

6.22 TIOTROPIUM

Solution for oral inhalation 2.5 microgram (as bromide monohydrate) per actuation (60 actuations), Spiriva[®] Respimat[®], Boehringer Ingelheim Pty Ltd

1 Purpose of Application

- 1.1 A minor resubmission to request an amendment to the listing of tiotropium solution from a Restricted Benefit to an Authority Required (STREAMLINED) restriction for the treatment of patients with severe asthma.

2 Requested listing

- 2.1 The submission requested a change of restriction level for the existing listing for severe asthma indication only. No other changes to the existing listings were requested.

For more detail on PBAC's view, see section 5 PBAC outcome.

3 Background

- 3.1 Tiotropium was TGA registered on July 2015 for: “add-on maintenance bronchodilator treatment in adult patients with asthma who are currently treated with the maintenance combination of inhaled corticosteroids (≥800 microgram budesonide/day or equivalent) and long-acting beta-2 agonists and who experienced one or more severe exacerbations in the previous year.”
- 3.2 A minor submission to amend the restriction level of tiotropium for the treatment of asthma to Authority Required (STREAMLINED) was rejected at the July 2017 PBAC meeting on the basis that there were other, more appropriate, options to address the issues raised.

For more detail on PBAC's view, see section 5 PBAC outcome.

4 Current Situation

- 4.1 The sponsor requested the PBAC to reconsider the request to change the restriction for the severe asthma indication on the basis of the recent PBS claims data obtained (i.e. from February 2017).
- 4.2 The submission reiterated that the current prescribing tools are unable to distinguish between the two PBS indications for tiotropium at dispensing and caused

misclassification of medicine claims, i.e. prescriptions that have been written for asthma are dispensed and claimed against the PBS item code for Chronic Obstructive Airways Disease (COPD) and vice versa.

- 4.3 At the July 2017 PBAC meeting, the Committee considered altering the restriction level for a single indication was not an appropriate method to distinguish between the asthma and COPD indications as a way to manage the Risk Sharing Arrangement (RSA) currently in place for the severe asthma indication.
- 4.4 The Department proposed that a method, analogous to a weighted pricing approach, could be used to determine the proportion of drug utilisation for each indication to inform the management of the RSA. In this approach, the Department and the sponsor would prospectively agree the proportions of the PBS market for tiotropium used in the asthma indication and that used in the COPD indication. The information that is available to inform the calculations needed to underpin this work, includes the agreed estimates for the severe asthma indication from the March 2016 PBAC consideration of tiotropium for asthma and the usage data from the long established tiotropium COPD indication. The RSA could then be managed by summing the total tiotropium use across all indications and applying the proportion attributed to the asthma indication to that sum.
- 4.5 The pre-PBAC response argued that the proposed approach did not address the misclassification between the two PBS indications for tiotropium, and has limited ability to accurately determine the proportion of tiotropium use for the severe asthma indication due to the complex COPD market.

For more detail on PBAC's view, see section 5 PBAC outcome.

5 PBAC Outcome

- 5.1 The PBAC did not recommend amending the Restricted Benefit listing of tiotropium for severe asthma to an Authority Required (STREAMLINED) listing. The PBAC restated its view that the use of different restriction levels for the same drug, solely for the purpose of managing a Risk Sharing Arrangement (RSA), was inappropriate and may lead to confusion for consumers and prescribers.
- 5.2 The PBAC recalled that it recommended the Restricted Benefit listing of tiotropium as add-on therapy for severe asthma at the March 2016 PBAC meeting on the basis of satisfactory cost-effectiveness over placebo (Public Summary Document, March 2016 PBAC Meeting).
- 5.3 The PBAC also recalled that it considered that a Risk Share Arrangement would be required to manage the high risk of use in patients with less severe asthma or in patients who are not taking their existing medication optimally (Public Summary Document, March 2016 PBAC Meeting).
- 5.4 The PBAC reiterated that the requested change in restriction level would result in

tiotropium being the only long-acting muscarinic antagonist (LAMA) medicine listed for asthma or COPD subject to an Authority Required (STREAMLINED) listing.

- 5.5 The PBAC maintained the view from its July 2017 consideration that the up-regulation in restriction level only for severe asthma indication would cause consumer and prescriber confusion, and may shift prescriber activity inappropriately toward the Restricted Benefit listing in COPD.
- 5.6 The PBAC restated that it was unconvinced that the requested change of restriction level for the severe asthma indication was an appropriate method to manage the existing Risk Sharing Arrangement (RSA). Further, the PBAC restated that it considered that this approach may not adequately address the sponsors concerns, which could be met by other approaches.
- 5.7 The PBAC considered that a more appropriate method to address the sponsor's concerns would be to determine the proportion of drug utilisation for each indication based on the agreed estimates for the severe asthma indication from the March 2016 PBAC consideration of tiotropium and the usage data from the tiotropium COPD indication. The PBAC noted the continued concern over the utilisation data of tiotropium for the COPD indication, however it indicated that these utilisation data have been stable for several years. The RSA could then be managed by summing the total tiotropium use across all indications and applying the proportion attributed to the asthma indication to that sum.
- 5.8 The PBAC noted that this submission is not eligible for an Independent Review as an Independent Review is not available in response to a request to modify an existing listing.

Outcome:

Rejected

6 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

7 Sponsor's Comment

The sponsor had no comment.