

30 September 2010

Proposal to amend the access criteria for Pulmonary Arterial Hypertension treatments

PHARMAC is seeking feedback on a proposal to widen the pulmonary arterial hypertension (PAH) funding criteria.

In summary, this proposal would result in (with effect from 1 December 2010):

- widening the pulmonary arterial hypertension (PAH) funding criteria to include:
 - Fontan repair.
 - Persistent pulmonary hypertension associated with premature/neonatal severe chronic lung disease or congenital diaphragmatic hernia.
 - Infantile severe chronic lung disease where there is supportive evidence that pulmonary vascular resistance had never normalised.
- a number of minor changes to the PAH application form (eg blood pressure and smoking history requirements)

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **Wednesday, 13 October 2010** to:

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All feedback received before the closing date will be considered by PHARMAC's Board (or Chief Executive acting under delegated authority) prior to making a decision on this proposal.

Details of the proposal

Changes to diagnosis criteria

Subsidised PAH treatments are funded via Special Authority (following application to and approval by the PAH panel – which determines if the patient complies with the funding criteria) for patients diagnosed with pulmonary arterial hypertension according to the WHO (Venice) clinical classifications as follows:

Group 1

- Idiopathic;
- Familial;
- Associated with:
 - Connective tissue disease;
 - Congenital systemic pulmonary shunts;
 - Portal hypertension;
 - HIV infection;
 - Drugs and toxins;
 - Other;
- Associated with significant venous or capillary involvement:
 - Pulmonary veno-occlusive disease (PVOD);
 - Pulmonary capillary haemangiomas (PCH)
- Persistent pulmonary hypertension of the newborn (PPHN)

Group 4

- Pulmonary arterial hypertension due to thrombotic and/or embolic disease

Group 5

- Miscellaneous group (e.g. sarcoidosis, histiocytosis X and lymphangiomatosis)

Under this proposal, the funding criteria would be widened to include the following diagnoses:

- Fontan repair.
- Persistent pulmonary hypertension associated with premature/neonatal severe chronic lung disease or congenital diaphragmatic hernia (under PPHN).
- Infantile severe chronic lung disease where there is supportive evidence that pulmonary vascular resistance had never normalised (under PPHN).

Changes to the application form

The PAH treatment application form would be amended (the proposed application form with tracked changes can be found on PHARMAC's website at <http://pharmac.govt.nz/2010/09/30?q=PAH+form> to include the above diagnoses and a requirement for the following additional information – to assist the PAH Panel determine if the patient complies with the additional funding criteria:

- Applications for Fontan repair
 - haemodynamic data; and,
 - cardiac catheter data, or at least a consideration of, at a clinically appropriate stage of the patient's management.

We note that due to the presence of a non-pulsatile circuit, a mean pulmonary artery pressure (PAPm) < 25mmHg would be acceptable.
- Applications for the treatment of persistent pulmonary hypertension of the newborn associated with severe chronic lung disease (CLD) or congenital diaphragmatic hernia (CDH):
 - an inpatient management summary, admission history, echocardiogram, and short and long term management plan (including weaning plan); and,

- cardiac catheter data, or at least a consideration of, at a clinically appropriate stage of the patients management where treatment is required for 12 months or more.

Independent of the proposal to widen the funding criteria, the PAH treatment application form would also be amended as follows:

- A requirement for blood pressure results would be included – to assist the PAH Panel when considering whether the patient meets the funding criteria
- A requirement for the patients' smoking history (only on the adult application form) would be included - for reporting purposes only
- The threshold for pulmonary vascular resistance would also be clarified - either 3 Wood units or 240 International Units (dyn s cm⁻⁵).

Background to the Proposal

Pulmonary Arterial Hypertension (PAH) treatments have been funded since July 2009 through application to the PAH Panel – given the difficulties in diagnosing these patients and in many instances the presence of co-morbidities, the PAH Panel determines whether the application complies with the criteria for funding as outlined on the application form. Current treatments funded include sildenafil, ambrisentan, bosentan and iloprost.

Funding of sildenafil for additional patient groups was considered by the Pharmacology and Therapeutics Advisory Committee (PTAC) in May 2010, and by the PAH Subcommittee of PTAC in May 2010. The PAH Subcommittee of PTAC recommended that sildenafil be funded for:

- Fontan patients (high priority)
- Neonatal/infantile PAH secondary to chronic lung disease (medium priority)
- PAH secondary to congenital diaphragmatic hernia (high priority)

Published minutes from PTAC and the PAH Subcommittee of PTAC relating to this proposal can be found on PHARMAC's website at:

<http://www.pharmac.govt.nz/2010/06/29>

<http://www.pharmac.govt.nz/2010/09/30?q=PAH>