

17 November 2004



Pharmaceutical Management Agency

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To All Interested Parties

By facsimile (2 pages)

PROPOSAL FOR THE LISTING OF TIOTROPIUM BROMIDE (SPIRIVA)

PHARMAC and Boehringer Ingelheim NZ Limited have entered into a provisional agreement relating to the supply of tiotropium bromide (Spiriva). Acceptance of this provisional agreement is subject to consultation and PHARMAC Board approval.

The main features of this proposal are as follows:

- PHARMAC would list tiotropium bromide (Spiriva) powder for inhalation, monodose device, 18 mcg per dose in Section B of the Pharmaceutical Schedule from 1 February 2005, at a price and subsidy of \$70.00 per 30 monodoses (ex manufacturer, exclusive of GST) under the following Special Authority criteria:

Tiotropium bromide

Special Authority for Subsidy

Initial application only from a general practitioner or relevant specialist. Approvals valid for 2 years for applications meeting the following criteria:

All of the following:

- 1 To be used for the long-term maintenance treatment of bronchospasm and dyspnoea associated with COPD; and
- 2 In addition to standard treatment, the patient has trialled a dose of at least 40 mcg ipratropium q.i.d for one month; and
- 3 The patient's breathlessness \geq grade 4 according to the Medical Research Council dyspnoea scale (see note). Grade must be stated on the application; and
- 4 $FEV_1 < 40\%$ of predicted (copy of actual result and predicted value to be included in application, or values to be stated on form); and
- 5 Either:
 - 5.1 Patient is not a smoker; or
 - 5.2 Patient is a smoker and been offered smoking cessation counselling; and
- 6 The patient has been offered annual influenza immunisation.

Renewal only from a general practitioner or relevant specialist. Approvals valid for 2 years for applications meeting the following criteria:

All of the following:

- 7 Patient is compliant with the medication; and
- 8 Patient has experienced improved COPD symptom control (prescriber determined); and
- 9 Applicant must supply recent measurement of FEV_1 (% of predicted). Details must be attached to the application (for reporting purposes only).

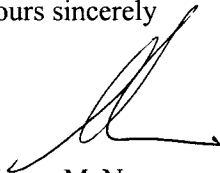
Note

Grade 4 = stops for breath after walking about 100 meters or after a few minutes on the level; Grade 5 = too breathless to leave the house, or breathless when dressing or undressing

- PHARMAC would amend the above Special Authority criteria to include patients who have an FEV₁ of less than 60% predicted and meet the other criteria, subject to Boehringer Ingelheim providing a satisfactory application to the Pharmacology and Therapeutic Advisory Committee (PTAC), and PHARMAC receiving a positive recommendation from PTAC for the amendment.
- A confidential risk-sharing arrangement would apply to the listing of Spiriva until 30 June 2010.
- Spiriva would be subject to reference pricing protection until 30 June 2010.
- PHARMAC would list tiotropium bromide (Spiriva) powder for inhalation, monodose device, 18 mcg per dose in Section H of the Pharmaceutical Schedule from 1 February 2005, at a price of \$70.00 per 30 monodoses (ex manufacturer, exclusive of GST).

PHARMAC's Board will consider the proposal at its December 2004 meeting. If you wish to make comments on this proposal, please forward them to Carolyn Macal tao at PHARMAC by **5 p.m. on Thursday, 2 December 2004**.

Yours sincerely



Wayne McNee
Chief Executive