Australian Government

Department of Health and Ageing

SCHEDULE OF PHARMACEUTICAL BENEFITS FOR APPROVED PHARMACISTS AND MEDICAL PRACTITIONERS

SUMMARY OF CHANGES

EFFECTIVE 1 MARCH 2007 — 31 MARCH 2007

PHARMACEUTICAL BENEFITS

This Schedule will take effect on 1 March 2007 and all previous issues are cancelled.
New Schedules will take effect monthly on the first day of each month.

Internet

The Schedule of Pharmaceutical Benefits is also available on the Internet. The address of the Schedule is www.pbs.gov.au

Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 March 2007 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	$5.15
	Dangerous drug fee	$2.71
	Extemporaneously-prepared	$7.19
Additional Fees (for safety net prices):	Ready-prepared	$0.99
	Extemporaneously-prepared	$1.38
Patient Co-payments:	General	$30.70
	Concessional	$4.90
Safety Net Thresholds:	General	$1059.00
	Concessional	$274.40
Safety Net Card Issue Fee:		$7.72

SUMMARY OF CHANGES

ADDITIONS

Additions — Items

9077R **Adalimumab,** injection 40 mg in 0.8 mL pre-filled syringe *(Humira)* [for the treatment of adult patients with active ankylosing spondylitis]

9078T **Adalimumab,** injection 40 mg in 0.8 mL pre-filled syringe *(Humira)* [for the treatment of adult patients with active ankylosing spondylitis] **(Diff. Max. Rpts)**

9064C **Goserelin Acetate and Bicalutamide,** pack containing 1 subcutaneous implant goserelin 3.6 mg (base) in pre-filled injection syringe and 28 tablets bicalutamide 50 mg *(ZolaCos CP 3.6/50)*

9065D **Goserelin Acetate and Bicalutamide,** pack containing 1 subcutaneous implant goserelin 10.8 mg (base) in pre-filled injection syringe and 28 tablets bicalutamide 50 mg *(ZolaCos CP 10.8/50 (28))*

9066E **Goserelin Acetate and Bicalutamide,** pack containing 1 subcutaneous implant goserelin 10.8 mg (base) in pre-filled injection syringe and 84 tablets bicalutamide 50 mg *(ZolaCos CP 10.8/50 (84))*

9075P **Risperidone,** tablet 3 mg (orally disintegrating) *(Risperdal Quicklet)*

9076Q **Risperidone,** tablet 4 mg (orally disintegrating) *(Risperdal Quicklet)*

Additions — Brands

1891M *Moxiclav Duo 500/125, AW* — **Amoxycillin with Clavulanic Acid,** tablet 500 mg-125 mg
5008N *Moxiclav Duo 500/125, AW* — **Amoxycillin with Clavulanic Acid,** tablet 500 mg-125 mg **(Dental)**
8254K *Moxiclav Duo Forte 875/125, AW* — **Amoxycillin with Clavulanic Acid,** tablet 875 mg-125 mg
5006L *Moxiclav Duo Forte 875/125, AW* — **Amoxycillin with Clavulanic Acid,** tablet 875 mg-125 mg **(Dental)**
1209P *Ciprofloxacin-BW, BF* — **Ciprofloxacin,** tablet 500 mg
1210Q *Ciprofloxacin-BW, BF* — **Ciprofloxacin,** tablet 750 mg
8220P *Citalopram Winthrop, SL* — **Citalopram Hydrobromide,** tablet 20 mg (base)
1370D *Enalapril Winthrop, SL* — **Enalapril Maleate,** tablet 5 mg
1368B *Enalapril Winthrop, SL* — **Enalapril Maleate,** tablet 10 mg
1369C *Enalapril Winthrop, SL* — **Enalapril Maleate,** tablet 20 mg
8513C *Mirtazapine Sandoz, SZ* — **Mirtazapine,** tablet 30 mg
2236Q *Sertraline Winthrop, SL* — **Sertraline Hydrochloride,** tablet 50 mg (base)
2237R *Sertraline Winthrop, SL* — **Sertraline Hydrochloride,** tablet 100 mg (base)
2011W *Ransim, RA* — **Simvastatin,** tablet 10 mg
2012X *Ransim, RA* — **Simvastatin,** tablet 20 mg
8173E *Ransim, RA* — **Simvastatin,** tablet 40 mg
8313M *Ransim, RA* — **Simvastatin,** tablet 80 mg

