Australian Government

Department of Health and Ageing

SCHEDULE OF PHARMACEUTICAL BENEFITS

SUMMARY OF CHANGES

EFFECTIVE 1 AUGUST 2008

PHARMACEUTICAL BENEFITS

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

Dispensing Fees:	Ready-prepared	$5.99
	Dangerous drug fee	$2.71
	Extemporaneously-prepared	$8.03
	Allowable additional patient charge*	$3.63
Additional Fees (for safety net prices):	Ready-prepared	$1.03
	Extemporaneously-prepared	$1.42
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

(see under 'RESTRICTIONS' and 'NOTES' below for full details)

9190Q **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen (*Humira*) [for the treatment of Crohn disease]

9191R **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen (*Humira*) **(Diff. Max. Rpts)** [for the treatment of Crohn disease]

9187M **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen, 6 (*Humira*) [for the treatment of Crohn disease]

9188N **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled syringe (*Humira*) [for the treatment of Crohn disease]

9189P **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled syringe (*Humira*) **(Diff. Max. Rpts)** [for the treatment of Crohn disease]

9186L **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled syringe, 6 (*Humira*) [for the treatment of Crohn disease]

9183H **Alendronate sodium with colecalciferol**, Tablet equivalent to 70 mg alendronic acid with 140 micrograms colecalciferol (*Fosamax Plus 70mg/140ug*)

9166K **Erlotinib**, Tablet 25 mg (as hydrochloride) (*Tarceva*)

9167L **Erlotinib**, Tablet 100 mg (as hydrochloride) (*Tarceva*)

9168M **Erlotinib**, Tablet 150 mg (as hydrochloride) (*Tarceva*)

9184J **Fludarabine phosphate**, Tablet 10 mg (*Fludara*)

9185K **Fludarabine phosphate**, Powder for I.V. injection 50 mg (*Fludara*)

9178C **Imatinib**, Tablet 100 mg (as mesylate) (*Glivec*) [for the treatment of Aggressive Systemic Mastocytosis with Eosinophilia]

9172R **Imatinib**, Tablet 100 mg (as mesylate) (*Glivec*) **(Diff. Restriction)** [for the treatment of dermatofibrosarcoma protuberans]

9174W **Imatinib**, Tablet 100 mg (as mesylate) (*Glivec*) **(Diff. Restriction)** [for the treatment of hypereosinophilic syndrome or chronic eosinophilic leukaemia]

9176Y **Imatinib**, Tablet 100 mg (as mesylate) (*Glivec*) **(Diff. Restriction)** [for the treatment of PDGFRB fusion gene-positive myelodysplastic or myeloproliferative disorder]

9179D **Imatinib**, Tablet 400 mg (as mesylate) (*Glivec*) [for the treatment of Aggressive Systemic Mastocytosis with Eosinophilia]

9173T **Imatinib**, Tablet 400 mg (as mesylate) (*Glivec*) **(Diff. Restriction)** [for the treatment of dermatofibrosarcoma protuberans]

9175X **Imatinib**, Tablet 400 mg (as mesylate) (*Glivec*) **(Diff. Restriction)** [for the treatment of hypereosinophilic syndrome or chronic eosinophilic leukaemia]

9177B **Imatinib**, Tablet 400 mg (as mesylate) (*Glivec*) **(Diff. Restriction)** [for the treatment of PDGFRB fusion gene-positive myelodysplastic or myeloproliferative disorder]

9169N **Levetiracetam**, Oral solution 100 mg per mL, 300 mL (*Keppra*)

9171Q **Nilotinib**, Capsule 200 mg (as hydrochloride monohydrate) (*Tasigna*)

5532E **Polyethylene glycol 400 with propylene glycol**, Eye drops 4 mg-3 mg per mL (0.4%-0.3%), single dose units 0.7 mL, 28 (*Systane*) **(Optometrical)**

9170P **Polyethylene glycol 400 with propylene glycol**, Eye drops 4 mg-3 mg per mL (0.4%-0.3%), single dose units 0.7 mL, 28 (*Systane*)

9180E **Sitagliptin**, Tablet 25 mg (as phosphate monohydrate) (*Januvia*)

9181F **Sitagliptin**, Tablet 50 mg (as phosphate monohydrate) (*Januvia*)

9182G **Sitagliptin**, Tablet 100 mg (as phosphate monohydrate) (*Januvia*)

Additions - PBS Therapeutic Group Exemption Code

(see under 'RESTRICTIONS' below for full details)

A therapeutic group premium applies to Eprosartan mesylate, tablet 400 mg (base) (Teveten). The following code has been established to provide for cases where an authority has been obtained that grants exemption from the therapeutic group premium:

8951D **Eprosartan mesylate**, Tablet 400 mg (base) (*Teveten*)

Additions - Brands

8094B *APO-Bicalutamide, TX; Bicalutamide-GA, GM; Calutex, SI; Cosamide, AF* — **Bicalutamide**, Tablet 50 mg
2964B *Cefalotin Sandoz, SZ* — **Cefalotin**, Powder for injection 1 g
3376Q *Cefalotin Sandoz, SZ* — **Cefalotin**, Powder for injection 1 g **(Dental)**
3058Y *Cephalexin Sandoz, SZ* — **Cephalexin**, Capsule 250 mg
3317N *Cephalexin Sandoz, SZ* — **Cephalexin**, Capsule 250 mg **(Dental)**
3161J *Ranzepam, RA* — **Diazepam**, Tablet 2 mg
5355W *Ranzepam, RA* — **Diazepam**, Tablet 2 mg **(Palliative Care)**
5357Y *Ranzepam, RA* — **Diazepam**, Tablet 2 mg **(Palliative Care) (Diff. Max. Rpts)**
5071X *Ranzepam, RA* — **Diazepam**, Tablet 2 mg **(Dental)**
3162K *Ranzepam, RA* — **Diazepam**, Tablet 5 mg
5356X *Ranzepam, RA* — **Diazepam**, Tablet 5 mg **(Palliative Care)**
5358B *Ranzepam, RA* — **Diazepam**, Tablet 5 mg **(Palliative Care) (Diff. Max. Rpts)**
5072Y *Ranzepam, RA* — **Diazepam**, Tablet 5 mg **(Dental)**
8505P *Gabatine 100, SI* — **Gabapentin**, Capsule 100 mg
1834M *Gabatine 300, SI* — **Gabapentin**, Capsule 300 mg
1835N *Gabatine 400, SI* — **Gabapentin**, Capsule 400 mg
1968N *Quinapril generichealth, GQ* — **Quinapril hydrochloride**, Tablet 5 mg (base)
1969P *Quinapril generichealth, GQ* — **Quinapril hydrochloride**, Tablet 10 mg (base)
1970Q *Quinapril generichealth, GQ* — **Quinapril hydrochloride**, Tablet 20 mg (base)
1944H *Tryzan Tabs 1.25, AF* — **Ramipril**, Tablet 1.25 mg
1945J *Tryzan Tabs 2.5, AF* — **Ramipril**, Tablet 2.5 mg
1946K *Tryzan Tabs 5, AF* — **Ramipril**, Tablet 5 mg
1316G *Tryzan Tabs 10, AF* — **Ramipril**, Tablet 10 mg
9120B *Ramipril-DP, GM; Ramipril generichealth, GQ* — **Ramipril**, Capsule 1.25 mg
9121C *Ramipril-DP, GM; Ramipril generichealth, GQ* — **Ramipril**, Capsule 2.5 mg
9122D *Ramipril-DP, GM; Ramipril generichealth, GQ* — **Ramipril**, Capsule 5 mg
8470T *GenRx Ramipril, GX; Ramipril-DP, GM; Ramipril generichealth, GQ* — **Ramipril**, Capsule 10 mg

Additions - Bioequivalence Indicator

The bioequivalence indicator ([a]) has been added to the following **brand**:

8094B *Cosudex, AP* — **Bicalutamide**, Tablet 50 mg

DELETIONS

Deletions - Items

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

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

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

8124N **Dicloxacillin**, Powder for injection 1 g (*Diclocil*)

5099J **Dicloxacillin**, Powder for injection 1 g (*Diclocil*) **(Dental)**

8123M **Dicloxacillin**, Powder for injection 500 mg (*Diclocil*)

5098H **Dicloxacillin**, Powder for injection 500 mg (*Diclocil*) **(Dental)**

1529L **Flucloxacillin**, Powder for syrup 250 mg (as magnesium) per 5 mL, 100 mL (*Flopen*)

5093C **Flucloxacillin**, Powder for syrup 250 mg (as magnesium) per 5 mL, 100 mL (*Flopen*) **(Dental)**

8850T **Methotrexate**, Solution concentrate for I.V. infusion 500 mg in 5 mL (*Methotrexate Ebewe*)

Deletions - Brands

8814X *Duatrol SR, ME* — **Paracetamol**, Tablet 665 mg (modified release)

5343F *Duatrol SR, ME* — **Paracetamol**, Tablet 665 mg (modified release) **(Palliative Care)**

5344G *Duatrol SR, ME* — **Paracetamol**, Tablet 665 mg (modified release) **(Palliative Care) (Diff. Max. Rpts)**

2095G *Ticlid, RO* — **Ticlopidine hydrochloride**, Tablet 250 mg

Deletions - Bioequivalence Indicators

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

8814X *Panadol Osteo, GC* — **Paracetamol**, Tablet 665 mg (modified release)

5343F *Panadol Osteo, GC* — **Paracetamol**, Tablet 665 mg (modified release) **(Palliative Care)**

5344G *Panadol Osteo, GC* — **Paracetamol**, Tablet 665 mg (modified release) **(Palliative Care) (Diff. Max. Rpts)**

2095G *Tilodene, AF* — **Ticlopidine hydrochloride**, Tablet 250 mg

ALTERATIONS

Alterations - Drug Name

From:

2964B **Cephalothin**, Powder for injection 1 g (*Keflin Neutral, HH*)

To:

2964B **Cefalotin**, Powder for injection 1 g (*Cefalotin Sandoz, Keflin Neutral, HH*)

Alterations - Brands

From:

9120B **Ramipril**, Capsule 1.25 mg (*Tryzan 1.25*)

To:

9120B **Ramipril**, Capsule 1.25 mg (*Tryzan Caps 1.25*)

From:

9121C **Ramipril**, Capsule 2.5 mg (*Tryzan 2.5*)

To:

9121C **Ramipril**, Capsule 2.5 mg (*Tryzan Caps 2.5*)

From:

9122D **Ramipril**, Capsule 5 mg (*Tryzan 5*)

To:

9122D **Ramipril**, Capsule 5 mg (*Tryzan Caps 5*)

From:

8470T **Ramipril**, Capsule 10 mg (*Tryzan 10*)

To:

8470T **Ramipril**, Capsule 10 mg (*Tryzan Caps 10*)

Alterations - Manufacturer's Code

		From	*To*
9022W	**Fenofibrate**, Tablet 48 mg (*Lipidil*)	LF	SM
9023X	**Fenofibrate**, Tablet 145 mg (*Lipidil*)	LF	SM

Alterations - Restrictions

(see under 'RESTRICTIONS' below for full details)

2478K **Dasatinib**, Tablet 20 mg (*Sprycel*)

2482P **Dasatinib**, Tablet 50 mg (*Sprycel*)

2485T **Dasatinib**, Tablet 70 mg (*Sprycel*)

8700X **Escitalopram oxalate**, Tablet 10 mg (base) (*Esipram, Lexapro*)

8701Y **Escitalopram oxalate**, Tablet 20 mg (base) (*Esipram, Lexapro*)

8561N **Meloxicam**, Tablet 7.5 mg (*Chem mart Meloxicam 7.5 mg, GenRx Meloxicam, Meloxibell, Meloxicam-GA, Meloxicam Ranbaxy, Meloxicam Sandoz, Meloxicam Winthrop, Movalis 7.5, Moxicam 7.5, Pharmacor Meloxicam 7.5, Terry White Chemists Meloxicam 7.5 mg, Mobic*)

8562P **Meloxicam**, Tablet 15 mg (*Chem mart Meloxicam 15 mg, GenRx Meloxicam, Meloxibell, Meloxicam-GA, Meloxicam Ranbaxy, Meloxicam Sandoz, Meloxicam Winthrop, Movalis 15, Moxicam 15, Pharmacor Meloxicam 15, Terry White Chemists Meloxicam 15 mg, Mobic*)

8887R **Meloxicam**, Capsule 7.5 mg (*Mobic*)

8888T **Meloxicam**, Capsule 15 mg (*Mobic*)

Alterations - Notes

(see under 'NOTES' below for full details)

9111M **Imatinib**, Tablet 100 mg (as mesylate) (*Glivec*)

9112N **Imatinib**, Tablet 400 mg (as mesylate) *(Glivec)*

SECTION 100 - HIGHLY SPECIALISED DRUGS PROGRAM

ADDITIONS

Additions - Item

(see under 'RESTRICTIONS' below for full details)

9630W **Telbivudine**, Tablet 600 mg (*Sebivo*)

DELETIONS

Deletions - Items

6285T **Baclofen**, Intrathecal injection 10 mg in 20 mL (*Lioresal Intrathecal*)
6110N **Cyclosporin**, Solution concentrate for I.V. infusion 250 mg in 5 mL (*Sandimmun*)
6340Q **Lopinavir with ritonavir**, Capsule 133.3 mg-33.3 mg (*Kaletra*)
6199G **Saquinavir mesylate**, Capsule 200 mg (base) (*Invirase*)

Deletions - Brand

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

Alterations - Restrictions

(see under 'RESTRICTIONS' below for full details)

6429J **Bosentan monohydrate**, Tablet 62.5 mg (base) (*Tracleer*)
6430K **Bosentan monohydrate**, Tablet 125 mg (base) (*Tracleer*)
9613Y **Infliximab**, Powder for I.V. infusion 100 mg (*Remicade*)
9612X **Infliximab**, Powder for I.V. infusion 100 mg *(Remicade)*

Alterations - Notes

(see under 'NOTES' below for full details)

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*)
Infliximab, Powder for I.V. infusion 100 mg (*Remicade*)
Sildenafil citrate, Tablet 20 mg (base) (*Revatio*)

Sitaxentan sodium, Tablet 100 mg (*Thelin*)

ADVANCE NOTICES

Advance Notices - Deletion of Item

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*)

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 REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for adult patients with severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 August 2008, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2008 is considered to be in their first cycle as of 1 August 2008.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2008.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, 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, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy 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, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, evidence of intestinal inflammation,), or the prior corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives 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, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application 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.

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

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 9 November 2007 or infliximab prior to 7 March 2007 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

NOTE:

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

9187M **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen, 6 (*Humira*)

Authority required

Initial 1 (new patients)
Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:
(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and
(b) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(c) has failed to achieve an adequate response to prior systemic therapy including:
(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and
(ii) immunosuppressive therapy including:
— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

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 necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) have a severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as assessed.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

The most recent CDAI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:
(a) two completed authority prescription forms; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition; and
(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(iii) the signed patient acknowledgement.

