

## 6.17 TIOTROPIUM

### **Solution for oral inhalation 2.5 microgram (as bromide monohydrate) per actuation**

### **Spiriva® Respimat®, Boehringer Ingelheim Pty Limited**

#### **1 Purpose of Application**

- 1.1 The minor submission requested to amend 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 asthma only. No other changes to the existing listings were requested.
- 2.2 No change to the restriction level for the COPD indication was requested. This was proposed to remain as a restricted benefit listing.
- 2.3 The current restriction for tiotropium in severe asthma consists of the following clinical criteria:
- Patient must have experienced at least one severe exacerbation, which has required documented use of systemic corticosteroids, in the previous 12 months while receiving optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, and
  - The treatment must be used in combination with a maintenance combination of an inhaled corticosteroid and a long acting beta-2 agonist.
- 2.4 The PBAC noted that optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.

#### **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 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).

- 3.3 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).

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

## **4 Consideration of evidence**

### ***Sponsor hearing***

- 4.1 There was no hearing for this item as it was a minor submission.

### ***Consumer comments***

- 4.2 The PBAC noted that no consumer comments were received for this item.

### ***Current Situation***

- 4.3 The submission claimed that pharmacists are unable to distinguish between the two PBS Restricted Benefit items for tiotropium at the time of dispensing. The sponsor claimed that because prescriptions for restricted benefits do not record the indication for which the drug is prescribed, pharmacists are free to choose which indication they record the dispensing against regardless of the prescription. The submission requested a change of restriction from Restricted Benefit to an Authority Required (STREAMLINED) for the asthma indication to prevent possible misclassification by pharmacists of the indication for which tiotropium is being dispensed.
- 4.4 The submission stated that the reason for the request was to enable proper management of the risk share arrangement for tiotropium in asthma.
- 4.5 The PBAC noted that patients with co-morbid asthma and COPD are also eligible to receive tiotropium under a Restricted Benefit PBS listing (Public Summary Document, March 2016 PBAC Meeting).

### **Estimated PBS usage & financial implications**

- 4.6 The minor submission estimated there to be no financial implications to the PBS as this is a request to change the current restriction level and will not result in any increase in the eligible population.

*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 for tiotropium to an Authority Required (STREAMLINED) restriction for the treatment of patients with severe asthma on the basis that there were other, more appropriate, options to address the issues raised by the sponsor.
- 5.2 The PBAC recalled that at the time of recommending this listing in March 2016 the PBAC also noted that sensitivity analyses indicated that use outside of the requested restriction would affect the cost-effectiveness and financial impact of this treatment considerably. The PBAC therefore considered that a Risk Sharing Arrangement to manage the risk of use in patients with less severe asthma or in patients who are not taking their existing medication optimally was required (Public Summary Document, March 2016 PBAC meeting).
- 5.3 The PBAC considered that the mechanism of using different restriction levels was not an appropriate mechanism to distinguish between the asthma and COPD indications in order to manage the Risk Sharing Arrangement for tiotropium in severe asthma as requested was inappropriate and would not address the sponsor's concerns.
- 5.4 The PBAC also noted that implementing the change as requested would result in tiotropium being the only LAMA medicine listed for asthma or COPD subject to an Authority Required (STREAMLINED) listing. The PBAC was concerned that the up-regulation in restriction level only for severe asthma indication would cause consumer and prescriber confusion, and may shift the prescribing activity toward the Restricted Benefit listing in COPD.
- 5.5 The PBAC noted that [REDACTED] cap in the Risk Sharing Arrangement had not been breached at the time of the submission, and therefore there was no indication that the current restriction level was not working effectively. Further, the PBAC noted that the proposed approach would not completely address the issue that prescriptions are claimed against the wrong indication, as there is also the possibility that a prescription could be written for the wrong indication.
- 5.6 The PBAC considered an alternative method of achieving the outcome sought by the sponsor would be to agree to a weighted price based on the projected of use of tiotropium in the asthma and COPD indications. This could be achieved without any change to the current restriction level for tiotropium.

- 5.7 Alternatively, the PBAC considered another way forward was to change both indications to Authority Required (STREAMLINED) listing which would avoid consumer and prescriber confusion and increase the likelihood that the prescriptions are for the correct indication. However, the PBAC noted that this would cause inconsistency with the listing of other asthma and COPD medications.
- 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.