ALTERATIONS

Restriction Changes (See under 'RESTRICTIONS' below for full details)

8778B **Etanercept,** injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL *(Enbrel)* [for the treatment of adult patients with active ankylosing spondylitis]
8779C **Etanercept,** injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL *(Enbrel)* [for the treatment of adult patients with active ankylosing spondylitis] **(Diff. Max. Qty)**

Alterations — Maximum Quantity

		From	*To*
8778B	**Etanercept,** injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL *(Enbrel)*	3	2
8170B	**Olanzapine,** tablet 2.5 mg *(Zyprexa)*	30	28
8185T	**Olanzapine,** tablet 5 mg *(Zyprexa)*	30	28
8186W	**Olanzapine,** tablet 7.5 mg *(Zyprexa)*	30	28
8187X	**Olanzapine,** tablet 10 mg *(Zyprexa)*	30	28

Alterations — Number of Repeats

		From	*To*
8778B	**Etanercept,** injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL *(Enbrel)*	..	3

SECTION 100 — HIGHLY SPECIALISED DRUGS PROGRAM

ADDITIONS

Additions — Items

9605M **Sildenafil Citrate,** tablet 20 mg (base) *(Revatio)*

DELETIONS

Deletions — Items

6231Y **Nelfinavir Mesylate,** oral powder 50 mg (base) per g, 144 g *(Viracept)*
6248W **Saquinavir,** soft gelatin capsule 200 mg *(Fortovase)*

ALTERATIONS

Restriction Changes (See under 'RESTRICTIONS' below for full details)

6429J **Bosentan Monohydrate,** tablet 62.5 mg (base) *(Tracleer)*
6430K **Bosentan Monohydrate,** tablet 125 mg (base) *(Tracleer)*
6477X **Epoprostenol Sodium,** powder for I.V. infusion 500 micrograms (base) with 1 vial diluent 50 mL *(Flolan)*
6478Y **Epoprostenol Sodium,** powder for I.V. infusion 1.5 mg (base) with 2 vials diluent 50 mL *(Flolan)*
6456T **Iloprost Trometamol,** solution for inhalation 20 micrograms (base) in 2 mL *(Ventavis)*
6448J **Infliximab,** powder for I.V. infusion 100 mg *(Remicade)* [for the treatment of adult patients with active ankylosing spondylitis]

SECTION 100 — HUMAN GROWTH PROGRAM

ADDITIONS

Additions — Items

9604L **Somatropin,** solution for injection 10 mg (30 i.u.) in 2 mL cartridge (with preservative) *(NutropinAq)*

ADVANCE NOTICES

Advance Notices — Deletion of Items

The following items will be deleted from the Schedule of Pharmaceutical Benefits on 1 **April** 2007:

Items discontinued by the manufacturer —

1508J **Hydroxocobalamin,** injection 1 mg in 1 mL *(Neo-Cytamen)*
2545Y **Oxandrolone,** tablet 2.5 mg *(Oxandrin)*

Deletions requested by the manufacturer —

1829G **Pethidine Hydrochloride,** injection 100 mg in 2 mL *(MX)*
5200Q **Pethidine Hydrochloride,** injection 100 mg in 2 mL *(MX)* **(Dental)**

Advance Notices — Deletion of Brands

The following brands will be deleted from the Schedule of Pharmaceutical Benefits on 1 **April** 2007:

Brands discontinued by the manufacturer —

1884E *Moxacin, CS* — **Amoxycillin,** capsule 250 mg
3301R *Moxacin, CS* — **Amoxycillin,** capsule 250 mg **(Dental)**
1886G *Moxacin, CS* — **Amoxycillin,** powder for syrup 125 mg per 5 mL, 100 mL
3302T *Moxacin, CS* — **Amoxycillin,** powder for syrup 125 mg per 5 mL, 100 mL **(Dental)**
1929M *Novantrone, SI* — **Mitozantrone Hydrochloride,** injection 20 mg (base) in 10 mL
1930N *Novantrone, SI* — **Mitozantrone Hydrochloride,** injection 25 mg (base) in 12.5 mL

RESTRICTIONS

Details of restriction text for new items and restriction alterations as noted above:

ADALIMUMAB
9077R injection 40 mg in 0.8 mL pre-filled syringe *(Humira)* [for the treatment of adult patients with active ankylosing spondylitis]

NOTE:
TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

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

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 TNF-alfa antagonists at any 1 time.

