Approval of funding of sildenafil for Raynaud’s phenomenon and bosentan for children with pulmonary arterial hypertension

PHARMAC is pleased to announce the approval of proposals for funding sildenafil for Raynaud’s phenomenon from 1 March 2013 and bosentan as a first-line treatment option for children with idiopathic pulmonary arterial hypertension (PAH) or pulmonary hypertension secondary to congenital heart disease from 1 February 2013.

Sildenafil for Raynaud’s phenomenon

This proposal was the subject of a consultation letter dated 10 December 2012, which can be found on PHARMAC’s website at www.pharmac.govt.nz/consultation.

From 1 March 2013, sildenafil will be subject to the following Special Authority restrictions:

**Initial application – (Raynaud’s phenomenon)** from any relevant practitioner. Approvals valid without further renewal unless notified for patients meeting the following criteria:

1. Patient has Raynaud’s phenomenon*; and
2. Patient has severe digital ischaemia (defined as severe pain requiring hospital admission or with a high likelihood of digital ulceration, digital ulcers or gangrene); and
3. Patient is following lifestyle management (proper body insulation, avoidance of cold exposure, smoking cessation support, avoidance of sympathomimetic drugs); and
4. Patient has persisting severe symptoms despite treatment with calcium channel blockers and nitrates (unless contraindicated or not tolerated).

**Notes**

1. Sildenafil is also funded for patients with pulmonary arterial hypertension who are approved by the Pulmonary Arterial Hypertension Panel (an application must be made to the Panel). Application details may be obtained from:
   - The Coordinator, PAH Panel
   - PHARMAC, PO Box 10 254, Wellington
   - Phone: (04) 916 7512 Facsimile: (04) 974 4858 Email: PAH@pharmac.govt.nz
2. Indications marked with * are Unapproved Indications.

Approvals for the PAH indication will continue to be processed manually as they are currently, but approvals for Raynaud’s phenomenon will be able to be processed electronically. Raynaud’s phenomenon is not a registered indication for sildenafil.

We appreciate all of the feedback that we received and acknowledge the time people took to respond. Consultation responses were largely supportive of the proposal.

Bosentan as a first-line treatment option for children with PAH

PHARMAC currently funds four PAH treatments: sildenafil (first-line), bosentan and ambrisentan (second-line, although ambrisentan is not being used), and iloprost (third-line). These treatments are used in adults and children for PAH and a number of related conditions.

While they have been shown to be efficacious in adults there is a paucity of trial evidence regarding their efficacy in and safety children. The FDA recently recommended (30 August...
2012) that sildenafil is not prescribed to children for PAH based on the STARTS-1 and STARTS-2 trials which showed that children taking high-dose sildenafil had a higher risk of death than children taking low-dose sildenafil and that the low doses are not effective in improving exercise ability. The PAH Subcommittee of the Pharmacology and Therapeutics Advisory Committee (PTAC) considered the trial data in December 2012 and recommended that an endothelin receptor antagonist (e.g. bosentan and ambrisentan) replace sildenafil as the first-line treatment for children with idiopathic PAH and pulmonary hypertension secondary to congenital heart disease requiring long-term therapy, and that sildenafil remain the first-line treatment for children with disease requiring short-term therapy and in diseases where there is no evidence or clinical experience with the use of endothelin receptor antagonists (e.g. Fontan circuits, congenital diaphragmatic hernias, persistent pulmonary hypertension of the newborn).

From 1 February 2013 the PAH Panel application forms for sildenafil, bosentan, ambrisentan and iloprost will be amended to enable bosentan to be used as a first-line treatment for children with idiopathic PAH or pulmonary hypertension secondary to congenital heart disease.

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.