

8 June 2009

Funding for pulmonary arterial hypertension treatments approved

PHARMAC is pleased to announce that the approval of a proposal relating to the funding of treatments for pulmonary arterial hypertension. This was the subject of a consultation letter dated 1 April 2009. In summary, the effect of the decision is that:

- Bosentan, iloprost and sildenafil will be subsidised for the treatment of pulmonary arterial hypertension from 1 July 2009.
- Access to these treatments will be managed by the Pulmonary Arterial Hypertension Panel, and subject to defined eligibility criteria.
- Patients currently accessing these treatments under the Hospital Exceptional Circumstances will automatically be eligible for Special Authority approval from 1 July 2009.

Details of the proposal

- Bosentan, iloprost and sildenafil will be listed in Section B of the Pharmaceutical Schedule from 1 July 2009 at the following prices and subsidies (ex-manufacturer and exclusive of GST):

Chemical	Presentation	Brand	Pack size	Price and subsidy
Bosentan	Tab 62.5 mg	Tracleer	60	\$4,585.00
Bosentan	Tab 125 mg	Tracleer	60	\$4,585.00
Iloprost	Nebuliser soln 10 µg per ml, 2 ml	Ventavis	30	\$1,185.00
Sildenafil	Tab 25 mg	Viagra	4	\$47.00
Sildenafil	Tab 50 mg	Viagra	4	\$59.50
Sildenafil	Tab 100 mg	Viagra	4	\$66.00

- The listing of each of these agents in Section B of the Pharmaceutical Schedule will be subject to the following restriction:

Special Authority – Hospital pharmacy [HP1]

Special Authority for Subsidy

Special Authority approved by the Pulmonary Arterial Hypertension Panel

Notes: Application details may be obtained from PHARMAC's website

<http://www.pharmac.govt.nz> or:

The Coordinator, PAH Panel

PHARMAC, PO Box 10 254

Wellington

Phone: (04) 916 7512

Facsimile: (04) 974 4858

Email: PAH@pharmac.govt.nz

- The access criteria and Special Authority forms for PAH treatments will be available from our website (www.pharmac.govt.nz). There are separate application forms for children aged less than 10 years.
- Special Authority applications will be reviewed by the Pulmonary Arterial Hypertension Panel.
- Patients currently receiving treatment for bosentan, iloprost or sildenafil under the Hospital Exceptional Circumstances mechanism will automatically receive Special Authority approvals for their current treatments. We will be in contact with clinicians directly in the next few weeks regarding this.
- Other aspects of the proposal were approved as outlined in the consultation letter.

Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received were considered in its entirety in making a decision on the proposed changes. Most responses were supportive of the proposal, and the following key issues were raised in relation to specific aspects of the proposal:

Theme	Comment
Respondents requested that the combined use of bosentan and iloprost also be an option in some circumstances.	Combination bosentan/iloprost therapy will be available for patients who require dual therapy but are intolerant of sildenafil.
Respondents noted that young children, who are generally treated with sildenafil, may require an oral liquid formulation.	We note that the Pharmaceutical Schedule rules allow subsidised compounding of an oral liquid with methylcellulose and syrup this circumstance.
Respondents questioned the composition of the Panel; in particular whether a rheumatologist should be included.	We consider that the members of the Panel, as proposed, have sufficient experience in the diagnosis and treatment of pulmonary arterial hypertension regardless of aetiology. We note that the Panel would be able to seek advice from external clinicians when required.
Respondents noted that there is a substantial difference between NYHA and WHO functional class criteria, and that they are not interchangeable.	The application forms have been amended to use a synthesised grading system produced by the Canadian Agency for Drugs and Technologies in Health.
Respondents questioned the intention of the statement that “fulfilling the eligibility criteria alone does not guarantee that subsidised pulmonary vasodilator treatment will be approved.”	This statement has been removed.

More information

If you have any questions about this decision, you can call our toll free number (9 am to 5 pm, Monday to Friday) on 0800 66 00 50.