From 1 March 2007, 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 March 2007 is considered to be in their first cycle as of 1 March 2007.

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 once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

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 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 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 March 2007.

(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 etanercept and adalimumab and 18 weeks of treatment for infliximab.

From 1 March 2007, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, 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.

(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 to an alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an 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 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 an 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 BASDAI, ESR and/or CRP 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.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program. However, this is not required for any subsequent BASDAI results for these patients, nor for patients who were 'grandfathered' on to TNF-alfa antagonist treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(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 at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

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

A patient who commenced treatment with adalimumab for active ankylosing spondylitis prior to 1 November 2006 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 will be authorised under this criterion.

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

Where pre-TNF-alfa antagonist treatment baselines cannot be provided, the following criteria must be met to demonstrate a response to treatment:
The BASDAI score must be either:
(i) no more than 20% greater than the score included in the initial application for PBS-subsidised treatment; or
(ii) no greater than 2.
AND
One of the following:
(a) an ESR measurement no greater than 25 mm per hour; or
(b) a CRP measurement no greater than 10 mg per L.

'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.

Authority required

Initial 1 (new patients)

First course of PBS-subsidised treatment with adalimumab, by a rheumatologist, of an adult with active ankylosing spondylitis who has radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis and who has not received any PBS-subsidised treatment with either adalimumab, etanercept or infliximab in this treatment cycle;

AND

(a) who has at least 2 of the following:

(i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or

(ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI) [for further information on the BASMI please refer to the Medicare Australia website at www.medicareaustralia.gov.au]; or

(iii) limitation of chest expansion relative to normal values for age and gender [for chest expansion normal values please refer to the Medicare Australia website at www.medicareaustralia.gov.au];

AND

(b) who has failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Medicare Australia website at www.medicareaustralia.gov.au.

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

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale;

AND

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which must include the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form [www.medicareaustralia.gov.au]; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) a signed patient acknowledgment form. Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment with the TNF-alfa antagonists (adalimumab, etanercept or infliximab) for ankylosing spondylitis will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

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

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Authority required
Initial 2 (change or re-commencement for all patients)
Initial course of PBS-subsidised treatment with adalimumab, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who, in this treatment cycle, has received prior PBS-subsidised treatment with either adalimumab, etanercept or infliximab for this condition and has not failed PBS-subsidised therapy with adalimumab.

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 after 1 March 2007, the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction prior to 1 March 2007, the patient must have been assessed for response to that course following at least 4 weeks of treatment. These assessments must be provided to Medicare Australia no later than 4 weeks from the date the 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 Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which includes a completed BASDAI Assessment Form with certification by the prescriber and the patient that the patient did not have access to their baseline BASDAI at the time of their assessment.

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

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

ADALIMUMAB

9078T injection 40 mg in 0.8 mL pre-filled syringe *(Humira)* [for the treatment of adult patients with active ankylosing spondylitis] **(Diff. Max. Rpts)**

Authority required
Initial ('grandfather' patients)
Initial PBS-subsidised course of adalimumab treatment, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who has radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis and who was receiving treatment with adalimumab prior to 1 November 2006;
AND
(a) is receiving treatment with adalimumab at the time of application;
AND
(b) has not received prior PBS-subsidised treatment with infliximab or etanercept;
AND

(c) whose current Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score is either:
(i) less than or equal to 5 on a 0-10 scale;
OR
(ii) improved by at least 2 from baseline;
AND
(d) who has:
(i) an ESR measurement no greater than 25 mm per hour; or
(ii) a CRP measurement no greater than 10 mg per L; or
(iii) an ESR or CRP measurement reduced by at least 20% from pre-treatment baseline.

The BASDAI assessment and ESR and/or CRP measurements provided must be no more than 1 month old at the time of application. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which includes the following:
(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
(ii) a completed BASDAI Assessment Form [www.medicareaustralia.gov.au]; and
(iii) a signed patient acknowledgment form included in the supporting information form. Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment with the TNF-alfa antagonists (adalimumab, etanercept or infliximab) for ankylosing spondylitis will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated.

The assessment of the patient's response to this initial course of therapy must be made within the 4 weeks prior to completion of the course in order to ensure continuity of treatment.

