11.08 TERBUTALINE
Powder for oral inhalation in breath actuated device containing terbutaline sulfate 500 micrograms per dose, 100 doses
Bricanyl Turbuhaler®, AstraZeneca Pty Ltd

1 Purpose of Application

1.1 The PBAC is asked to advise whether terbutaline powder for oral inhalation (Bricanyl Turbuhaler®) should be retained on the PBS on the basis of clinical need, or whether available forms of salbutamol for oral inhalation are suitable alternatives.

1.2 If terbutaline is to be retained on the PBS on the basis of clinical need, the PBAC is asked to define the patient population that would be unable to use alternative treatment options.

2 Background

2.1 The sponsor of terbutaline submitted a price increase request to the Department in January 2019 on the basis of commercial viability. The Department considered that there was a high risk of withdrawal from the PBS if a price increase was not granted.

2.2 Two forms of terbutaline are listed on the PBS, an injection and a powder for oral inhalation. A price increase was requested for the powder for oral inhalation form only. Terbutaline powder for oral inhalation has been PBS-listed since 1 August 1991 and is listed as an unrestricted benefit. It is used as a reliever inhaler for the management of bronchospasm.

2.3 There are three forms of an alternative short-acting beta-2 agonist (SABA), salbutamol, available on the PBS as unrestricted benefit listings; pressurised metered dose inhaler (pMDI), nebules, and capsules containing powder for oral inhalation. The therapeutic relativity is 100 micrograms of salbutamol for oral inhalation is approximately equivalent to 250 micrograms terbutaline for oral inhalation by similar administration method.

2.4 The PBAC Executive considered the price increase request at its April 2019 meeting. The PBAC Executive noted that 31,000 patients are currently using terbutaline powder for oral inhalation. If the price increase as requested by the sponsor was agreed, from the current AEMP $3.75 to $6.82, the estimated cost to government would be $3.21 million over five years. The PBAC Executive considered it would be appropriate to seek further advice from respiratory physicians to assist in determining whether the removal of this product from the PBS would result in an unmet clinical need or whether suitable alternatives were available.

For more detail on PBAC's view, see section 4 PBAC outcome.

3 Current situation

3.1 At the request of the PBAC Executive, clinical advice was sought from respiratory physicians, who expressed concerns over the potential removal of terbutaline powder for oral inhalation from the PBS, noting an ongoing clinical need for the treatment of bronchospasm in the following patient groups:

- Patients unable to use a pMDI: Asthma and chronic obstructive pulmonary disease guidelines place a strong emphasis on choosing the most appropriate inhaler device for each patient due to the high prevalence of incorrect inhaler technique.
- Increased palpitations caused by the use of salbutamol: While salbutamol and terbutaline have similar adverse event profiles, occasionally patients report more palpitations with salbutamol than with terbutaline, and therefore need an alternative SABA. If terbutaline powder for oral inhalation were to be withdrawn, the only available SABA would be salbutamol.
- pMDI can cause paradoxical bronchoconstriction: Around 8% of asthma patients may experience paradoxical bronchoconstriction with pMDIs[1]. This is thought to be a reaction to the excipients in the inhalers.
- Lack of alternative therapies: Some patients cannot coordinate actuation and inspiration with a pMDI, so without availability of SABA by Turbuhaler, they would need to carry a spacer for as-needed use. The Secretariat noted that a breath-actuated salbutamol pMDI, Airomir Autohaler (PBS item code 8354Q) is currently PBS listed as a restricted benefit for patients unable to achieve co-ordinated use of other metered dose inhalers containing salbutamol, however the DPMQ for breath-actuated salbutamol ($39.31) is higher than salbutamol pMDI without breath-actuation ($19.71) or terbutaline ($19.39).

For more detail on PBAC's view, see section 4 PBAC outcome.

4 PBAC Outcome

4.1 The PBAC recommended that terbutaline powder for oral inhalation be retained on the PBS on the basis that there is a clinical need for ongoing access in patients who are unable to use short-acting beta-2 agonist (SABA) pressurised metered dose inhalers (pMDI) for the treatment of bronchospasm.

4.2 The PBAC noted the clinical advice from respiratory physicians regarding concerns about the potential withdrawal of terbutaline powder for oral inhalation from the PBS. Based on this clinical advice, the PBAC considered that terbutaline powder for oral

[1] Magee JS et al. Paradoxical bronchoconstriction with short-acting beta agonist. Am J Case Rep 2018;19:1204-7 (available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6192384)

inhalation provides a valuable therapeutic option to the following patient groups:

- Patients unable to use a pMDI;
- Patients who suffer from adverse effects with the use of salbutamol; and
- Patients who experience paradoxical bronchoconstriction with pMDI.

4.3 The PBAC considered that the current unrestricted benefit listing of terbutaline powder for oral inhalation should be amended to an Authority Required (STREAMLINED) listing. In addition, the PBAC considered the restriction criteria should be amended to restrict use only to patient groups in which terbutaline powder for oral inhalation is considered necessary because alternative treatment options are not suitable.

Outcome:
Recommended

5 Recommended listing

5.1 Amend existing listing as follows (Item code: 2817G):

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer	
TERBUTALINE 500 microgram/actuation powder for inhalation, 100 actuations	2	5	Bricanyl Turbuhaler	AstraZeneca Pty Ltd

Category / Program:	GENERAL – General Schedule (Code GE)
Prescriber type:	☐Dental ☒Medical Practitioners ☒Nurse practitioners ☐Optometrists ☐Midwives
Condition:	Bronchospasm
PBS Indication:	Bronchospasm
Restriction Level / Method:	☐Restricted benefit ☐Authority Required – In Writing ☐Authority Required – Telephone/Electronic/Emergency ☒Streamlined
Clinical criteria:	Patient must be unable to achieve co-ordinated use of a metered dose inhaler containing a short-acting beta-2 agonist. OR Patient must have developed a clinically important product-related adverse event during treatment with another short-acting beta-2 agonist.
Prescriber Instructions:	Device (inhaler) technique should be reviewed at each clinical visit and before initiating treatment with this medicine.

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.