

5.19 EPOPROSTENOL

Powder for I.V. infusion 500 micrograms (as sodium),

Powder for I.V. infusion 1.5 mg (as sodium),

Flolan[®],

GlaxoSmithKline Australia Pty Ltd.

1 Purpose of Application

- 1.1 The minor submission requested to remove the administration sets from the current listing of epoprostenol which, in the relevant PBS Legislative Instrument, would result in the removal of an existing form of epoprostenol, and the concurrent listing of a new brand of an existing form of epoprostenol. The sponsor also notified a change to the diluent formulation of the Flolan epoprostenol powder for infusion.

2 Requested listing

- 2.1 The minor submission did not request any changes to the current listing, as reflected in the PBS Schedule.

For more detail on PBAC's view, see section 5 "PBAC outcome"

3 Background

- 3.1 Epoprostenol sodium is TGA registered for the long-term treatment, via continuous intravenous infusion, in WHO functional Class III or Class IV patients with:
- idiopathic pulmonary arterial hypertension;
 - familial pulmonary arterial hypertension; and,
 - pulmonary arterial hypertension associated with the scleroderma spectrum of diseases.
- 3.2 Epoprostenol sodium was recommended for listing by the PBAC at the March 2006 meeting for the treatment of severe (Class III or IV) primary pulmonary hypertension (now referred to as pulmonary arterial hypertension).
- 3.3 The TGA approved the new formulation of the diluent for the Flolan brand of epoprostenol sodium on 3 February 2016.
- 3.4 The new formulation of diluent contains an increased amount of sodium hydroxide (42.4 mg compared to 73.3 mg) to raise the final pH of the diluent from 10.5 to 12. The minor submission stated that epoprostenol is more stable at a higher pH meaning an increased stability of the reconstituted solution. The minor submission argued that although the change is minor, the higher stability would mean a reduction in frequency of reconstitution and need for an icepack during patient administration under normal ambient conditions.
- 3.5 The minor submission proposed an alternative method of supplying the

administration sets at no additional cost to patients, on the basis that the supply of the sets with the PBS listing for epoprostenol sodium was unsustainable. The minor submission noted that the sponsor of Veletri® (an alternative brand of epoprostenol sodium listed on the PBS) currently supplies infusion administration sets via an alternative method.

For more detail on PBAC's view, see section 5 "PBAC outcome"

4 Consideration of the evidence

Sponsor hearing

4.1 There was no hearing for this item as it was a minor submission.

Consumer comments

4.1 The PBAC noted that no consumer comments were received for this item.

Economic analysis

4.2 As a minor submission, there was no economic comparison presented.

Estimated PBS usage & financial implications

4.3 The PBAC considered that there would be no additional financial impact to the government as the changes to supply the Flolan brand of epoprostenol sodium with the new diluent formulation and to remove the administration pack were proposed at the same price as for the currently listed forms of epoprostenol sodium. The PBAC also noted that the sponsor also confirmed that they will bear the cost of supplying the administration sets, and patients will not face any additional costs as a result of this change.

For more detail on PBAC's view, see section 5 "PBAC outcome"

5 PBAC Outcome

5.1 The PBAC recommended the listing of epoprostenol sodium (Flolan) without the administration set, as a new brand of the currently listed drug epoprostenol with the same form as the Veletri® brand. The PBAC also noted the change to the diluent formulation of the Flolan brand and that this may offer some advantages in terms of reconstitution and storage during infusion.

5.2 In making this recommendation, the PBAC noted that although the administration set was being removed from the pack supplied through the PBS, the sponsor had provide an assurance it would continue to provide the administration sets through an alternative method of supply at no additional cost to the patient.

- 5.3 The PBAC recommended that the existing brand equivalence arrangements should still apply.

Outcome:

Recommended

6 Recommended listing

Add new item:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
EPOPROSTENOL epoprostenol 500 microgram injection [1 vial] (& inert substance diluent [2 x 50 mL vials], 1 pack	1	1	Flolan®	GlaxoSmithKline Australia Pty Ltd

Category / Program	Section 100 – Highly Specialised Drugs Program
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
PBS Indication:	Pulmonary arterial hypertension (PAH)
Treatment phase:	Initial 1 (new patients)
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined
Clinical criteria:	Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must have been assessed by a physician at a designated hospital; AND Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH; OR Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; AND The treatment must be the sole PBS-subsidised PAH agent for this condition.
Prescriber	Applications for authorisation must be in writing and must include:

<p>Instructions</p>	<p>(1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgement.</p> <p>Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.</p> <p>Test requirements to establish baseline for initiation of treatment are as follows: The first written application for PBS-subsidised treatment with the first PAH agent 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 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 patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. The test results provided must not be more than 2 months old at the time of application.</p> <p>The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats may be requested.</p> <p>The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.</p> <p>Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised</p>
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	<p>therapy with this agent.</p> <p>The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.</p> <p>PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p>
Administrative Advice	<p>Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</p> <p>Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au</p> <p>Applications for authority to prescribe should be forwarded to: Department of Human Services Complex Drugs Reply Paid 9826 HOBART TAS 7001</p> <p>Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.</p> <p>Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 1.5 mg (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 1.5 mg injection vial are equivalent for the purposes of substitution.</p> <p>Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 500 micrograms (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 500 microgram injection vial are equivalent for the purposes of substitution.</p>

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
EPOPROSTENOL epoprostenol 500 microgram injection [1 vial] (& inert substance diluent [2 x 50 mL vials], 1 pack	1	1	Flolan®	GlaxoSmithKline Australia Pty Ltd