A patient ceasing treatment or swapping to an alternate agent and wishing to demonstrate a response to treatment, must be assessed no earlier than 12 weeks from the commencement of PBS-subsidised treatment. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

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

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

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

<u>Authority required</u>
Continuing treatment for all patients
Continuing PBS-subsidised treatment, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who:
(a) has demonstrated a response to treatment with adalimumab; and
(b) whose most recent course of PBS-subsidised therapy in this treatment cycle was with adalimumab.

Response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:
(a) an ESR measurement no greater than 25 mm per hour; or
(b) a CRP measurement no greater than 10 mg per L; or
(c) an ESR or CRP measurement reduced by at least 20% from baseline.

For a 'grandfather' patient who does not have baselines prior to commencing treatment with a TNF-alfa antagonist, see Note 5 for a definition of response to treatment.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The first application for continuing treatment following an initial treatment course must be made following a minimum of 12 weeks of treatment with adalimumab.

Applications for continuing treatment must be made in writing and should be posted to Medicare Australia no less than 2 weeks prior to the completion of the current treatment course.

Written applications for authorisation must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which includes a completed BASDAI Assessment Form with certification by the prescriber and the patient that the patient did not have access to their baseline BASDAI at the time of their continuing treatment assessment.

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

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

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

GOSERELIN ACETATE AND BICALUTAMIDE

9064C pack containing 1 subcutaneous implant goserelin 3.6 mg (base) in pre-filled injection syringe and 28 tablets bicalutamide 50 mg *(ZolaCos CP 3.6/50)*

9065D pack containing 1 subcutaneous implant goserelin 10.8 mg (base) in pre-filled injection syringe and 28 tablets bicalutamide 50 mg *(ZolaCos CP 10.8/50 (28))*

9066E pack containing 1 subcutaneous implant goserelin 10.8 mg (base) in pre-filled injection syringe and 84 tablets bicalutamide 50 mg *(ZolaCos CP 10.8/50 (84))*

Authority required
Metastatic (equivalent to stage D) prostatic carcinoma in patients for whom a combination of an antiandrogen and a GnRH (LH-RH) agonist is required.
NOTE:
No applications for increased maximum quantities and/or repeats will be authorised.

RISPERIDONE

9075P tablet 3 mg (orally disintegrating) *(Risperdal Quicklet)*

9076Q tablet 4 mg (orally disintegrating) *(Risperdal Quicklet)*

Authority required
Schizophrenia.

Authority required
Adjunctive therapy to mood stabilisers for up to 6 months, of an episode of acute mania associated with bipolar I disorder.

ETANERCEPT

8778B injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL *(Enbrel)* [for the treatment of adult patients with active ankylosing spondylitis]

Authority required

Initial 1 (new patients)

First course of PBS-subsidised treatment with etanercept, by a rheumatologist, of an adult with active ankylosing spondylitis who has radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis and who has not received any PBS-subsidised treatment with either adalimumab, etanercept or infliximab in this treatment cycle;

AND

(a) who has at least 2 of the following:

(i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or

(ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI) [for further information on the BASMI please refer to the Medicare Australia website at www.medicareaustralia.gov.au]; or

(iii) limitation of chest expansion relative to normal values for age and gender [for chest expansion normal values please refer to the Medicare Australia website at www.medicareaustralia.gov.au];

AND

(b) who has failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Medicare Australia website at www.medicareaustralia.gov.au.

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

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale;

AND

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which must include the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form [www.medicareaustralia.gov.au]; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) a signed patient acknowledgment form. Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment with the TNF-alfa antagonists (adalimumab, etanercept or infliximab) for ankylosing spondylitis will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

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

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Authority required
Initial 2 (change or re-commencement for all patients)
Initial course of PBS-subsidised treatment with etanercept, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who, in this treatment cycle, has received prior PBS-subsidised treatment with either adalimumab, etanercept or infliximab for this condition and has not failed PBS-subsidised therapy with etanercept.

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
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 Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which includes a completed BASDAI Assessment Form with certification by the prescriber and the patient that the patient did not have access to their baseline BASDAI at the time of their assessment.

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

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

ETANERCEPT

8779C injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL *(Enbrel)* [for the treatment of adult patients with active ankylosing spondylitis] **(Diff. Max. Qty)**

Authority required
Continuing treatment for all patients
Continuing PBS-subsidised treatment, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who:
(a) has demonstrated a response to treatment with etanercept; and
(b) whose most recent course of PBS-subsidised therapy in this treatment cycle was with etanercept.

