CONSULTATION

PHARMAC
Pharmaceutical Management Agency

10 December 2012

Proposal to fund sildenafil for the treatment of Raynaud's phenomenon

PHARMAC is seeking feedback on a proposal to:

- Fund sildenafil for patients with Raynaud's phenomenon who meet the Special Authority eligibility criteria.

The proposal does not affect the eligibility of patients, or the use of sildenafil, in pulmonary arterial hypertension – these applications would continue to require approval of the Pulmonary Arterial Hypertension Panel.

Further details of this proposal, including how to provide feedback, the Special Authority criteria and background information can be found below.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **5 pm Friday, 21 December 2012** to:

Stephen Woodruffe
Therapeutic Group Manager
PHARMAC

Email: stephen.woodruffe@pharmac.govt.nz

Phone: 04 916 7555

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.

We are not able to treat any part of your feedback as confidential unless you specifically request that we do. If you would like us to withhold any commercially sensitive, confidential proprietary, or personal information included in your submission, please clearly state this in your submission and identify the relevant sections of your submission that you would like withheld.

Feedback we receive is subject to the Official Information Act 1982 (OIA) and we will consider any request to have information withheld in accordance with our obligations under the OIA.

Level 9, 40 Mercer Street, PO Box 10-254, Wellington 6143, New Zealand
Phone: 64 4 460 4990 - Fax: 64 4 460 4995 - www.pharmac.govt.nz

Details of the proposal

From 1 February 2013 we propose to widen funding for sildenafil to include patients with Raynaud's phenomenon who met the following eligibility criteria - sildenafil funding for pulmonary arterial hypertension (PAH) would not be affected and would continue to require approval from the Pulmonary Arterial Hypertension Panel:

Initial application – Raynaud's phenomenon.

Applications 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.
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 Most patients with Raynaud's Phenomenon who have severe digital ischemia that does not respond adequately to calcium channel blockers and nitrates will have Secondary Raynaud's Phenomenon, most commonly secondary to connective tissue diseases.

Should this proposal be approved, the above criteria would also apply to the use of sildenafil for Raynaud's phenomenon in DHB hospitals from 1 July 2013.

Background

Sildenafil is currently funded for patients with Pulmonary Arterial Hypertension following approval from the Pulmonary Arterial Hypertension Panel.

In May 2012 the Pharmacology and Therapeutics Advisory Committee (PTAC) recommended that sildenafil should also be funded for patients with secondary Raynaud's phenomenon. In making this recommendation PTAC noted:

- The evidence supporting sildenafil in Raynaud's phenomenon (RP) is limited to small studies and case reports for Secondary RP including Fries et al. (Circulation. 2005;112;2980-2985), Brueckner et al. (Ann Rheum Dis 2010;69:1475-1478), and Herrick et al. (Arthritis & Rheumatism 2011;69:775-782).
- Support from the New Zealand Rheumatology Association for sildenafil's use in severe/refractory RP following failure of calcium channel blockers and as an alternative to iloprost.
- A treatment algorithm by Baumhakel and Bohm (Vascular Health Risk Management 2010;6:207-214) restricting sildenafil to Secondary RP following calcium channel blockers and/or nitrates in severe ischemia, digital ulcers and stable patients.

PTAC considered that there is a lack of treatment options for patients with severe disease and that sildenafil would provide a clinical benefit in patients with severe secondary RP. PTAC also noted that bosentan had been trialled in digital ulcers but considered that the results were not encouraging as there was no effect on digital ulcer healing (Matucci-Cerinic & Seibold. Rheumatlogy 2008;47:v46-v47; Matucci-Cerinic et al. Ann Rheum Dis 2011;70:32-38).