Category / Program	Section 100 – Highly Specialised Drugs Program
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
PBS Indication:	Pulmonary arterial hypertension (PAH)
Treatment phase:	Initial 2 (change or re-commencement of therapy for all patients)
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic

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	<input type="checkbox"/> Streamlined
Clinical criteria:	<p>Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent;</p> <p>OR</p> <p>Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and must have received prior treatment with a PBS-subsidised PAH agent other than this agent;</p> <p>OR</p> <p>Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and must have failed to respond to a prior PBS-subsidised PAH agent;</p> <p>AND</p> <p>The treatment must be the sole PBS-subsidised PAH agent for this condition.</p>
Prescriber Instructions	<p>Applications for authorisation must be in writing and must include:</p> <ol style="list-style-type: none"> (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and (4) for WHO Functional Class III patients, where this is the first application for this agent, assessment details of the PBS-subsidised PAH agent they have failed to respond to. <p>Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.</p> <p>The test results provided must not be more than 2 months old at the time of application.</p> <p>Response to a PAH agent is defined as follows:</p> <p>For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.</p> <p>For 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.</p> <p>For 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.</p> <p>For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.</p> <p>The maximum quantity authorised will be limited to provide sufficient supply for 1</p>

	<p>month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats may be requested.</p> <p>The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.</p> <p>Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.</p> <p>The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.</p> <p>PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <p>Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.</p> <p>Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.</p> <p>For eligible patients, applications to swap between the 7 PAH agents 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 recommence PBS-subsidised treatment with the drug they are ceasing.</p>
<p>Administrative Advice</p>	<p>Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.</p> <p>Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Complex Drugs Reply Paid 9826 HOBART TAS 7001</p>

	<p>Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.</p> <p>Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 1.5 mg (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 1.5 mg injection vial are equivalent for the purposes of substitution.</p> <p>Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 500 micrograms (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 500 microgram injection vial are equivalent for the purposes of substitution.</p>
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EPOPROSTENOL epoprostenol 500 microgram injection [1 vial] (& inert substance diluent [2 x 50 mL vials], 1 pack	1	1	Flolan®	GlaxoSmithKline Australia Pty Ltd

Category / Program	Section 100 – Highly Specialised Drugs Program
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
PBS Indication:	Pulmonary arterial hypertension (PAH)
Treatment phase:	Initial 1 (new patients) or Initial 2 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required - In Writing <input checked="" type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined
Clinical criteria:	<p>Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment;</p> <p>OR</p> <p>Patient must have received insufficient therapy with this agent under the Initial 2 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment;</p> <p>OR</p> <p>Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment;</p> <p>AND</p> <p>The treatment must be the sole PBS-subsidised PAH agent for this condition;</p> <p>AND</p> <p>The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.</p>
Administrative Advice	<p>Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</p> <p>Written applications for authorisation under this criterion should be forwarded to: Department of Human Services Complex Drugs Reply Paid 9826 HOBART TAS 7001</p>
Caution	This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of

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	therapy.
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Category / Program	Section 100 – Highly Specialised Drugs Program
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
PBS Indication:	Pulmonary arterial hypertension (PAH)
Treatment phase:	First Continuing treatment
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined
Clinical criteria:	Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition; AND Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment; AND The treatment must be the sole PBS-subsidised PAH agent for this condition
Prescribing Instructions	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 which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT). Test requirements to establish response to treatment for continuation of treatment are as follows: 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 the

	<p>written First Continuing treatment application, 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 patient specific reason why the test(s) could not be conducted must be provided with the application. The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.</p> <p>Response to a PAH agent is defined as follows: For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For 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 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 one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.</p> <p>The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.</p> <p>A maximum of 5 repeats will be authorised.</p> <p>An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.</p> <p>Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.</p> <p>The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, eprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.</p> <p>PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p>
<p>Administrative Advice</p>	<p>Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Complex Drugs Reply Paid 9826</p>

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	<p>HOBART TAS 7001</p> <p>Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.</p> <p>Text Required Flag Set</p>
Caution	<p>This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.</p>

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer
EPOPROSTENOL epoprostenol 500 microgram injection [1 vial] (& inert substance diluent [2 x 50 mL vials], 1 pack	1	1	Flolan® GlaxoSmithKline Australia Pty Ltd

Category / Program	Section 100 – Highly Specialised Drugs Program
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
PBS Indication:	Pulmonary arterial hypertension (PAH)
Treatment phase:	Subsequent Continuing treatment
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required - In Writing <input checked="" type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined
Clinical criteria:	<p>Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition;</p> <p>OR</p> <p>Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition;</p> <p>AND</p> <p>The treatment must be the sole PBS-subsidised PAH agent for this condition.</p>
Prescribing Instructions	<p>Patients who have previously received PBS-subsidised treatment with this drug for this condition under the Continuing treatment (all patients) prior to 1 May 2016 are eligible to continue PBS subsidised treatment with this drug under this criteria.</p> <p>The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.</p> <p>A maximum of 5 repeats will be authorised.</p> <p>An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure</p>

	<p>continuity of treatment.</p> <p>PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <p>The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.</p>
Administrative Advice	<p>Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</p> <p>Written applications for authorisation under this criterion should be forwarded to: Department of Human Services Complex Drugs Reply Paid 9826 HOBART TAS 7001</p> <p>Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.</p>

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
EPOPROSTENOL epoprostenol 1.5 mg injection [1 vial] (& inert substance diluent [2 x 50 mL vials], 1 pack	1	1	Flolan®	GlaxoSmithKline Australia Pty Ltd

Listing for PAH same as above

7 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

8 Sponsor's Comment

The sponsor had no comment.