Progressive multifocal leukoencephalopathy (PML) has been reported with this drug.

9624M **Natalizumab**, Solution concentrate for I.V. infusion 300 mg in 15 mL (*Tysabri*)

Private hospital authority required

Initial treatment, as monotherapy, by neurologists, of clinically definite relapsing-remitting multiple sclerosis in an ambulatory (without assistance or support) patient 18 years of age or older, who has experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years.

The diagnosis must be confirmed by magnetic resonance imaging of the brain and/or spinal cord and the date of the scan included in the authority application, unless the authority application is accompanied by written certification provided by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient.

A maximum quantity of 6 infusions will be issued with the initial authority.

Private hospital authority required

Continuing treatment, as monotherapy, of clinically definite relapsing-remitting multiple sclerosis in a patient previously issued with an authority prescription for this drug who does not show continuing progression of disability while on treatment with this drug, and who has demonstrated compliance with, and an ability to tolerate, this therapy.

A maximum quantity of 3 infusions will be issued with the continuing authority.

6363X **Pegfilgrastim**, Injection 6 mg in 0.6 mL single use pre-filled syringe (*Neulasta*)

Private hospital authority required

For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia

Private hospital authority required

A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Private hospital authority required

A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Private hospital authority required

A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination,

dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Private hospital authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in

acute lymphoblastic leukaemia

Private hospital authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in

breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide)

Private hospital authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in

germ cell tumours

Private hospital authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in

infants and children with CNS tumours

Private hospital authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in

neuroblastoma

Private hospital authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in

non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen)

Private hospital authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in

relapsed Hodgkin disease

Private hospital authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in

sarcoma

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.

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 **Peginterferon alfa-2a**, Injection 135 micrograms in 0.5 mL single use pre-filled syringe (*Pegasys*)
6449K **Peginterferon alfa-2a**, Injection 180 micrograms in 0.5 mL single use pre-filled syringe (*Pegasys*)

Private hospital authority required

Monotherapy in patients with chronic hepatitis B and compensated liver disease who satisfy all of the following criteria:

(1) Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy);

(2)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection; or

(b) Elevated HBV DNA levels in conjunction with documented chronic hepatitis B infection;

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

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

(5) Are not 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).

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

Private hospital authority required

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.

9131N **Pemetrexed disodium**, Powder for I.V. infusion 100 mg (base) (*Alimta*)
9130M **Pemetrexed disodium**, Powder for I.V. infusion 500 mg (base) (*Alimta*)

Authority required

Locally advanced or metastatic non-small cell lung cancer, after prior platinum-based chemotherapy.

Doses greater than 500 mg per metre squared body surface area (BSA) will not be approved for PBS subsidy. The patient's BSA must be provided at the time of the authority approval

Authority required

Mesothelioma in combination with cisplatin.

Doses greater than 500 mg per metre squared body surface area (BSA) will not be approved for PBS subsidy. The patient's BSA must be provided at the time of the authority approval

9629T **Raltegravir potassium**, Tablet 400 mg (base) (*Isentress*)

Private hospital authority required

Treatment, in combination with other antiretroviral agents, of HIV infection in an antiretroviral experienced patient with:

(a) evidence of HIV replication (viral load greater than 10,000 copies per mL); and/or

(b) CD4 cell counts of less than 500 per cubic millimetre.

A patient must have failed previous treatment with, or have resistance to, 3 different antiretroviral regimens which have included:

(i) at least 1 non-nucleoside reverse transcriptase inhibitor; and

(ii) at least 1 nucleoside reverse transcriptase inhibitor; and

(iii) at least 1 protease inhibitor

8496E **Donepezil hydrochloride**, Tablet 10 mg (*Aricept*)
8495D **Donepezil hydrochloride**, Tablet 5 mg (*Aricept*)
8771P **Galantamine hydrobromide**, Capsule 16 mg (base) (prolonged release) (*Reminyl*)
8772Q **Galantamine hydrobromide**, Capsule 24 mg (base) (prolonged release) (*Reminyl*)
8770N **Galantamine hydrobromide**, Capsule 8 mg (base) (prolonged release) (*Reminyl*)
9162F **Rivastigmine**, Transdermal patch 18 mg (releasing approximately 9.5 mg per 24 hours) (*Exelon Patch 10*)
9161E **Rivastigmine**, Transdermal patch 9 mg (releasing approximately 4.6 mg per 24 hours) (*Exelon Patch 5*)
8497F **Rivastigmine hydrogen tartrate**, Capsule 1.5 mg (base) (*Exelon*)
8498G **Rivastigmine hydrogen tartrate**, Capsule 3 mg (base) (*Exelon*)
8499H **Rivastigmine hydrogen tartrate**, Capsule 4.5 mg (base) (*Exelon*)
8500J **Rivastigmine hydrogen tartrate**, Capsule 6 mg (base) (*Exelon*)
8563Q **Rivastigmine hydrogen tartrate**, Oral solution 2 mg (base) per mL, 120 mL (*Exelon*)

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 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

Authority required

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 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

Authority required

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

2142R **Sevelamer hydrochloride**, Tablet 800 mg (*Renagel*)

Authority required

Maintenance therapy, following initiation and stabilisation of treatment with sevelamer hydrochloride, of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on other products and where

serum phosphate is greater than 1.6 mmol per L

Authority required

Maintenance therapy, following initiation and stabilisation of treatment with sevelamer hydrochloride, of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on other products and where

the serum calcium times phosphate product is greater than 4.0

9620H **Sevelamer hydrochloride**, Tablet 800 mg (*Renagel*)

Private hospital authority required

Management of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on other products and where serum phosphate is greater than 1.6 mmol per L.

Private hospital authority required

Management of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on other products and where the serum calcium times phosphate product is greater than 4.0.

9628R **Somatropin (recombinant human growth hormone)**, Injection 0.6 mg (1.8 i.u.) with diluent in single use syringe (without preservative) (*Genotropin MiniQuick*)

Restricted benefit

Short stature in accordance with the 'Guidelines for the Availability of Human Growth Hormone (hGH) as a Pharmaceutical Benefit'

NOTE:

These guidelines may be obtained from the Department of Health and Ageing's internet site at http://www.health.gov.au/internet/main/publishing.nsf/Content/ pbs-hghguidelines-contents, or from:

Growth Hormone Program

Access and Systems Branch

Department of Health and Ageing

GPO Box 9848

CANBERRA ACT 2601

Contact telephone number (02) 6289 7274

9160D **Terbinafine hydrochloride**, Cream 10 mg per g (1%), 15 g (*Lamisil*)

Authority required (STREAMLINED)

2354

Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person

9165J **Tyrosine with carbohydrate**, Sachets 4 g containing 1 g tyrosine, 30 (*Tyrosine Amino Acid Supplement*)

Restricted benefit

Phenylketonuria

NOTES

The text of notes mentioned above:

6429J **Bosentan monohydrate**

6430K **Bosentan monohydrate**

CAUTION:

Bosentan monohydrate is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of treatment with this drug.

NOTE:

Any queries concerning the arrangements to prescribe bosentan monohydrate 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 bosentan monohydrate should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

These prices are based on special supply arrangements—see Pharmaceutical Benefits Pricing Authority relativity sheet for full details.

NOTE:

Bosentan monohydrate is not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with scleroderma, where the total lung capacity is less than 70% of that predicted.

Bosentan monohydrate is not PBS-subsidised when used in combination with PBS-subsidised iloprost trometamol, PBS-subsidised epoprostenol sodium, PBS-subsidised sildenafil citrate or PBS-subsidised sitaxentan sodium.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment with:

(a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, in patients with disease of WHO Functional Class III or IV severity; AND

(b) iloprost trometamol, of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND

(c) epoprostenol sodium, of primary pulmonary hypertension, in patients with disease of WHO Functional Class III or IV severity; AND

(d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND

(e) sitaxentan sodium, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.

Adult patients:

From 1 April 2008, adult patients with primary pulmonary hypertension will be able to access, through the PBS, bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 5 drugs, they may swap between bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary (unless the prescriber wishes to submit new baselines).

Patients may only swap to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

Adult patients with pulmonary arterial hypertension secondary to scleroderma will be able to access, through the PBS, bosentan monohydrate, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 4 drugs, they may swap between bosentan monohydrate, iloprost trometamol, sildenafil citrate and

sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary (unless the prescriber wishes to submit new baselines).