Response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:
(a) an ESR measurement no greater than 25 mm per hour; or
(b) a CRP measurement no greater than 10 mg per L; or
(c) an ESR or CRP measurement reduced by at least 20% from baseline.

For a 'grandfather' patient who does not have baselines prior to commencing treatment with a TNF-alfa antagonist, see Note 5 for a definition of response to treatment.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction after 1 March 2007, the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction prior to 1 March 2007, the patient must have been assessed for response to that course following at least 4 weeks of treatment.

Applications for continuing treatment must be made in writing and should be posted to Medicare Australia no less than 2 weeks prior to the completion of the current treatment course.

Written applications for authorisation must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which includes a completed BASDAI Assessment Form with certification by the prescriber and the patient that the patient did not have access to their baseline BASDAI at the time of their continuing treatment assessment.

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

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

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

SILDENAFIL CITRATE

9605M 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, or PBS-subsidised epoprostenol 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 adult 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.

Adult patients:
From 1 March 2007, adult patients with primary pulmonary hypertension will be able to access, through the PBS, bosentan monohydrate, iloprost trometamol, epoprostenol sodium or sildenafil citrate (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, epoprostenol sodium and sildenafil citrate at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary (unless the prescriber wishes to submit new baselines).

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

Patients may only swap to bosentan monohydrate, iloprost trometamol or sildenafil citrate 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 or sildenafil citrate (WHO Class III only). Once these patients are approved initial treatment with 1 of these 2 drugs, they may swap between iloprost trometamol and sildenafil citrate at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary (unless the prescriber wishes to submit new baselines).

Patients may only swap to iloprost trometamol or sildenafil citrate 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 or sildenafil citrate.

Patients under 18 years of age:
From 1 March 2007, patients aged less than 18 years with primary pulmonary hypertension are eligible to receive PBS-subsidised treatment with bosentan monohydrate, epoprostenol sodium or sildenafil citrate (WHO Class III only). Once these patients are approved initial treatment with 1 of these 3 drugs, they may swap between bosentan monohydrate, epoprostenol sodium and sildenafil citrate at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary (unless the prescriber wishes to submit new baselines). They may qualify for treatment with iloprost trometamol when they are aged 18 years or older.

Patients may only swap to bosentan monohydrate, epoprostenol sodium or sildenafil citrate 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 or sildenafil citrate 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.

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 or with sildenafil citrate on or after 1 March 2007, 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 or sildenafil citrate prior to being commenced on PBS-subsidised treatment with the first of either bosentan monohydrate, iloprost trometamol, epoprostenol sodium or sildenafil citrate, 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 or sildenafil citrate, whichever of the 4 drugs the patient received first.

NOTE:
(ii) Patients who received non-PBS-subsidised treatment with sildenafil citrate prior to 1 March 2007.
For patients with primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease who were commenced on sildenafil citrate treatment prior to 1 March 2007 and who have received less than 6 months of treatment with sildenafil citrate 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 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 sildenafil citrate treatment prior to 1 March 2007 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 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 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 sildenafil citrate. The requirements specific to bosentan monohydrate, iloprost trometamol and epoprostenol sodium are given in parts 6 and 7 of the NOTE included in the bosentan monohydrate, iloprost trometamol and epoprostenol 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 or epoprostenol 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.
Patients who commence PBS-subsidised sildenafil citrate treatment after 1 March 2007 and patients who received 6 or more months of sildenafil citrate treatment prior to 1 March 2007 are eligible to receive up to 6 months of treatment per authority application.

Patients who commenced treatment with sildenafil citrate prior to 1 March 2007 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 sildenafil citrate prior to 1 March 2007 will be eligible to commence PBS-subsidised treatment with sildenafil citrate. Thereafter, to be eligible for further PBS-subsidised supply, these patients must demonstrate a response to sildenafil citrate 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 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 and sildenafil citrate.
For eligible patients, applications to swap between these 4 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.

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

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

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

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

(3) a signed patient acknowledgment form indicating that the patient understands and acknowledges that PBS-subsidised treatment with sildenafil citrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with epoprostenol sodium for primary pulmonary hypertension, OR with iloprost trometamol for primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with bosentan monohydrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, 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 is commenced on sildenafil citrate treatment due to an adverse event or a contraindication to vasodilator treatment, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

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

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

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

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

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

(3) a signed patient acknowledgment form indicating that the patient understands and acknowledges that PBS-subsidised treatment with sildenafil citrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with epoprostenol sodium for primary pulmonary hypertension, OR with iloprost trometamol for primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with bosentan monohydrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].

