

23 July 2010

Proposal to fund modafinil (Modavigil) for narcolepsy

PHARMAC is seeking feedback on a proposal to fund modafinil (Modavigil) from 1 October 2010 for patients with narcolepsy through a provisional agreement with CSL Biotherapies (NZ) Limited.

Under this proposal modafinil would be funded subject to Special Authority criteria restricting its use to patients with narcolepsy who cannot tolerate methylphenidate or dexamphetamine or in whom both methylphenidate and dexamphetamine are contraindicated.

Details of the proposal can be found below and on the following page.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **Friday, 6 August 2010** to:

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Therapeutic Group Manager	Fax: 04 460 4995
PHARMAC	Post: PO Box 10 254, Wellington 6143

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

Modafinil (Modavigil) 100 mg tablets would be listed in Section B of the Pharmaceutical Schedule from 1 October 2010 at a price and subsidy of \$72.50 per pack of 30 tablets.

Modafinil would be subject to the following Special Authority criteria:

Initial application only from a neurologist or respiratory specialist. Approvals valid for 24 months for applications meeting the following criteria:

All of the following:

- 1 The patient has excessive daytime sleepiness associated with narcolepsy occurring almost daily for three months or more; and
- 2 Hypersomnia not better explained by another disorder; and
- 3 Either:
 - 3.1 Definite history of cataplexy and a Multiple Sleep Latency Test (MSLT) with a mean sleep latency less than or equal to 8 minutes; or

- 3.2 A MSLT with a mean sleep latency of less than or equal to 8 minutes and 2 or more sleep onset rapid eye movement periods; and
- 4 The MSLT must be preceded by nocturnal polysomnography and sleep prior to the MSLT must be at least 6 hours; and
- 5 Either:
 - 5.1 An effective dose of a subsidised formulation of methylphenidate or dexamphetamine has been trialled and discontinued because of intolerable side effects; or
 - 5.2 Methylphenidate and dexamphetamine are contraindicated.

Renewal application only from a neurologist or respiratory specialist. Approvals valid for 24 months where the treatment remains appropriate and the patient is benefiting from treatment.

Background

The Pharmacology and Therapeutics Advisory Committee reviewed an application from CSL to fund modafinil at its February 2007 meeting.

The Committee considered that modafinil would most benefit patients with narcolepsy with excessive daytime sleepiness, particularly those who cannot tolerate or who have contraindications to currently funded treatments. The Committee recommended that modafinil be listed on the Pharmaceutical Schedule subject to criteria restricting its use to patients with diagnosed excessive daytime sleepiness associated with narcolepsy who cannot tolerate methylphenidate and dexamphetamine or in whom methylphenidate and dexamphetamine were contraindicated, with a low priority.

The full minute from this review can be found on PHARMAC's website at <http://www.pharmac.govt.nz/2007/02/01>.

If this proposal is approved there would be no outstanding funding applications with respect to modafinil.