Patients may only swap to bosentan monohydrate, iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

Adult patients with pulmonary arterial hypertension secondary to connective tissue disease other than scleroderma will be able to access, through the PBS, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 3 drugs, they may swap between iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary (unless the prescriber wishes to submit new baselines).

Patients may only swap to iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

Patients with drug-induced pulmonary arterial hypertension are only eligible for treatment with iloprost trometamol. They may not swap to bosentan monohydrate, epoprostenol sodium, sildenafil citrate or sitaxentan sodium.

Patients under 18 years of age:

From 1 April 2008, patients aged less than 18 years with primary pulmonary hypertension are eligible to receive PBS-subsidised treatment with bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 5 drugs, they may swap between bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary (unless the prescriber wishes to submit new baselines).

Patients may only swap to bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma.

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or

(ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or

(iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

2. Definition of WHO Functional Class III or IV disease severity.

(a) WHO Functional Class III disease severity is defined as follows:

Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.

(b) WHO Functional Class IV disease severity is defined as follows:

Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.

The first written application for PBS-subsidised treatment with the first of either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application.

NOTE:

Where patients were initiated on PBS-subsidised treatment either with bosentan monohydrate on or after 1 March 2004, with iloprost trometamol on or after 1 April 2005, with epoprostenol sodium on or after 1 August 2006, with sildenafil citrate on or after 1 March 2007, or with sitaxentan sodium on or after 1 April 2008, the test results provided with the initial application must be no more than 2 months old at the time of application. These results will form the baseline against which response assessments will be made.

Where patients received treatment with either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium prior to being commenced on PBS-subsidised treatment with the first of either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium, the test requirements above still apply. The results that will form the baseline against which response assessments will be made will be those measured at the time patients commenced non-PBS-subsidised treatment with either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium, whichever of the 5 drugs the patient received first.

(b) Continuation of treatment.

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a reason why the test(s) could not be conducted must be provided with the application.

The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

5. Definition of response to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, sitaxentan sodium or prior vasodilator treatment.

For adult patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

6. Authority approval requirements. [The following 2 sections are only relevant to the PBS listing of bosentan monohydrate. The requirements specific to iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium are given in parts 6 and 7 of the NOTE included in the iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium Schedule entry respectively.]

(a) Initiation of PBS-subsidised treatment with bosentan monohydrate, where the patient has not received prior PBS-subsidised treatment with iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium.

All applications for initial treatment must be made in writing, must include 2 separate authority prescriptions and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA)-approved Product Information. No repeats will be authorised for this prescription. The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Where the 62.5 mg tablet strength is required, please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. The approved second authority prescription will be returned to the prescriber by Medicare Australia 2 weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the 6 month initial treatment course. Medicare Australia will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

(b) Continuation of treatment.

Written applications for continuing treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6 months of treatment, based on the dosage recommendations in the TGA-approved Product Information.

Applications for continuing treatment will only be approved for patients who have currently demonstrated a response to treatment with bosentan monohydrate.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with bosentan monohydrate should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

(c) Swapping between bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate and sitaxentan sodium.

For eligible patients, applications to swap between these 5 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant restriction, in order to maximise the choice of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate treatment should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

(d) Cessation of treatment.

Patients who fail to demonstrate a response to PBS-subsidised bosentan monohydrate treatment at the times where an assessment is required must cease PBS-subsidised bosentan monohydrate therapy.

For patients ceasing treatment, approval will only be granted to provide sufficient supply of the 62.5 mg tablet strength to allow gradual dose reduction over a period of no more than 1 month duration. Prescribers should telephone Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) to receive authorisation for this final supply and to ensure no unintended break in treatment occurs.

7. Re-treatment with bosentan monohydrate.

Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with bosentan monohydrate under any circumstances.

8. Further information.

A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at www.medicareaustralia.gov.au.

Cetuximab - 9138Y, 9098W, 9139B

NOTE:

A maximum lifetime supply for this indication is limited to a maximum of 8 treatments per site and to 10 treatments per site for patients in whom radiotherapy is interrupted.

Epoprostenol sodium - 6477X, 6478Y

NOTE:

Any queries concerning the arrangements to prescribe epoprostenol sodium 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 epoprostenol sodium should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

NOTE:

Epoprostenol sodium is not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with scleroderma, where the total lung capacity is less than 70% of that predicted.