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

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

<u>Public and private hospital authority required</u>
Initial (grandfather patients)
Application for initial PBS-subsidised treatment with sildenafil citrate of patients who were receiving treatment with sildenafil citrate prior to 1 March 2007, who have not received prior PBS-subsidised treatment with bosentan monohydrate, iloprost trometamol or epoprostenol sodium and who have been assessed by a physician from a designated hospital to have:
(a) WHO Functional Class III primary pulmonary hypertension;
OR
(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease.

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) for patients who have received less than 6 months of sildenafil citrate treatment at the time of application — a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results of the following 3 tests, where available, at the time treatment with sildenafil citrate was commenced:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; or
(b) for patients who have received 6 or more months of sildenafil citrate treatment at the time of application — a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results of the following 3 tests, both at the time treatment with sildenafil citrate was commenced and at the time of application, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) the date of commencement of sildenafil citrate treatment; and

(4) a signed patient acknowledgment form indicating that the patient understands and acknowledges that PBS-subsidised treatment with sildenafil citrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR epoprostenol sodium for primary pulmonary hypertension, OR with iloprost trometamol for primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with bosentan monohydrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, 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. The number of repeats authorised will be dependent on the duration of prior sildenafil citrate therapy. Where patients have received less than 6 months of non-PBS-subsidised treatment with sildenafil citrate, 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 sildenafil citrate, 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).

<u>Public and private hospital authority required</u>
Initial (change or re-commencement for all patients)
Application for initial PBS-subsidised treatment with sildenafil citrate of patients with either of the following:
(a) WHO Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease who wish to re-commence PBS-subsidised sildenafil citrate after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with sildenafil citrate;
OR
(b) WHO Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with iloprost trometamol;
OR
(c) WHO Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma and whose most recent course of PBS-subsidised treatment was with bosentan monohydrate;
OR
(d) WHO Class III 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) a completed authority prescription form [see Note for authority approval requirements]; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised sildenafil citrate, epoprostenol sodium, iloprost trometamol or bosentan monohydrate, whichever was initiated first, was granted; and
(3) the date of the first application for PBS-subsidised treatment with sildenafil citrate, epoprostenol sodium, iloprost trometamol or bosentan monohydrate, whichever was initiated first; and
(4) the results of the patient's response to treatment with their last course of PBS-subsidised sildenafil citrate, epoprostenol sodium, iloprost trometamol or bosentan monohydrate.

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

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

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

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

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

BOSENTAN MONOHYDRATE

6429J tablet 62.5 mg (base) *(Tracleer)*
6430K tablet 125 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 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 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 form indicating that the patient understands and acknowledges that PBS-subsidised treatment with bosentan monohydrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, 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, 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 is commenced on bosentan monohydrate treatment due to an adverse event or a contraindication to vasodilator treatment, 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).

<u>Public and private hospital authority required</u>
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 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 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 form indicating that the patient understands and acknowledges that PBS-subsidised treatment with bosentan monohydrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, 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, 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).

<u>Public and private hospital authority required</u>
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 form, 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 is commenced on bosentan monohydrate treatment due to an adverse event or a contraindication to vasodilator treatment, 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 form, 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 (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 or sildenafil citrate;
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 or sildenafil citrate, 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 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, iloprost trometamol, 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
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 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.

EPOPROSTENOL SODIUM

6477X powder for I.V. infusion 500 micrograms (base) with 1 vial diluent 50 mL *(Flolan)*
6478Y powder for I.V. infusion 1.5 mg (base) with 2 vials diluent 50 mL *(Flolan)*

Public and private hospital authority required
Initial (new adult patients)
Application for initial PBS-subsidised treatment with epoprostenol sodium of adult patients who have not received prior PBS-subsidised treatment with bosentan monohydrate, iloprost trometamol 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 a mean right atrial pressure of 8 mmHg or less, as measured by RHC, unless a RHC is contraindicated on clinical grounds.