A maximum of 16 weeks treatment will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab 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). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

Authority required

Initial 2
Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:
(a) has a documented history of severe refractory Crohn disease; and
(b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and

(c) has not failed PBS-subsidised therapy with adalimumab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:
(a) two completed authority prescription forms; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; and
(ii) details of prior TNF alfa antagonist treatment including details of date and duration of treatment.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab 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). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

Authority required

Initial 1
Initial PBS-subsidised treatment with adalimumab by a gastroenterologist, or consultant physician as specified in the NOTE below of a patient who satisfies the following criteria:
(a) has confirmed Crohn disease defined by standard clinical, endoscopic and/or imaging features, including histological evidence with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and
(b) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy; and
(c) has evidence of intestinal inflammation; and

(d) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(e) has failed to achieve an adequate response to prior systemic drug therapy including:
(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and
(ii) immunosuppressive therapy including:
— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

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 necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted 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 application:
(a) have evidence of intestinal inflammation, including:
(i) blood: higher than normal platelet count, or, 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/OR
(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR
(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;
AND/OR
(b) be assessed clinically as being in a high faecal output state;
AND/OR
(c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of adalimumab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:
(a) two completed authority prescription forms; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(ii) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
(iii) date of the most recent clinical assessment; and
(iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum of 16 weeks treatment will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab 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). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

Authority required

Initial 2
Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:
(a) has a documented history of severe refractory Crohn disease; and
(b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and
(c) has not failed PBS-subsidised therapy with adalimumab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.
If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:
(a) two completed authority prescription forms; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criteria, if relevant; and
(ii). details of prior TNF alfa antagonist treatment including details of date and duration of treatment.

A maximum of 16 weeks of treatment will be approved under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats.

The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab 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). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

Authority required

Initial 1
Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:
(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and
(b) has extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; and
(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(d) has failed to achieve an adequate response to prior systemic therapy including:
(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and
(ii) immunosuppressive therapy including:
— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

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 necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted 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 application:
(a) have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220;
AND/OR
(b) have evidence of active intestinal inflammation, including:

(i) blood: higher than normal platelet count, or, 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/OR
(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR
(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;
AND/OR
(c) be assessed clinically as being in a high faecal output state;
AND/OR
(d) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of adalimumab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:
(a) two completed authority prescription forms; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(ii) (1) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; or
(2) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the dates of assessment of the patient's condition, if relevant; and
(iii) date of the most recent clinical assessment; and
(iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum of 16 weeks treatment of adalimumab will be authorised under his criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab 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). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy after the first dose so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

9190Q **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen (*Humira*)

9186L **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled syringe, 6 (*Humira*)
9188N **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled syringe (*Humira*)

Authority required

Initial 1 (new patients)
Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:
(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and
(b) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(c) has failed to achieve an adequate response to prior systemic therapy including:
(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and
(ii) immunosuppressive therapy including:
— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

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 necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) have a severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as assessed.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

The most recent CDAI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:
(a) two completed authority prescription forms; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition; and
(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(iii) the signed patient acknowledgement.

A maximum of 16 weeks treatment will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab 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). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

Authority required

Initial 2
Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:
(a) has a documented history of severe refractory Crohn disease; and
(b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and
(c) has not failed PBS-subsidised therapy with adalimumab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:
(a) two completed authority prescription forms; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; and
(ii) details of prior TNF alfa antagonist treatment including details of date and duration of treatment.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab 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). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

Authority required

Initial 1
Initial PBS-subsidised treatment with adalimumab by a gastroenterologist, or consultant physician as specified in the NOTE below of a patient who satisfies the following criteria:
(a) has confirmed Crohn disease defined by standard clinical, endoscopic and/or imaging features, including histological evidence with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and
(b) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy; and
(c) has evidence of intestinal inflammation; and
(d) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(e) has failed to achieve an adequate response to prior systemic drug therapy including:
(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and
(ii) immunosuppressive therapy including:
— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

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 necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted 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 application:
(a) have evidence of intestinal inflammation, including:
(i) blood: higher than normal platelet count, or, 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/OR
(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR
(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;
AND/OR
(b) be assessed clinically as being in a high faecal output state;
AND/OR
(c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of adalimumab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:
(a) two completed authority prescription forms; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(ii) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
(iii) date of the most recent clinical assessment; and
(iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum of 16 weeks treatment will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab 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). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

Authority required

Initial 2
Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:
(a) has a documented history of severe refractory Crohn disease; and
(b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and
(c) has not failed PBS-subsidised therapy with adalimumab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.
If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:
(a) two completed authority prescription forms; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criteria, if relevant; and
(ii). details of prior TNF alfa antagonist treatment including details of date and duration of treatment.

A maximum of 16 weeks of treatment will be approved under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab 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). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

Authority required

Initial 1
Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:
(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and
(b) has extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; and
(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(d) has failed to achieve an adequate response to prior systemic therapy including:
(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and
(ii) immunosuppressive therapy including:

— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

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 necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted 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 application:
(a) have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220;
AND/OR
(b) have evidence of active intestinal inflammation, including:
(i) blood: higher than normal platelet count, or, 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/OR
(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR
(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;
AND/OR
(c) be assessed clinically as being in a high faecal output state;
AND/OR
(d) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of adalimumab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:
(a) two completed authority prescription forms; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(ii) (1) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; or
(2) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the dates of assessment of the patient's condition, if relevant; and
(iii) date of the most recent clinical assessment; and
(iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum of 16 weeks treatment of adalimumab will be authorised under his criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats.

The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab 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). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy after the first dose so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

9191R **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen (*Humira*)
9189P **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled syringe (*Humira*)

Authority required

Initial 3 (grandfather)
Initial PBS-subsidised supply with adalimumab for continuing treatment by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who:
(a) has a documented history of severe refractory Crohn disease and was receiving treatment with adalimumab prior to 9 November 2007; and
(b) had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with adalimumab. Where a baseline CDAI assessment is not available, please call Medicare Australia on 1800 700 270 to discuss; and
(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(d) has demonstrated or sustained an adequate response to treatment with adalimumab. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to adalimumab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; and
(ii) the signed patient acknowledgement.

The current CDAI assessment must be no more than 1 month old at the time of application. The baseline CDAI assessment must be from immediately prior to commencing treatment with adalimumab.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to

the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

A maximum of 24 weeks treatment will be approved under this criterion.
Where fewer than 5 repeats are requested at the time of 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 may qualify for PBS-subsidised treatment under this restriction once only

Authority required

Continuing PBS-subsidised treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:
(a) has a documented history of severe refractory Crohn disease; and
(b) has demonstrated or sustained an adequate response to treatment with adalimumab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to adalimumab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition.

The CDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with adalimumab, a CDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

Patients are eligible to receive continuing adalimumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

A maximum of 24 weeks treatment will be authorised under this criterion.
Where fewer than 5 repeats are requested at the time of 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)

Authority required

Continuing PBS-subsidised treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:
(a) has a documented history of severe refractory Crohn disease with intestinal inflammation and with short gut syndrome or with an ileostomy or colostomy; and

(b) has demonstrated or sustained an adequate response to treatment with adalimumab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to adalimumab treatment is defined as:
(a) improvement of intestinal inflammation as demonstrated by:
(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR
(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR
(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or
(b) reversal of high faecal output state; or
(c) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy or the date of clinical assessment.

The patient's assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with adalimumab, an assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

Patients are eligible to receive continuing adalimumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

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

Authority required

Continuing PBS-subsidised treatment with adalimumab by a gastroenterologist, or consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:
(a) has a documented history of severe refractory Crohn disease with extensive intestinal inflammation affecting more than 50 cm of the small intestine; and
(b) has demonstrated or sustained an adequate response to treatment with adalimumab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to adalimumab treatment is defined as:
(a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or
(b) improvement of intestinal inflammation as demonstrated by:

(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR
(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR
(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or
(c) reversal of high faecal output state; or
(d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; or
(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy; or
(iii) the date of clinical assessment.

All assessments must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with adalimumab, an assessment of the patient's response must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

Patients are eligible to receive continuing adalimumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

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

Authority required

Initial 3
Initial PBS-subsidised supply for continuing treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist, of a patient who:
(a) has a documented history of severe refractory Crohn disease and was receiving treatment with adalimumab prior to 9 November 2007; and
(b) (1) has a history of extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; or
(2) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy with a documented history of intestinal inflammation; and
(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(d) has demonstrated or sustained an adequate response to treatment with adalimumab according to the criteria included in the relevant continuation restriction. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

The same criteria used to determine an inadequate response to prior treatment at baseline must be used to determine response to treatment and eligibility for continuing therapy, according to the criteria included in the continuing treatment restriction.

An adequate response to adalimumab treatment is defined as:
(a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater then 150; or
(b) improvement of intestinal inflammation as demonstrated by:
(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR
(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR
(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or
(c) reversal of high faecal output state; or
(d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) (1) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet, where relevant, including the date of the assessment of the patient's condition; or
(2) the reports and dates of the current and baseline pathology or diagnostic imaging test(s) in order to assess response to therapy; or
(3) the date of clinical assessment(s); and
(ii) the signed patient acknowledgement.

The patient's assessment must be no more than 1 month old at the time of application. The baseline CDAI assessments must be from immediately prior to commencing treatment with adalimumab. Where a baseline assessment is not available, please call Medicare Australia on 1800 700 270 to discuss.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

Patients are eligible to receive continuing adalimumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

Patients who fail to demonstrate or sustain a response to treatment with adalimumab for Crohn disease as specified in the criteria for continuing treatment with adalimumab, will not be eligible to recommence PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased.

A maximum of 24 weeks treatment will be authorised under this criterion.
Where fewer than 5 repeats are requested at the time of this 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 may qualify for PBS-subsidised treatment under this restriction once only

9183H **Alendronate sodium with colecalciferol**, Tablet equivalent to 70 mg alendronic acid with 140 micrograms colecalciferol (*Fosamax Plus 70mg/140ug*)

Authority required (STREAMLINED)

2645

Treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in a patient aged 70 years of age or older with a Bone Mineral Density (BMD) T-score of -3.0 or less.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated

Authority required (STREAMLINED)

2646

Treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body

NOTE:

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, disodium etidronate, raloxifene hydrochloride and strontium ranelate

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

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, pulmonary arterial hypertension secondary to scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), 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. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

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. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

(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. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

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 with pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are only eligible for treatment with bosentan monohydrate. They may not swap to epoprostenol sodium, iloprost trometamol, 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. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

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, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology).

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) 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, with sitaxentan sodium on or after 1 April 2008, or with bosentan monohydrate (for PAH associated with congenital systemic-to-pulmonary shunt) on or after 1 August 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

NOTE:

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

6430K **Bosentan monohydrate**, Tablet 125 mg (base) (*Tracleer*)
6429J **Bosentan monohydrate**, Tablet 62.5 mg (base) (*Tracleer*)

Public and private hospital authority required

Initial (new adult patients)
Application for initial PBS-subsidised treatment with bosentan monohydrate of adult patients who have not received prior PBS-subsidised treatment with iloprost trometamol, 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 scleroderma 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) two completed authority prescription forms [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 bosentan monohydrate for primary pulmonary hypertension, pulmonary arterial hypertension secondary to scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), OR with iloprost trometamol for primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, 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. No repeats will be authorised for the first authority prescription issued under this criterion [see Note for full details of authority approval requirements]. A maximum of 4 repeats will be authorised for the second authority prescription issued under this criterion. Where fewer than 4 repeats are initially requested with the second authority prescription, 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 adult patients)
Application for initial PBS-subsidised treatment with bosentan monohydrate of adult patients who have not received prior PBS-subsidised treatment with iloprost trometamol, 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 scleroderma 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 IV primary pulmonary hypertension; OR
(d) WHO Functional Class IV pulmonary arterial hypertension secondary to scleroderma.

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) two completed authority prescription forms [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 bosentan monohydrate for primary pulmonary hypertension, pulmonary arterial hypertension secondary to scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), OR with iloprost trometamol for primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, 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. No repeats will be authorised for the first authority prescription issued under this criterion [see Note for full details of authority approval requirements]. A maximum of 4 repeats will be authorised for the second authority prescription issued under this criterion. Where fewer than 4 repeats are initially requested with the second authority prescription, 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 under 18 years of age)
Application for initial PBS-subsidised treatment of patients aged less than 18 years who have not received prior PBS-subsidised treatment with epoprostenol sodium or sildenafil citrate and who have been assessed by a physician from a designated hospital to have:
WHO Functional Class III primary pulmonary hypertension and either a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, normal right ventricular function as assessed by ECHO.

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

Applications for authorisation must be in writing and must include:
(1) two completed authority prescription forms [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 patient acknowledgment, signed by the parent or authorised guardian, indicating that they understand and acknowledge that PBS-subsidised treatment with bosentan monohydrate, epoprostenol sodium or sildenafil citrate for primary pulmonary hypertension 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. No repeats will be authorised for the first authority prescription issued under this criterion [see Note for full details of authority approval requirements]. A maximum of 4 repeats will be authorised for the second authority prescription issued under this criterion. Where fewer than 4 repeats are initially requested with the second authority prescription, 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 under 18 years of age)

Application for initial PBS-subsidised treatment of patients aged less than 18 years who have not received prior PBS-subsidised treatment with epoprostenol sodium or sildenafil citrate and who have been assessed by a physician from a designated hospital to have:
(a) WHO Functional Class III primary pulmonary hypertension and either a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular dysfunction as assessed by ECHO; OR
(b) WHO Functional Class IV primary pulmonary hypertension.

Applications for authorisation must be in writing and must include:
(1) two completed authority prescription forms [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 patient acknowledgment, signed by the parent or authorised guardian, indicating that they understand and acknowledge that PBS-subsidised treatment with bosentan monohydrate, epoprostenol sodium or sildenafil citrate for primary pulmonary hypertension 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. No repeats will be authorised for the first authority prescription issued under this criterion [see Note for full details of authority approval requirements]. A maximum of 4 repeats will be authorised for the second authority prescription issued under this criterion. Where fewer than 4 repeats are initially requested with the second authority prescription, 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 bosentan monohydrate of a patient who has been assessed by a physician from a designated hospital to have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology).

Applications for authorisation must be in writing and must include:
(1) two completed authority prescription forms [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 bosentan monohydrate for primary pulmonary hypertension, pulmonary arterial hypertension secondary to scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), OR with iloprost trometamol for primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, 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].

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.

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. No repeats will be authorised for the first authority prescription issued under this criterion [see Note for full details of authority approval requirements]. A maximum of 4 repeats will be authorised for the second authority prescription issued under this criterion. Where fewer than 4 repeats are initially requested with the second authority prescription, 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 (grandfather patients)
Application for initial PBS-subsidised treatment with bosentan monohydrate of a patient who was receiving treatment with bosentan monohydrate prior to 1 August 2008 and who has been assessed by a physician from a designated hospital to have pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology).

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 bosentan monohydrate for primary pulmonary hypertension, pulmonary arterial hypertension secondary to scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), OR with iloprost trometamol for primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, 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].

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.

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. The number of repeats authorised will be dependent on the duration of prior bosentan monohydrate therapy. Where patients have received less than 6 months of non-PBS-subsidised treatment with bosentan monohydrate, sufficient repeats to allow the patient to complete a total of 6 months of combined PBS-subsidised and

non-PBS-subsidised therapy may be requested. Where patients have received 6 months or more of non-PBS-subsidised treatment with bosentan monohydrate, a maximum of 5 repeats may be requested. Where fewer than the maximum allowable number of repeats are requested at the time of application, authority approvals for the remainder of the allowable repeats 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 adult patients)
Application for initial treatment with bosentan monohydrate of adult patients with either of the following:

(a) primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma who wish to re-commence PBS-subsidised bosentan monohydrate after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with bosentan monohydrate; OR
(b) primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma and whose most recent course of PBS-subsidised treatment was with iloprost trometamol, sildenafil citrate or sitaxentan sodium; OR
(c) primary pulmonary hypertension and whose most recent course of PBS-subsidised treatment was with epoprostenol sodium.

Applications for authorisation must be in writing and must include:
(1) two completed authority prescription forms [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 bosentan monohydrate, iloprost trometamol, 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 bosentan monohydrate, iloprost trometamol, 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 bosentan monohydrate, iloprost trometamol, 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. No repeats will be authorised for the first authority prescription issued under this criterion [see Note for full details of authority approval requirements]. A maximum of 4 repeats will be authorised for the second authority prescription issued under this criterion. Where fewer than 4 repeats are initially requested with the second authority prescription, 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 patients under 18 years of age)
Application for initial treatment with bosentan monohydrate of patients aged less than 18 years with either of the following:
(a) primary pulmonary hypertension who wish to re-commence PBS-subsidised bosentan monohydrate after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with bosentan monohydrate; OR
(b) primary pulmonary hypertension and whose most recent course of PBS-subsidised treatment was with epoprostenol sodium or sildenafil citrate.

Applications for authorisation must be in writing and must include:
(1) two completed authority prescription forms [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 bosentan monohydrate, epoprostenol sodium or sildenafil citrate, whichever was initiated first, was granted; and
(3) the date of the first application for PBS-subsidised treatment with bosentan monohydrate, epoprostenol sodium or sildenafil citrate, whichever was initiated first; and
(4) the results of the patient's response to treatment with their last course of PBS-subsidised bosentan monohydrate, epoprostenol sodium or sildenafil citrate.

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. No repeats will be authorised for the first authority prescription issued under this criterion [see Note for full details of authority approval requirements]. A maximum of 4 repeats will be authorised for the second authority prescription issued under this criterion. Where fewer than 4 repeats are initially requested with the second authority prescription, 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 bosentan monohydrate of patients who have received approval for initial PBS-subsidised treatment with bosentan monohydrate and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of bosentan monohydrate 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 will be authorised.

Where fewer than 5 repeats are initially requested under this criterion, 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

Cessation of treatment (all patients)
Final PBS-subsidised supply for patients with WHO Functional Class III or IV primary pulmonary hypertension or WHO Functional Class III or IV pulmonary arterial hypertension secondary to scleroderma or WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), who have not responded to bosentan monohydrate therapy [see Note for definition of response], to allow for gradual cessation of treatment.

Applications for authorisation under this criterion should be made on the telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) [see Note on authority approval requirements].

Approval will only be granted for the 62.5 mg tablet strength. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment.

Under no circumstances will telephone approvals be granted for treatment that would extend the final treatment period beyond 1 month

2478K **Dasatinib**, Tablet 20 mg (*Sprycel*)
2482P **Dasatinib**, Tablet 50 mg (*Sprycel*)
2485T **Dasatinib**, Tablet 70 mg (*Sprycel*)

NOTE:

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

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Any queries concerning patients who are enrolled on the Dasatinib Compassionate Program 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 dasatinib should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Authority required

Initial treatment, as the sole PBS-subsidised therapy, of a patient with chronic myeloid leukaemia in any disease phase bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL, who has active leukaemia (as defined by presence on current pathology assessments of either the Philadelphia chromosome on cytogenetic or FISH analysis, or the presence of the transcript BCR-ABL and morphological evidence of leukaemia) and who has failed an adequate trial of imatinib.

Failure of an adequate trial of imatinib is defined as:

(i) Lack of response to initial imatinib therapy, defined as either:

— failure to achieve a haematological response after a minimum of 3 months therapy with imatinib for patients initially treated in chronic phase; or

— failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or

— failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib; OR

(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib therapy (Note: a *BCR/ABL* qPCR>1% alone is not evidence of loss of response); OR

(iii) Development of accelerated phase or blast crisis in a patient previously prescribed imatinib for any phase of chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%; or

(3) Peripheral basophils greater than or equal to 20%; or

(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

Blast crisis is defined as either:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or

(2) Extramedullary involvement other than spleen and liver; OR

(iv) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia; OR

(v) Detection of a mutation in BCR-ABL (L248V, G250E, Q252H/R, Y253H/F, E255K/V, H396P/R, and D276G) that infers high level imatinib resistance. (Patients with these mutations but without active leukaemia, will not be approved); OR

(vi) Grade 3 or 4 non-haematological toxicity that is imatinib related.

Applications for authorisation must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Chronic Myeloid Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and

(c) a signed patient acknowledgement; and

(d) a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of chronic myeloid leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript. (The date of the relevant pathology report needs to be provided); and

(e) a copy of the current confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement or details of Grade 3 or 4 non-haematological toxicity

NOTE:

Dasatinib will only be subsidised for patients with chronic myeloid leukaemia who are not receiving concomitant PBS-subsidised imatinib mesylate, nilotinib or interferon alfa therapy.

Patients should be commenced on a dose of dasatinib of at least 100 mg (base) daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to dasatinib therapy or a peripheral blood BCR-ABL level of less than 1% at 12 monthly intervals, irrespective of the daily dasatinib dose received.

Dasatinib is not PBS-subsidised for patients with CML that is resistant to nilotinib.

Authority required

Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial treatment with dasatinib as a pharmaceutical benefit for chronic myeloid leukaemia, and who has demonstrated either a major cytogenetic response, or less than 1% BCR-ABL level in the blood, to dasatinib in the preceding 12 months.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Chronic Myeloid Leukaemia Dasatinib Authority Application Form for continuing treatment; and

(3) demonstration of continued response to treatment as evidenced by either:

(a) major cytogenetic response [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided; or

(b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided

NOTE:

Definitions of response.

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.

A bone marrow or peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

Authority approval requirements.

For the purposes of assessing response to PBS-subsidised treatment with dasatinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted as follows:

(i) between 10 and 12 months of the commencement of treatment with dasatinib, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and

(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

For each authority application where eligibility for continuing PBS-subsidised treatment is to be demonstrated, a copy of the cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or a copy of the quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted as described in (i) and (ii) above. For bone marrow analyses, where the standard karyotyping conducted at the time of application is not informative, a copy of a cytogenetic analysis conducted on the bone marrow using FISH with BCR-ABL specific probe must be submitted with the authority application. A copy of the non-informative standard karyotype analysis must be included with the authority application.

Where a patient has previously received PBS-subsidised treatment with dasatinib, no approval will be granted for PBS-subsidised re-treatment where that patient has at any time failed to meet the criteria for continuing treatment.

8951D **Eprosartan mesylate**, Tablet 400 mg (base) *(Tevelen)*

Authority required

Adverse effects occurring with all of the base-priced drugs

Drug interactions occurring with all of the base-priced drugs

Drug interations expected to occur with all of the base-priced drugs

Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance

9167L **Erlotinib**, Tablet 100 mg (as hydrochloride) (*Tarceva*)
9168M **Erlotinib**, Tablet 150 mg (as hydrochloride) (*Tarceva*)
9166K **Erlotinib**, Tablet 25 mg (as hydrochloride) (*Tarceva*)

Authority required

Initial PBS-subsidised treatment, as monotherapy, in a patient with locally advanced or metastatic (stage IIIB or IV) non-small cell lung cancer with a WHO performance status of 3 or less, after prior treatment with platinum-based chemotherapy, where:

(1) (a) disease progression has occurred following treatment with docetaxel or pemetrexed; or
(b) treatment with docetaxel and pemetrexed is either contraindicated or cannot be tolerated; and
(2) further cytotoxic chemotherapy is not appropriate

Authority required

Continuing PBS-subsidised treatment, as monotherapy, in a patient with locally advanced or metastatic (stage IIIB or IV) non-small cell lung cancer who has previously been issued with an authority prescription for this drug and who does not have progressive disease

Authority required

Initial PBS-subsidised treatment, as monotherapy, in a patient with locally advanced or metastatic (stage IIIB or IV) non-small cell lung cancer, after prior treatment with platinum-based chemotherapy:
(1) where:
(a) disease progression occurred following treatment with docetaxel or pemetrexed; or
(b) treatment with docetaxel and pemetrexed was either contraindicated or could not be tolerated; and
(2) who has received treatment with erlotinib under the Erlotinib Access Programme prior to 1 August 2008; and
(3) who does not have progressive disease

8700X **Escitalopram oxalate**, Tablet 10 mg (base) (*Esipram, Lexapro*)
8701Y **Escitalopram oxalate**, Tablet 20 mg (base) (*Esipram, Lexapro*)

Restricted benefit

Major depressive disorders

Restricted benefit

Moderate to severe generalised anxiety disorder (GAD), as defined by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria, in a patient who has not responded to non-pharmacological therapy and for whom a GP Mental Health Care Plan, as described under item 2710 of the Medicare Benefits Schedule, has been prepared

Restricted benefit

Moderate to severe generalised anxiety disorder (GAD), as defined by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria, in a patient who has not responded to non-pharmacological therapy andwho has been assessed by a psychiatrist

Continuing PBS subsidised treatment, for moderate to severe generalised anxiety disorder (GAD), of a patient commenced on escitalopram prior to 1 March 2008

Restricted benefit

Moderate to severe social anxiety disorder (social phobia, SAD), as described by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria, in a patient who has not responded to non-pharmacological therapy and for whom a GP Mental Health Care Plan, as described under item 2710 of the Medicare Benefits Schedule, has been prepared

Restricted benefit

Moderate to severe social anxiety disorder (social phobia, SAD), as described by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria, in a patient who has not responded to non-pharmacological therapy and who has been assessed by a psychiatrist

Continuing PBS subsidised treatment, for moderate to severe social anxiety disorder (social phobia; SAD), of a patient commenced on escitalopram prior to 1 March 2008

9185K **Fludarabine phosphate**, Powder for I.V. injection 50 mg (*Fludara*)
9184J **Fludarabine phosphate**, Tablet 10 mg (*Fludara*)

Authority required

B-cell chronic lymphocytic leukaemia in combination with cyclophosphamide where the patient has advanced disease (Binet Stage B or C) or evidence of progressive Stage A disease.

Stage A progressive disease is defined by at least one of the following: persistent rise in lymphocyte count with doubling time less than 12 months; a downward trend in haemoglobin or platelets, or both; more than 50% increase in the size of liver, spleen, or lymph nodes, or appearance of these signs if not previously present; constitutional symptoms attributable to disease.

The diagnosis of chronic lymphocytic leukaemia (CLL) must have been established based on:
(a) a lymphocytosis, with more than 5,000 million lymphocytes per L in the peripheral blood; and
(b) a clonal population of B-cells (CD5/CD19) documented by flow cytometry

9178C **Imatinib**, Tablet 100 mg (as mesylate) (*Glivec*)
9179D **Imatinib**, Tablet 400 mg (as mesylate) (*Glivec*)

Authority required

Initial PBS-subsidised treatment of a patient with aggressive systemic mastocytosis with eosinophilia where:
(1) there is confirmed evidence of the FIP1L1-PDGFRA fusion gene; and
(2) the patient has previously failed an adequate trial of one or more of the following conventional therapies:
— corticosteroids;
— hydroxyurea.

Maximum dose: 400 mg per day.

Applications for authorisation for initial treatment must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
(c) a copy of the pathology report confirming the presence of the FIP1L1-PDGFRA fusion gene; and
(d) a copy of the bone marrow biopsy report and/or other tissue biopsy report confirming the diagnosis of aggressive systemic mastocytosis and a copy of the full blood examination report demonstrating eosinophilia; and
(e) details of symptomatic organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate; and
(f) details of prior treatment trialled and the response; and
(g) a signed patient acknowledgement

Authority required

Continuing PBS-subsidised treatment of a patient with aggressive systemic mastocytosis confirmed to carry the FIP1L1-PDGFRA fusion gene, who has previously been issued with an authority prescription for imatinib and who has demonstrated a clinically significant response.

Maximum dose: 400 mg per day.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
(c) a statement that the disease has not progressed on imatinib therapy

9172R **Imatinib**, Tablet 100 mg (as mesylate) (*Glivec*)
9173T **Imatinib**, Tablet 400 mg (as mesylate) (*Glivec*)

Authority required

Initial PBS-subsidised treatment of a patient with unresectable, locally recurrent or metastatic dermatofibrosarcoma protuberans.

Maximum dose: 800 mg per day.

(1) Where the application for authority to prescribe is being sought on the basis of unresectable tumour, written evidence in support of that claim must be provided; and
(2) Where the application for authority to prescribe is being sought on the basis of locally recurrent disease, the site of the local recurrence must be specified; and

(3) Where the application for authority to prescribe is being sought on the basis of metastatic disease, the site(s) of metastatic disease must be provided.

Applications for authorisation for initial treatment must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
(c) a signed patient acknowledgement

Authority required

Continuing PBS-subsidised treatment of a patient with unresectable, locally recurrent or metastatic dermatofibrosarcoma protuberans who has previously been issued with an authority prescription for imatinib and who has demonstrated a response, but whose disease remains unresectable.

Maximum dose: 800 mg per day.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
(c) a statement that the disease has not progressed on imatinib therapy

9174W **Imatinib**, Tablet 100 mg (as mesylate) (*Glivec*)
9175X **Imatinib**, Tablet 400 mg (as mesylate) (*Glivec*)

Authority required

Initial PBS-subsidised treatment of a patient with hypereosinophilic syndrome or chronic eosinophilic leukaemia requiring treatment and confirmed to carry the FIP1L1-PDGFRA fusion gene.

Maximum dose: 400 mg per day.

Applications for authorisation for initial treatment must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
(c) a copy of the pathology report confirming the presence of the FIP1L1-PDGFRA fusion gene; and
(d) a copy of the full blood examination report confirming the presence of hypereosinophilic syndrome or chronic eosinophilic leukaemia; and
(e) details of organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate; and
(f) a signed patient acknowledgement

Authority required

Continuing PBS-subsidised treatment of a patient with hypereosinophilic syndrome or chronic eosinophilic leukaemia who has previously been issued with an authority prescription for imatinib and who has achieved and maintained a complete haematological response.

Maximum dose: 400 mg per day.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
(c) a copy of the full blood examination report which demonstrates a complete haematological response, with a normal eosinophil count; and
(d) a statement that the disease has not progressed on imatinib therapy

9176Y **Imatinib**, Tablet 100 mg (as mesylate) (*Glivec*)
9177B **Imatinib**, Tablet 400 mg (as mesylate) (*Glivec*)

Authority required

Initial PBS-subsidised treatment of a patient with a myelodysplastic or myeloproliferative disorder where:

(1) there is confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement either by standard karyotyping, or FISH or PDGFRB fusion gene transcript; and
(2) the patient has previously failed an adequate trial of one or more of the following conventional therapies:
— cytarabine;
— etoposide;
— hydroxyurea.

Maximum dose: 400 mg per day.

Applications for authorisation for initial treatment must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
(c) a copy of the pathology report confirming the platelet-derived growth factor receptor (PDGFR) gene re-arrangement; and
(d) a copy of the bone marrow biopsy report which demonstrates the presence of a myelodysplastic or myeloproliferative disorder; and
(e) details of the prior therapy trialled and the response; and
(f) a signed patient acknowledgement

Authority required

Continuing PBS-subsidised treatment of a patient with a PDGFRB fusion gene-positive myelodysplastic or myeloproliferative disorder who has previously been issued with an authority prescription for imatinib and who has demonstrated a clinically significant response.

Maximum dose: 400 mg per day.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
(c) a statement that the disease has not progressed on imatinib therapy

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 REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for adult patients with severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 August 2008, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment

cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2008 is considered to be in their first cycle as of 1 August 2008.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2008.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, 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, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy 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, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, evidence of intestinal inflammation,), or the prior corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives 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, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application 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.

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

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 9 November 2007 or infliximab prior to 7 March 2007 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

9613Y **Infliximab**, Powder for I.V. infusion 100 mg (*Remicade*)

Public and private hospital authority required

Initial 1 (new patients)
Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:
(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and
(b) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(c) has failed to achieve an adequate response to prior systemic therapy including:
(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and
(ii) immunosuppressive therapy including:
— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

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 necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) have a severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as assessed.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

The most recent CDAI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition; and
(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab 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). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

Public and private hospital authority required

Initial 2
Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:
(a) has a documented history of severe refractory Crohn disease; and
(b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and
(c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; and
(ii) details of prior TNF alfa antagonist treatment including details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of infliximb consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab 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). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

Public and private hospital authority required

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:
(a) has a documented history of severe refractory Crohn disease; and
(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition.

The CDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, a CDAI assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number 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 will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of 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)

Public and private hospital authority required

Initial 1
Initial PBS-subsidised treatment with infliximab by a gastroenterologist, or consultant physician as specified in the NOTE below of a patient who satisfies the following criteria:

(a) has confirmed Crohn disease defined by standard clinical, endoscopic and/or imaging features, including histological evidence with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and
(b) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy; and
(c) has evidence of intestinal inflammation; and
(d) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(e) has failed to achieve an adequate response to prior systemic drug therapy including:
(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and
(ii) immunosuppressive therapy including:
— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

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 necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted 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 application:
(a) have evidence of intestinal inflammation, including:
(i) blood: higher than normal platelet count, or, 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/OR
(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR
(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;
AND/OR
(b) be assessed clinically as being in a high faecal output state;
AND/OR
(c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of infliximab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(ii) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iii) date of the most recent clinical assessment; and
(iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab 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). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

Public and private hospital authority required

Initial 2
Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:
(a) has a documented history of severe refractory Crohn disease; and
(b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and
(c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.
If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criteria, if relevant; and

(ii). details of prior TNF alfa antagonist treatment including details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will 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 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). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

Public and private hospital authority required

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:
(a) has a documented history of severe refractory Crohn disease with intestinal inflammation and with short gut syndrome or with an ileostomy or colostomy; and
(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:
(a) improvement of intestinal inflammation as demonstrated by:
(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR
(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR
(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or
(b) reversal of high faecal output state; or
(c) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy or the date of clinical assessment.

The patient's assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to

the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number 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 will be authorised. No applications for increased repeats will 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)

Public and private hospital authority required

Initial 1
Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:
(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and
(b) has extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; and
(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(d) has failed to achieve an adequate response to prior systemic therapy including:
(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and
(ii) immunosuppressive therapy including:
— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

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 necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted 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 application:
(a) have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220;
AND/OR
(b) have evidence of active intestinal inflammation, including:
(i) blood: higher than normal platelet count, or, 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/OR
(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;
AND/OR
(c) be assessed clinically as being in a high faecal output state;
AND/OR
(d) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of adalimumab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(ii) (1) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; or
(2) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the dates of assessment of the patient's condition, if relevant; and
(iii) date of the most recent clinical assessment; and
(iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks -, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab 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). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

Public and private hospital authority required

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, or consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:
(a) has a documented history of severe refractory Crohn disease with extensive intestinal inflammation affecting more than 50 cm of the small intestine; and
(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to adalimumab treatment is defined as:
(a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or
(b) improvement of intestinal inflammation as demonstrated by:
(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR
(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR
(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or
(c) reversal of high faecal output state; or
(d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; or
(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy; or
(iii) the date of clinical assessment.

All assessments must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient's response must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number 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 will be authorised. No applications for increased repeats will 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)

Public and private hospital authority required

Initial 3 (grandfather)
Initial PBS-subsidised supply with infliximab for continuing treatment by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who:
(a) has a documented history of severe refractory Crohn disease and was receiving treatment with infliximab prior to 7 March 2007; and

(b) had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with infliximab. Where a baseline CDAI assessment is not available, please call Medicare Australia on 1800 700 270 to discuss; and
(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(d) has demonstrated or sustained an adequate response to treatment with infliximab. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; and
(ii) the signed patient acknowledgement.

The current CDAI assessment must be no more than 1 month old at the time of application. The baseline CDAI assessment must be from immediately prior to commencing treatment with infliximab.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number 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 will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of 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 may qualify for PBS-subsidised treatment under this restriction once only

Public and private hospital authority required

Initial 3
Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist, of a patient who:
(a) has a documented history of severe refractory Crohn disease and was receiving treatment with infliximab prior to 7 March 2007; and
(b) (1) has a history of extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; or
(2) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy with a documented history of intestinal inflammation; and

(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(d) has demonstrated or sustained an adequate response to treatment with infliximab according to the criteria included in the relevant continuation restriction. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

The same criteria used to determine an inadequate response to prior treatment at baseline must be used to determine response to treatment and eligibility for continuing therapy, according to the criteria included in the continuing treatment restriction.

An adequate response to infliximab treatment is defined as:
(a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater then 150; or
(b) improvement of intestinal inflammation as demonstrated by:
(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR
(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR
(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or
(c) reversal of high faecal output state; or
(d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) (1) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet, where relevant, including the date of the assessment of the patient's condition; or
(2) the reports and dates of the current and baseline pathology or diagnostic imaging test(s) in order to assess response to therapy; or
(3) the date of clinical assessment(s); and
(ii) the signed patient acknowledgement.

The patient's assessment must be no more than 1 month old at the time of application. The baseline CDAI assessments must be from immediately prior to commencing treatment with infliximab. Where a baseline assessment is not available, please call Medicare Australia on 1800 700 270 to discuss.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number 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 will be authorised. No applications for increased repeats will 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 may qualify for PBS-subsidised treatment under this restriction once only

9169N **Levetiracetam**, Oral solution 100 mg per mL, 300 mL (*Keppra*)

Authority required

Treatment of partial epileptic seizures, which are not controlled satisfactorily by other anti-epileptic drugs in a patient unable to take a solid dose form of levetiracetam

8888T **Meloxicam**, Capsule 15 mg (*Mobic*)
8887R **Meloxicam**, Capsule 7.5 mg (*Mobic*)
8562P **Meloxicam**, Tablet 15 mg (*Chem mart Meloxicam 15 mg, GenRx Meloxicam, Meloxibell, Meloxicam-GA, Meloxicam Ranbaxy, Meloxicam Sandoz, Meloxicam Winthrop, Movalis 15, Moxicam 15, Pharmacor Meloxicam 15, Terry White Chemists Meloxicam 15 mg, Mobic*)
8561N **Meloxicam**, Tablet 7.5 mg (*Chem mart Meloxicam 7.5 mg, GenRx Meloxicam, Meloxibell, Meloxicam-GA, Meloxicam Ranbaxy, Meloxicam Sandoz, Meloxicam Winthrop, Movalis 7.5, Moxicam 7.5, Pharmacor Meloxicam 7.5, Terry White Chemists Meloxicam 7.5 mg, Mobic*)

NOTE:

The use of meloxicam for the treatment of the following conditions is not subsidised through the PBS:

(a) acute pain;

(b) soft tissue injury;

(c) arthrosis without an inflammatory component.

Restricted benefit

Symptomatic treatment of osteoarthritis

Restricted benefit

Symptomatic treatment of rheumatoid arthritis

9171Q **Nilotinib**, Capsule 200 mg (as hydrochloride monohydrate) (*Tasigna*)

NOTE:

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

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Any queries concerning patients who are enrolled on the Nilotinib Compassionate Program may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Applications for authority to prescribe nilotinib should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Authority required

Initial treatment, as the sole PBS-subsidised therapy, of a patient with chronic myeloid leukaemia in chronic or accelerated phase bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL, who has active leukaemia (as defined by presence on current pathology assessments of either the Philadelphia chromosome on cytogenetic or FISH analysis, or the presence of the transcript BCR-ABL and morphological evidence of leukaemia in sites other than peripheral blood) and who has failed an adequate trial of imatinib.

Failure of an adequate trial of imatinib is defined as:

(i) Lack of response to initial imatinib therapy, defined as either:

— failure to achieve a haematological response after a minimum of 3 months therapy with imatinib for patients initially treated in chronic phase; or

— failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or

— failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib; OR

(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib therapy (Note: a BCR/ABL qPCR greater than 1% alone is not evidence of loss of response); OR

(iii) Development of accelerated phase in a patient previously prescribed imatinib for the chronic phase of chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or

(3) Peripheral basophils greater than or equal to 20%; or

(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR

(iv) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib therapy in patients with accelerated phase chronic myeloid leukaemia, provided that blast crisis has been excluded on bone marrow biopsy; OR

(v) Detection of a mutation in BCR-ABL (L248V, G250E, Q252H/R, Y253H/F, E255K/V, H396P/R, and D276G) that infers high level imatinib resistance. (Patients with these mutations but without active leukaemia, will not be approved); OR

(vi) Grade 3 or 4 non-haematological toxicity that is imatinib related.

Applications for authorisation must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Chronic Myeloid Leukaemia Nilotinib PBS Authority Application - Supporting Information Form; and

(c) a signed patient acknowledgement; and

(d) a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of chronic myeloid leukaemia in bone marrow plus qualitative RT-PCR evidence of BCR-ABL transcript. (The date of the relevant pathology report needs to be provided); and

(e) Details of Grade 3 or 4 non-haematological imatinib related toxicity

NOTE:

Nilotinib will only be subsidised for patients with chronic myeloid leukaemia who are not receiving concomitant PBS-subsidised imatinib mesylate, dasatinib or interferon alfa therapy.

Patients should be commenced on a dose of nilotinib of 400 mg twice daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to nilotinib therapy or a peripheral blood BCR-ABL level of less than 1% at 12 monthly intervals, irrespective of the daily nilotinib dose received.

Nilotinib is not PBS-subsidised for patients with CML that is resistant to dasatinib.Nilotinib is not TGA-registered and not PBS-subsidised for patients with CML in blast crisis.Requests for doses of greater than nilotinib 400 mg twice daily will not be approved.

Authority required

Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial treatment with nilotinib as a pharmaceutical benefit for chronic myeloid leukaemia, and who has demonstrated either a major cytogenetic response, or less than 1% BCR-ABL level in the blood, to nilotinib in the preceding 12 months.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Chronic Myeloid Leukaemia Nilotinib Authority Application Form for continuing treatment; and

(3) demonstration of continued response to treatment as evidenced by either:

(a) major cytogenetic response [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided; or

(b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided

NOTE:

Definitions of response.A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.

A bone marrow or peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

Authority approval requirements.

For the purposes of assessing response to PBS-subsidised treatment with nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted as follows:

(i) between 10 and 12 months of the commencement of treatment with nilotinib, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and

(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

For each authority application where eligibility for continuing PBS-subsidised treatment is to be demonstrated, a copy of the cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or a copy of the quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted as described in (i) and (ii) above. For bone marrow analyses, where the standard karyotyping conducted at the time of application is not informative, a copy of a cytogenetic analysis conducted on the bone marrow using FISH with BCR-ABL specific probe must be submitted with the authority application. A copy of the non-informative standard karyotype analysis must be included with

the authority application.Where a patient has previously received PBS-subsidised treatment with nilotinib, no approval will be granted for PBS-subsidised re-treatment where that patient has at any time failed to meet the criteria for continuing treatment.

5532E **Polyethylene glycol 400 with propylene glycol**, Eye drops 4 mg-3 mg per mL (0.4%-0.3%), single dose units 0.7 mL, 28 (*Systane*)

Authority required

Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

9170P **Polyethylene glycol 400 with propylene glycol**, Eye drops 4 mg-3 mg per mL (0.4%-0.3%), single dose units 0.7 mL, 28 (*Systane*)

Authority required (STREAMLINED)

1359

Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

9182G **Sitagliptin**, Tablet 100 mg (as phosphate monohydrate) (*Januvia*)
9180E **Sitagliptin**, Tablet 25 mg (as phosphate monohydrate) (*Januvia*)
9181F **Sitagliptin**, Tablet 50 mg (as phosphate monohydrate) (*Januvia*)

NOTE:

Sitagliptin is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a thiazolidinedione (glitazone)

Authority required

Dual oral combination therapy with metformin or a sulfonylurea

Type 2 diabetes, in combination with metformin or a sulfonylurea, in a patient whose HbA1c is greater than 7% prior to initiation of sitagliptin despite treatment with either metformin or a sulfonylurea and where a combination of metformin and a sulfonylurea is contraindicated or not tolerated.

The date and level of the qualifying HbA1c must be documented in the patient's medical records. The date of the HbA1c measurement, which must be no more than 4 months old at the time treatment is initiated, must be provided when the first authority application is made.

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

(a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) red cell transfusion within the previous 3 months.

A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring must be documented in the patient's medical records. The date of measurement of the most recent blood glucose level, which must be no more than 4 months old at the time treatment is initiated, must be provided when the first authority application is made

9630W **Telbivudine**, Tablet 600 mg (*Sebivo*)

Private hospital authority required

Treatment, as sole PBS-subsidised therapy, in a patient with HBeAg-positive chronic hepatitis B who is nucleoside analogue naive and satisfies 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

NOTES

The text of notes mentioned above:

6477X **Epoprostenol sodium**, Powder for I.V. infusion 500 micrograms (base) with vial diluent 50 mL *(Flolan)*

6478Y **Epoprostenol sodium**, Powder for I.V. infusion 1.5 mg (base) with 2 vials diluent 50 mL *(Flolan)*

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. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

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. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

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. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

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. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

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, or with bosentan monohydrate (for PAH associated with congenital systemic-to-pulmonary shunt) on or after 1 August 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.

NOTE:

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.

NOTE:

(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**, Solution for inhalation 20 micrograms (base) in 2 mL *(Ventavis)*

NOTE:

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

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

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. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

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. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

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. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

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. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

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, or with bosentan monohydrate (for PAH associated with congenital systemic-to-pulmonary shunt) on or after 1 August 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

9111M **Imatinib**, Tablet 100 mg (as mesylate) *(Glivec)*

9112N **Imatinib**, Tablet 400 mg (as mesylate) *(Glivec)*

No applications for increased repeats will be authorised.

9605M **Sildenafil citrate**, Tablet 20 mg (base) *(Revatio)*

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 9826

GPO 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. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

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. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

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. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

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. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

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, or with bosentan monohydrate (for PAH associated with congenital systemic-to-pulmonary shunt) on or after 1 August 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 sildenafil citrate, bosentan monohydrate, iloprost trometamol, epoprostenol sodium, 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 sildenafil citrate. The requirements specific to bosentan monohydrate, iloprost trometamol, epoprostenol sodium and sitaxentan sodium are given in parts 6 and 7 of the NOTE included in the bosentan monohydrate, iloprost trometamol, epoprostenol sodium and sitaxentan sodium Schedule entry respectively.]

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

(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 sildenafil citrate.

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 sildenafil citrate 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 sildenafil citrate treatment at the times where an assessment is required must cease PBS-subsidised sildenafil citrate therapy.

7. Re-treatment with sildenafil citrate.

Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with sildenafil citrate 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.

9622K **Sitaxentan sodium**, Tablet 100 mg *(Thelin)*

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. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

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. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

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. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

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. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

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, or with bosentan monohydrate (for PAH associated with congenital systemic-to-pulmonary shunt) on or after 1 August 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 August 2008 and all previous issues are cancelled.

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