Epoprostenol sodium is not PBS-subsidised when used in combination with PBS-subsidised bosentan monohydrate, PBS-subsidised iloprost trometamol, PBS-subsidised sildenafil citrate or PBS-subsidised sitaxentan sodium.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment with:

(a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, in patients with disease of WHO Functional Class III or IV severity; AND

(b) iloprost trometamol, of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND

(c) epoprostenol sodium, of primary pulmonary hypertension, in patients with disease of WHO Functional Class III or IV severity; AND

(d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND

(e) sitaxentan sodium, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.

Adult patients:

From 1 April 2008, adult patients with primary pulmonary hypertension will be able to access, through the PBS, bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 5 drugs, they may swap between bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary (unless the prescriber wishes to submit new baselines).

Patients may only swap to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

Adult patients with pulmonary arterial hypertension secondary to scleroderma will be able to access, through the PBS, bosentan monohydrate, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 4 drugs, they may swap between bosentan monohydrate, iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary (unless the prescriber wishes to submit new baselines).

Patients may only swap to bosentan monohydrate, iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

Adult patients with pulmonary arterial hypertension secondary to connective tissue disease other than scleroderma will be able to access, through the PBS, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 3 drugs, they may swap between iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity

of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary (unless the prescriber wishes to submit new baselines).

Patients may only swap to iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

Patients with drug-induced pulmonary arterial hypertension are only eligible for treatment with iloprost trometamol. They may not swap to bosentan monohydrate, epoprostenol sodium, sildenafil citrate or sitaxentan sodium.

Patients under 18 years of age:

From 1 April 2008, patients aged less than 18 years with primary pulmonary hypertension are eligible to receive PBS-subsidised treatment with bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 5 drugs, they may swap between bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary (unless the prescriber wishes to submit new baselines).

Patients may only swap to bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma.

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or

(ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or

(iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

2. Definition of WHO Functional Class III or IV disease severity.

(a) WHO Functional Class III disease severity is defined as follows:

Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.

(b) WHO Functional Class IV disease severity is defined as follows:

Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.

The first written application for PBS-subsidised treatment with the first of either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application.

NOTE:

Where patients were initiated on PBS-subsidised treatment either with bosentan monohydrate on or after 1 March 2004, with iloprost trometamol on or after 1 April 2005, with epoprostenol sodium on or after 1 August 2006, with sildenafil citrate on or after 1 March 2007, or with sitaxentan sodium on or after 1 April 2008, the test results provided with the initial application must be no more than 2 months old at the time of application. These results will form the baseline against which response assessments will be made.

Where patients received treatment with either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium prior to being commenced on PBS-subsidised treatment with the first of either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium, the test requirements above still apply. The results that will form the baseline against which response assessments will be made will be those measured at the time patients commenced non-PBS-subsidised treatment with either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium, whichever of the 5 drugs the patient received first.

(b) Continuation of treatment.

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a reason why the test(s) could not be conducted must be provided with the application.

The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

5. Definition of response to epoprostenol sodium, bosentan monohydrate, iloprost trometamol, sildenafil citrate, sitaxentan sodium or prior vasodilator treatment.

For adult patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

6. Authority approval requirements. [The following 2 sections are only relevant to the PBS listing of epoprostenol sodium. The requirements specific to bosentan monohydrate, iloprost trometamol, sildenafil citrate and sitaxentan sodium are given in parts 6 and 7 of the NOTE included in the bosentan monohydrate, iloprost trometamol, sildenafil citrate and sitaxentan sodium Schedule entry respectively.]

(a) Initiation of PBS-subsidised treatment with epoprostenol sodium, where the patient has not received prior PBS-subsidised treatment with bosentan monohydrate, iloprost trometamol, sildenafil citrate or sitaxentan sodium.

All applications for initial treatment must be made in writing, must include an authority prescription and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months, based on the dosage recommendations in the TGA-approved Product Information.

(b) Continuation of treatment.

Written applications for continuing treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6 months of treatment, based on the dosage recommendations in the TGA-approved Product Information.

Applications for continuing treatment will only be approved for patients who have currently demonstrated a response to treatment with epoprostenol sodium.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with epoprostenol sodium should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

(c) Swapping between bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate and sitaxentan sodium.

For eligible patients, applications to swap between these 5 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant restriction, in order to maximise the choice of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate treatment should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

(d) Cessation of treatment.

Patients who fail to demonstrate a response to PBS-subsidised epoprostenol sodium treatment at the times where an assessment is required must cease PBS-subsidised epoprostenol sodium therapy.

7. Re-treatment with epoprostenol sodium.

Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with epoprostenol sodium under any circumstances.

8. Further information.

A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at www.medicareaustralia.gov.au.

6456T **Iloprost trometamol**

NOTE:

Iloprost trometamol is not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with scleroderma, where the total lung capacity is less than 70% of that predicted.

Iloprost trometamol is not PBS-subsidised when used in combination with PBS-subsidised bosentan monohydrate, PBS-subsidised epoprostenol sodium, PBS-subsidised sildenafil citrate or PBS-subsidised sitaxentan sodium.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment with:

(a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, in patients with disease of WHO Functional Class III or IV severity; AND

(b) iloprost trometamol, of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND

(c) epoprostenol sodium, of primary pulmonary hypertension, in patients with disease of WHO Functional Class III or IV severity; AND

(d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND

(e) sitaxentan sodium, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.

Adult patients:

From 1 April 2008, adult patients with primary pulmonary hypertension will be able to access, through the PBS, bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 5 drugs, they may swap between bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary (unless the prescriber wishes to submit new baselines).

Patients may only swap to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

Adult patients with pulmonary arterial hypertension secondary to scleroderma will be able to access, through the PBS, bosentan monohydrate, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 4 drugs, they may swap between bosentan monohydrate, iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary (unless the prescriber wishes to submit new baselines).

Patients may only swap to bosentan monohydrate, iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

Adult patients with pulmonary arterial hypertension secondary to connective tissue disease other than scleroderma will be able to access, through the PBS, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 3 drugs, they may swap between iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary (unless the prescriber wishes to submit new baselines).

Patients may only swap to iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

Patients with drug-induced pulmonary arterial hypertension are only eligible for treatment with iloprost trometamol. They may not swap to bosentan monohydrate, epoprostenol sodium, sildenafil citrate or sitaxentan sodium.

Patients under 18 years of age:

From 1 April 2008, patients aged less than 18 years with primary pulmonary hypertension are eligible to receive PBS-subsidised treatment with bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 5 drugs, they may swap between bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary (unless the prescriber wishes to submit new baselines).

Patients may only swap to bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma.

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or

(ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or

(iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

2. Definition of WHO Functional Class III or IV disease severity.

(a) WHO Functional Class III disease severity is defined as follows:Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.

(b) WHO Functional Class IV disease severity is defined as follows:Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.The first written application for PBS-subsidised treatment with the first of either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan

sodium should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application.

This price is based on special supply arrangements—see Pharmaceutical Benefits Pricing Authority relativity sheet for full details.

NOTE:

Where patients were initiated on PBS-subsidised treatment either with bosentan monohydrate on or after 1 March 2004, with iloprost trometamol on or after 1 April 2005, with epoprostenol sodium on or after 1 August 2006, with sildenafil citrate on or after 1 March 2007, or with sitaxentan sodium on or after 1 April 2008, the test results provided with the initial application must be no more than 2 months old at the time of application. These results will form the baseline against which response assessments will be made.

Where patients received treatment with either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium prior to being commenced on PBS-subsidised treatment with the first of either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium, the test requirements above still apply. The results that will form the baseline against which response assessments will be made will be those measured at the time patients commenced non-PBS-subsidised treatment with either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium, whichever of the 5 drugs the patient received first.

(b) Continuation of treatment.The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a reason why the test(s) could not be conducted must be provided with the application.

The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

5. Definition of response to iloprost trometamol, bosentan monohydrate, epoprostenol sodium, sildenafil citrate, sitaxentan sodium or prior vasodilator treatment.

For adult patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

6. Authority approval requirements. [The following 2 sections are only relevant to the PBS listing of iloprost trometamol. The requirements specific to bosentan monohydrate, epoprostenol sodium, sildenafil citrate and sitaxentan sodium are given in parts 6 and 7 of the NOTE included in the bosentan monohydrate, epoprostenol sodium, sildenafil citrate and sitaxentan sodium Schedule entry respectively.]

(a) Initiation of PBS-subsidised treatment with iloprost trometamol, where the patient has not received prior PBS-subsidised treatment with bosentan monohydrate, epoprostenol sodium, sildenafil citrate or sitaxentan sodium.All applications for initial treatment must be made in writing, must include an authority prescription and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months, based on the dosage recommendations in the TGA-approved Product Information.

(b) Continuation of treatment.Written applications for continuing treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6 months of treatment, based on the dosage recommendations in the TGA-approved Product Information.

Applications for continuing treatment will only be approved for patients who have currently demonstrated a response to treatment with iloprost trometamol.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with iloprost trometamol should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

(c) Swapping between bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate and sitaxentan sodium.For eligible patients, applications to swap between these 5 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant restriction, in order to maximise the choice of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate treatment should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

(d) Cessation of treatment.Patients who fail to demonstrate a response to PBS-subsidised iloprost trometamol treatment at the times where an assessment is required must cease PBS-subsidised iloprost trometamol therapy.

7. Re-treatment with iloprost trometamol.

Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with iloprost trometamol under any circumstances.

8. Further information.

A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at www.medicareaustralia.gov.au.

Pemetrexed disodium - 9131N, 9130M

NOTE:

No applications for increased maximum quantities for the 500 mg vial will be authorised.

Sildenafil citrate - 9605M

NOTE:

Any queries concerning the arrangements to prescribe sildenafil citrate 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 sildenafil citrate should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826GPO Box 9826

HOBART TAS 7001

NOTE:

Sildenafil citrate is not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with scleroderma, where the total lung capacity is less than 70% of that predicted.

Sildenafil citrate is not PBS-subsidised when used in combination with PBS-subsidised bosentan monohydrate, PBS-subsidised iloprost trometamol, PBS-subsidised epoprostenol sodium or PBS-subsidised sitaxentan sodium.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment with:

(a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, in patients with disease of WHO Functional Class III or IV severity; AND

(b) iloprost trometamol, of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND

(c) epoprostenol sodium, of primary pulmonary hypertension, in patients with disease of WHO Functional Class III or IV severity; AND

(d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND

(e) sitaxentan sodium, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.

Adult patients:

From 1 April 2008, adult patients with primary pulmonary hypertension will be able to access, through the PBS, bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 5 drugs, they may swap between bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary (unless the prescriber wishes to submit new baselines).

Patients may only swap to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

Adult patients with pulmonary arterial hypertension secondary to scleroderma will be able to access, through the PBS, bosentan monohydrate, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 4 drugs, they may swap between bosentan monohydrate, iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This

means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary (unless the prescriber wishes to submit new baselines).

Patients may only swap to bosentan monohydrate, iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

Adult patients with pulmonary arterial hypertension secondary to connective tissue disease other than scleroderma will be able to access, through the PBS, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 3 drugs, they may swap between iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary (unless the prescriber wishes to submit new baselines).

Patients may only swap to iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

Patients with drug-induced pulmonary arterial hypertension are only eligible for treatment with iloprost trometamol. They may not swap to bosentan monohydrate, epoprostenol sodium, sildenafil citrate or sitaxentan sodium.

Patients under 18 years of age:

From 1 April 2008, patients aged less than 18 years with primary pulmonary hypertension are eligible to receive PBS-subsidised treatment with bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 5 drugs, they may swap between bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary (unless the prescriber wishes to submit new baselines).

Patients may only swap to bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma.

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or

(ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or

(iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

2. Definition of WHO Functional Class III or IV disease severity.

(a) WHO Functional Class III disease severity is defined as follows:

Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.

(b) WHO Functional Class IV disease severity is defined as follows:

Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.

The first written application for PBS-subsidised treatment with the first of either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application.

NOTE:

Sildenafil citrate is not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with scleroderma, where the total lung capacity is less than 70% of that predicted.

Sildenafil citrate is not PBS-subsidised when used in combination with PBS-subsidised bosentan monohydrate, PBS-subsidised iloprost trometamol, PBS-subsidised epoprostenol sodium or PBS-subsidised sitaxentan sodium.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment with:

(a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, in patients with disease of WHO Functional Class III or IV severity; AND

(b) iloprost trometamol, of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND

(c) epoprostenol sodium, of primary pulmonary hypertension, in patients with disease of WHO Functional Class III or IV severity; AND

(d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND

(e) sitaxentan sodium, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.

Adult patients:

From 1 April 2008, adult patients with primary pulmonary hypertension will be able to access, through the PBS, bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate (WHO Class

III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 5 drugs, they may swap between bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary (unless the prescriber wishes to submit new baselines).

Patients may only swap to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

Adult patients with pulmonary arterial hypertension secondary to scleroderma will be able to access, through the PBS, bosentan monohydrate, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 4 drugs, they may swap between bosentan monohydrate, iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary (unless the prescriber wishes to submit new baselines).

Patients may only swap to bosentan monohydrate, iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

Adult patients with pulmonary arterial hypertension secondary to connective tissue disease other than scleroderma will be able to access, through the PBS, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 3 drugs, they may swap between iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary (unless the prescriber wishes to submit new baselines).

Patients may only swap to iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

Patients with drug-induced pulmonary arterial hypertension are only eligible for treatment with iloprost trometamol. They may not swap to bosentan monohydrate, epoprostenol sodium, sildenafil citrate or sitaxentan sodium.

Patients under 18 years of age:

From 1 April 2008, patients aged less than 18 years with primary pulmonary hypertension are eligible to receive PBS-subsidised treatment with bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 5 drugs, they may swap between bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary (unless the prescriber wishes to submit new baselines).

Patients may only swap to bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma.

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or

(ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or

(iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

2. Definition of WHO Functional Class III or IV disease severity.

(a) WHO Functional Class III disease severity is defined as follows:

Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.

(b) WHO Functional Class IV disease severity is defined as follows:

Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.

The first written application for PBS-subsidised treatment with the first of either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application.

Sitaxentan sodium

CAUTION:

Sitaxentan sodium is a category X drug and must not be given to pregnant women. Pregnancy must be excluded before the start of treatment and avoided during treatment with this drug.

NOTE:

Any queries concerning the arrangements to prescribe sitaxentan sodium 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 sitaxentan sodium should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

NOTE:

Sitaxentan sodium is not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with scleroderma, where the total lung capacity is less than 70% of that predicted.

Sitaxentan sodium is not PBS-subsidised when used in combination with PBS-subsidised bosentan monohydrate, PBS-subsidised iloprost trometamol, PBS-subsidised epoprostenol sodium or PBS-subsidised sildenafil citrate.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment with:

(a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, in patients with disease of WHO Functional Class III or IV severity; AND

(b) iloprost trometamol, of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND

(c) epoprostenol sodium, of primary pulmonary hypertension, in patients with disease of WHO Functional Class III or IV severity; AND

(d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND

(e) sitaxentan sodium, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.

Adult patients:

From 1 April 2008, adult patients with primary pulmonary hypertension will be able to access, through the PBS, bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 5 drugs, they may swap between bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary (unless the prescriber wishes to submit new baselines).

Patients may only swap to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

Adult patients with pulmonary arterial hypertension secondary to scleroderma will be able to access, through the PBS, bosentan monohydrate, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 4 drugs, they may swap between bosentan monohydrate, iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary (unless the prescriber wishes to submit new baselines).

Patients may only swap to bosentan monohydrate, iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

Adult patients with pulmonary arterial hypertension secondary to connective tissue disease other than scleroderma will be able to access, through the PBS, iloprost trometamol, sildenafil citrate (WHO Class III

only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 3 drugs, they may swap between iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary (unless the prescriber wishes to submit new baselines).

Patients may only swap to iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

Patients with drug-induced pulmonary arterial hypertension are only eligible for treatment with iloprost trometamol. They may not swap to bosentan monohydrate, epoprostenol sodium, sildenafil citrate or sitaxentan sodium.

Patients under 18 years of age:

From 1 April 2008, patients aged less than 18 years with primary pulmonary hypertension are eligible to receive PBS-subsidised treatment with bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 5 drugs, they may swap between bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary (unless the prescriber wishes to submit new baselines).

Patients may only swap to bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma.

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or

(ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or

(iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

2. Definition of WHO Functional Class III or IV disease severity.

(a) WHO Functional Class III disease severity is defined as follows:

Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.

(b) WHO Functional Class IV disease severity is defined as follows:

Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.

(i) New patients.

The first written application for PBS-subsidised treatment with the first of either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application.

NOTE:

Where patients were initiated on PBS-subsidised treatment either with bosentan monohydrate on or after 1 March 2004, with iloprost trometamol on or after 1 April 2005, with epoprostenol sodium on or after 1 August 2006, with sildenafil citrate on or after 1 March 2007, or with sitaxentan sodium on or after 1 April 2008, the test results provided with the initial application must be no more than 2 months old at the time of application. These results will form the baseline against which response assessments will be made.

Where patients received treatment with either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium prior to being commenced on PBS-subsidised treatment with the first of either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium, the test requirements above still apply. The results that will form the baseline against which response assessments will be made will be those measured at the time patients commenced non-PBS-subsidised treatment with either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium, whichever of the 5 drugs the patient received first.

(ii) Patients who received non-PBS-subsidised treatment with sitaxentan sodium prior to 1 April 2008.

For patients with primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease who were commenced on sitaxentan sodium treatment prior to 1 April 2008 and who have received less than 6 months of treatment with sitaxentan sodium at the time of application, the first application for PBS-subsidised treatment must include, where available, all 3 test results at the time that the patient commenced treatment with sitaxentan sodium, sildenafil citrate, epoprostenol sodium, bosentan monohydrate or iloprost trometamol, whichever was initiated first.

For patients with primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease who were commenced on sitaxentan sodium treatment prior to 1 April 2008 and who have received 6 or more months of treatment at the time of application, the first application for PBS-subsidised treatment must include, where available, all 3 test results at the time that the patient commenced treatment with sitaxentan sodium, sildenafil citrate, epoprostenol sodium, bosentan monohydrate or iloprost trometamol, whichever was initiated first. The results at the time of application for initial PBS-subsidised treatment must also be provided and must be no older than 3 months.

(b) Continuation of treatment.

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a reason why the test(s) could not be conducted must be provided with the application.

The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

5. Definition of response to sitaxentan sodium, sildenafil citrate, bosentan monohydrate, iloprost trometamol, epoprostenol sodium or prior vasodilator treatment.

For adult patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

6. Authority approval requirements. [The following 2 sections are only relevant to the PBS listing of sitaxentan sodium. The requirements specific to bosentan monohydrate, iloprost trometamol, epoprostenol sodium and sildenafil citrate are given in parts 6 and 7 of the NOTE included in the bosentan monohydrate, iloprost trometamol, epoprostenol sodium and sildenafil citrate Schedule entry respectively.]

(a) Initiation of PBS-subsidised treatment with sitaxentan sodium, where the patient has not received prior PBS-subsidised treatment with bosentan monohydrate, iloprost trometamol, epoprostenol sodium or sildenafil citrate.

All applications for initial treatment must be made in writing, must include an authority prescription and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months.

Patients who commence PBS-subsidised sitaxentan sodium treatment after 1 April 2008 and patients who received 6 or more months of sitaxentan sodium treatment prior to 1 April 2008 are eligible to receive up to 6 months of treatment per authority application.

Patients who commenced treatment with sitaxentan sodium prior to 1 April 2008 and who have received less than 6 months of treatment at the time of application are eligible to receive sufficient supply to allow the patient to complete a total of 6 months of combined PBS-subsidised and non-PBS-subsidised treatment.

All patients with primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease who commenced treatment with sitaxentan sodium prior to 1 April 2008 will be eligible to commence PBS-subsidised treatment with sitaxentan sodium. Thereafter, to be eligible for further PBS-subsidised supply, these patients must demonstrate a response to sitaxentan sodium treatment, as defined above under definition of response.

(b) Continuation of treatment.

Written applications for continuing treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6 months of treatment, based on the dosage recommendations in the TGA-approved Product Information.

Applications for continuing treatment will only be approved for patients who have currently demonstrated a response to treatment with sitaxentan sodium.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with sitaxentan sodium should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

(c) Swapping between bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate and sitaxentan sodium.

For eligible patients, applications to swap between these 5 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant restriction, in order to maximise the choice of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate treatment should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

(d) Cessation of treatment.

Patients who fail to demonstrate a response to PBS-subsidised sitaxentan sodium treatment at the times where an assessment is required must cease PBS-subsidised sitaxentan sodium therapy.

7. Re-treatment with sitaxentan sodium.

Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with sitaxentan sodium under any circumstances.

8. Further information.

A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at www.medicareaustralia.gov.au.

REPATRIATION PHARMACEUTICAL BENEFITS

This Schedule is effective from 1 July 2008 and all previous issues are cancelled.

New Schedules take effect on the first day of each month.