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

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

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form [see Note for authority approval requirements]; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) a signed patient acknowledgment form indicating that the patient understands and acknowledges that PBS-subsidised treatment with epoprostenol sodium for primary pulmonary hypertension, OR with iloprost trometamol for primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with bosentan monohydrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, OR with sildenafil citrate 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 is commenced on epoprostenol sodium treatment due to an adverse event or a contraindication to vasodilator treatment, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

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

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

<u>Public and private hospital authority required</u>
Initial (new adult patients)
Application for initial PBS-subsidised treatment with epoprostenol sodium of adult patients who have not received prior PBS-subsidised treatment with bosentan monohydrate, iloprost trometamol 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 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 IV primary pulmonary hypertension.

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

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

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

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

Public and private hospital authority required
Initial (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 bosentan monohydrate or sildenafil citrate and who have been assessed by a physician from a designated hospital to have WHO Functional Class III primary pulmonary hypertension with 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) 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 patient acknowledgment form, signed by the parent or authorised guardian, indicating that they understand and acknowledge that PBS-subsidised treatment with epoprostenol sodium, bosentan monohydrate 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 is commenced on epoprostenol sodium treatment due to an adverse event or a contraindication to vasodilator treatment, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

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

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats will be authorised under this criterion. Where fewer than 5 repeats are initially requested, 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 bosentan monohydrate 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) 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 patient acknowledgment form, signed by the parent or authorised guardian, indicating that they understand and acknowledge that PBS-subsidised treatment with epoprostenol sodium, bosentan monohydrate 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. A maximum of 5 repeats will be authorised under this criterion. Where fewer than 5 repeats are initially requested, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required
Initial (change or re-commencement for all adult patients)
Application for initial PBS-subsidised treatment with epoprostenol sodium of adult patients with either of the following:
(a) primary pulmonary hypertension who wish to re-commence PBS-subsidised epoprostenol sodium after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with epoprostenol sodium;
OR
(b) primary pulmonary hypertension and whose most recent course of PBS-subsidised treatment was with bosentan monohydrate, iloprost trometamol or sildenafil citrate.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form [see Note for authority approval requirements]; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised epoprostenol sodium, iloprost trometamol, bosentan monohydrate or sildenafil citrate, whichever was initiated first, was granted; and
(3) the date of the first application for PBS-subsidised treatment with epoprostenol sodium, iloprost trometamol, bosentan monohydrate, 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 epoprostenol sodium, iloprost trometamol, bosentan monohydrate 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. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required
Initial (change or re-commencement for all patients under 18 years of age)
Application for initial PBS-subsidised treatment with epoprostenol sodium of patients aged less than 18 years with either of the following:
(a) primary pulmonary hypertension who wish to re-commence PBS-subsidised epoprostenol sodium after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with epoprostenol sodium;
OR
(b) primary pulmonary hypertension and whose most recent course of PBS-subsidised treatment was with bosentan monohydrate or sildenafil citrate.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form [see Note for authority approval requirements]; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised epoprostenol sodium, bosentan monohydrate or sildenafil citrate, whichever was initiated first, was granted; and
(3) the date of the first application for PBS-subsidised treatment with epoprostenol sodium, bosentan monohydrate 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 epoprostenol sodium, bosentan monohydrate 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. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

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

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

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

ILOPROST TROMETAMOL
6456T solution for inhalation 20 micrograms (base) in 2 mL *(Ventavis)*

Public and private hospital authority required
Initial (new patients)
Application for initial PBS-subsidised treatment with iloprost trometamol of adult patients who have not received prior PBS-subsidised treatment with bosentan monohydrate, 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 a mean right atrial pressure of 8 mmHg or less, as measured by RHC, unless a RHC is contraindicated on clinical grounds;
OR
(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, unless a RHC is contraindicated on clinical grounds;
OR
(c) WHO Functional Class III drug-induced pulmonary arterial hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, unless a RHC is contraindicated on clinical grounds.

Patients must have failed to respond [see Note for definition of response] to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists.
In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the test results of the ECHO composite assessment plus 6MWT or the ECHO composite assessment only.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form [see Note for authority approval requirements]; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) a signed patient acknowledgment form indicating that the patient understands and acknowledges that PBS-subsidised treatment with iloprost trometamol for primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with bosentan monohydrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, OR with epoprostenol sodium for primary pulmonary hypertension, OR with sildenafil citrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, 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 is commenced on iloprost trometamol treatment due to an adverse event or a contraindication to vasodilator treatment, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

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

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

<u>Public and private hospital authority required</u>
Initial (new patients)
Application for initial PBS-subsidised treatment with iloprost trometamol of adult patients who have not received prior PBS-subsidised treatment with bosentan monohydrate, 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 a mean right atrial pressure greater than 8 mmHg, as measured by RHC, unless a RHC is contraindicated on clinical grounds;
OR
(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, unless a RHC is contraindicated on clinical grounds;
OR
(c) WHO Functional Class III drug-induced pulmonary arterial hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, unless a RHC is contraindicated on clinical grounds;
OR
(d) WHO Functional Class IV primary pulmonary hypertension;
OR
(e) WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease;
OR
(f) WHO Functional Class IV drug-induced pulmonary arterial hypertension.

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

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

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

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

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

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form [see Note for authority approval requirements]; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised iloprost trometamol, bosentan monohydrate, epoprostenol sodium or sildenafil citrate, whichever was initiated first, was granted; and
(3) the date of the first application for PBS-subsidised treatment with iloprost trometamol, bosentan monohydrate, epoprostenol sodium 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 iloprost trometamol, 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. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

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

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

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

INFLIXIMAB

6448J powder for I.V. infusion 100 mg *(Remicade)* [for the treatment of adult patients with active ankylosing spondylitis]

Public and private hospital authority required
Initial 1 (new patients)
First course of PBS-subsidised treatment with infliximab, by a rheumatologist, of an adult with active ankylosing spondylitis who has radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis and who has not received any PBS-subsidised treatment with either adalimumab, etanercept or infliximab in this treatment cycle;
AND
(a) who has at least 2 of the following:
(i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or
(ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI) [for further information on the BASMI please refer to the Medicare Australia website at www.medicareaustralia.gov.au]; or
(iii) limitation of chest expansion relative to normal values for age and gender [for chest expansion normal values please refer to the Medicare Australia website at www.medicareaustralia.gov.au];
AND
(b) who has failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Medicare Australia website at www.medicareaustralia.gov.au.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:
(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale;
AND
(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which must include the following:
(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
(ii) a completed BASDAI Assessment Form [www.medicareaustralia.gov.au]; and
(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and
(iv) a signed patient acknowledgment form. Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment with the TNF-alfa antagonists (adalimumab, etanercept or infliximab) for ankylosing spondylitis will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 18 weeks of treatment with infliximab will be approved under this criterion.

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

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 18 weeks of treatment may be requested by telephone.

<u>Public and private hospital authority required</u>
Initial 2 (change or re-commencement for all patients)
Initial course of PBS-subsidised treatment with infliximab, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who, in this treatment cycle, has received prior PBS-subsidised treatment with either adalimumab, etanercept or infliximab for this condition and has not failed PBS-subsidised therapy with infliximab.

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 after 1 March 2007, the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction prior to 1 March 2007, the patient must have been assessed for response to that course following at least 4 weeks of treatment. These assessments must be provided to Medicare Australia no later than 4 weeks from the date the 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 Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes a completed BASDAI Assessment Form with certification by the prescriber and the patient that the patient did not have access to their baseline BASDAI at the time of their assessment.

A maximum of 18 weeks of treatment with infliximab will be approved under this criterion.

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

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 18 weeks of treatment may be requested by telephone.

<u>Public and private hospital authority required</u>
Continuing treatment for all patients
Continuing PBS-subsidised treatment, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who:
(a) has demonstrated a response to treatment with infliximab; and
(b) whose most recent course of PBS-subsidised therapy in this treatment cycle was with infliximab.

Response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:
(a) an ESR measurement no greater than 25 mm per hour; or
(b) a CRP measurement no greater than 10 mg per L; or
(c) an ESR or CRP measurement reduced by at least 20% from baseline.

For a 'grandfather' patient who does not have baselines prior to commencing treatment with a TNF-alfa antagonist, see Note 5 for a definition of response to treatment.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction after 1 March 2007, the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction prior to 1 March 2007, the patient must have been assessed for response to that course following at least 4 weeks of treatment.

Applications for continuing treatment must be made in writing and should be posted to Medicare Australia no less than 2 weeks prior to the completion of the current treatment course.

Written applications for authorisation must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes a completed BASDAI Assessment Form with certification by the prescriber and the patient that the patient did not have access to their baseline BASDAI at the time of their continuing treatment assessment.

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

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

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

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone.