

6.12 SALBUTAMOL

Nebuliser solution 2.5 mg (as sulfate) in 2.5 mL single dose ampoules, 20,

Nebuliser solution 5 mg (as sulfate) in 2.5 mL single dose ampoules, 20,

Ventolin Nebules[®],

GlaxoSmithKline Australia Pty Ltd.

1 Purpose of Application

- 1.1 The minor submission requested an amendment to the current PBS listing for the treatment of asthma and chronic obstructive pulmonary disease (COPD) to decrease the pack size from 30 to 20 ampoules while retaining the same maximum quantity of ampoules per script.

2 Requested Listing:

- 2.1 The submission requested the following changes to the existing listing:

Suggestions and additions proposed by the Secretariat to the requested listing are added in italics and suggested deletions are crossed out with strikethrough.

Public Summary Document – November 2016 PBAC Meeting

Name, Restriction, Manner of administration and form	Max. Qty (Packs)	Max. Qty (Units)	No. of Rpts	Proprietary Name and Manufacturer
SALBUTAMOL 2.5 mg/2.5 mL inhalation: solution, 2.5 mL ampoules, 20	3	60-3	5	Ventolin Nebules® GlaxoSmithKline Australia Pty Ltd

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Condition:	Asthma Chronic obstructive pulmonary disease (COPD)
PBS Indication:	Asthma Chronic obstructive pulmonary disease (COPD)
Restriction Level / Method:	<input checked="" type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined
Clinical criteria:	Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.
Administrative Advice	<u>Note:</u> Pharmaceutical benefits that have a 30 × 2 pack size and a 20 × 3 pack size are equivalent for the purposes of substitution.

Name, Restriction, Manner of administration and form	Max. Qty (Packs)	Max. Qty (Units)	No. of Rpts	Proprietary Name and Manufacturer
SALBUTAMOL 2.5 mg/2.5 mL inhalation: solution, 2.5 mL ampoules, 20	1	20-1	0	Ventolin Nebules® GlaxoSmithKline Australia Pty Ltd

Category / Program	Prescriber Bag
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined

Public Summary Document – November 2016 PBAC Meeting

Name, Restriction, Manner of administration and form	Max. Qty (Packs)	Max. Qty (Units)	No. of Rpts	Proprietary Name and Manufacturer
SALBUTAMOL 5 mg/2.5 mL inhalation: solution, 2.5 mL ampoules, 20	3	60 3	5	Ventolin Nebules® GlaxoSmithKline Australia Pty Ltd

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Condition:	Asthma Chronic obstructive pulmonary disease (COPD)
PBS Indication:	Asthma Chronic obstructive pulmonary disease (COPD)
Restriction Level / Method:	<input checked="" type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined
Clinical criteria:	Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.
Administrative Advice	<u>Note:</u> Pharmaceutical benefits that have a 30 × 2 pack size and a 20 × 3 pack size are equivalent for the purposes of substitution.

Name, Restriction, Manner of administration and form	Max. Qty (Packs)	Max. Qty (Units)	No. of Rpts	Proprietary Name and Manufacturer
SALBUTAMOL 5 mg/2.5 mL inhalation: solution, 2.5 mL ampoules, 20	1	20 1	0	Ventolin Nebules® GlaxoSmithKline Australia Pty Ltd

Category / Program	Prescriber Bag
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined

2.2 In the pre-PBAC response, the sponsor proposed that the maximum quantity (units) be changed from 3 to 60 to reflect the number of ampoules being dispensed under the maximum quantity.

- 2.3 The sponsor noted that that supplies of the pack of 30 ampoules will be available until 1 March 2017; therefore, there will be a period where both packs are available on the PBS. In the pre-PBAC response, the sponsor suggested adding a “note” to clarify that the different presentations be treated as equivalent during this period.

For more detail on PBAC’s view, see section 7 “PBAC outcome”

3 Suitability for pharmacist substitution

- 3.1 Ventolin Nebules[®] are currently “a” flagged with the following PBS-listed salbutamol brands:
- APO-Salbutamol[®]
 - Butamol[®] 2.5 and 5
 - Pharmacor Salbutamol[®] 2.5 and 4
 - Salbutamol Actavis[®]
 - Salbutamol Sandoz[®]
 - Asmol[®] 2.5 and 5 uni-dose

4 Background

- 4.1 Salbutamol was TGA registered on 13 August 1991 for the relief of bronchospasm in patients with asthma or chronic obstructive pulmonary disease, and for acute prophylaxis against exercise-induced asthma, or in other situations known to induce bronchospasm.
- 4.2 The sponsor received a TGA category 3 approval for the reduced pack size from 30 ampoules to 20 ampoules per pack on 21 September 2016.
- 4.3 Salbutamol has been listed on the PBS for over twenty years for the indications stated in paragraph 1.1.
- 4.4 The submission stated that the requested change to pack size aligns with international packaging requirements.
- 4.5 The sponsor requested the 30 and 20 pack presentations be simultaneously available on the PBS, as the packs of 30 ampoules will be available for a period beyond October 2016. The PBAC noted that this request would result in creating a new item code in the PBS Schedule, with the same prescribing rules as the original 30 pack.
- 4.6 The sponsor requested that the pack of 20 ampoules be dispensed under the same item code as that of the 30 pack. Therefore, the sponsor proposed that the “maximum quantity (units)” should be described in terms of the number of ampoules dispensed under the “maximum quantity (packs)”. For example, the requested MQ

(packs) for a pack of 20 ampoules is 3, so the proposed MQ (units) is 60. The PBAC noted the Department's advice that the Legal Instruments (LIs) for Ventolin Nebules[®] and other salbutamol brands state the form, strength, and number of ampoules; for example, "salbutamol nebuliser solution 2.5 mg (as sulphate) in 2.5 mL single dose units, 30". As the LIs already describe the number of ampoules in the pack, the MQ (units) corresponds to the MQ (packs) on the PBS. Changing the MQ (packs) for Ventolin Nebules[®] as requested would be inconsistent with other currently listed brands of salbutamol.

- 4.7 The sponsor acknowledged that dispensing both pack sizes may not be an option under the emergency drug supply program. If the pack of 20 ampoules cannot retain the current "a" flags as the pack of 30 ampoules, the sponsor suggested in their Pre-PBAC response that *Ventolin Nebules*[®] be removed from the list of brands available through the emergency drug supply program.

For more detail on PBAC's view, see section 7 "PBAC outcome"

5 Pricing considerations

- 5.1 The sponsor did not request a change to the current dispensing price per maximum quantity (DPMQ) under both the General Schedule (2.5 mg DPMQ = \$█, 5 mg DPMQ = \$19.98) and the Prescriber Bag program (2.5 mg DPMQ = \$█, 5 mg DPMQ = \$█).
- 5.2 Under the General Schedule listing, Ventolin Nebules[®] have an additional brand premium (2.5 mg = \$█, 5 mg = \$█) incorporated in the listing.

6 Consideration of the evidence

Sponsor hearing

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

Consumer comments

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

Clinical trials

- 6.3 As a minor submission, no new clinical trials were presented in the submission.

Economic analysis

6.4 As a minor submission, an economic comparison was not relevant.

Estimated PBS usage & financial implications

6.5 The minor submission estimated there to be no financial implications to the PBS as the pack of 30 ampoules will be substituted by the new pack of 20 ampoules.

7 PBAC Outcome

7.1 The PBAC recommended the change to the current General Schedule listing of Ventolin Nebules[®] by decreasing the pack size and increasing the maximum quantity in terms of packs to maintain the current MQ of 60 ampoules, as the MQ is consistent with similar PBS-listed drugs.

7.2 The PBAC recommended the change to the current emergency supply drug program listing of Ventolin Nebules[®] by decreasing the pack size to 20 ampoules.

7.3 The PBAC recommended that the 20 ampoule presentation be “a” flagged with the PBS-listed salbutamol brands as stated in 3.1, as well as the 30 ampoule presentation.

7.4 The PBAC recommended the addition of the following administrative note to both strengths and number of ampoules of the General Schedule listings:

Pharmaceutical benefits that have a 30 × 2 pack size and a 20 × 3 pack size are equivalent for the purposes of substitution.

7.5 The PBAC maintained that salbutamol be exempt from the Safety Net early supply rule.

7.6 The PBAC noted that this submission is not eligible for an Independent Review. Independent Review is not available in response to a request to modify or extend an existing listing.

Outcome:

Recommended

8 Recommended listing

8.1 Amend maximum quantity as follows:

Public Summary Document – November 2016 PBAC Meeting

Name, Restriction, Manner of administration and form	Max. Qty (Packs)	Max. Qty (Units)	No. of Rpts	Proprietary Name and Manufacturer
SALBUTAMOL 2.5 mg/2.5 mL inhalation: solution, 2.5 mL ampoules, 20	3	3	5	Ventolin Nebules® GlaxoSmithKline Australia Pty Ltd

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Condition:	Asthma Chronic obstructive pulmonary disease (COPD)
PBS Indication:	Asthma Chronic obstructive pulmonary disease (COPD)
Restriction Level / Method:	<input checked="" type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined
Clinical criteria:	Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.
Administrative Advice	Pharmaceutical benefits that have a 30 × 2 pack size and a 20 × 3 pack size are equivalent for the purposes of substitution.

Public Summary Document – November 2016 PBAC Meeting

Name, Restriction, Manner of administration and fom	Max. Qty (Packs)	Max. Qty (Units)	No. of Rpts	Proprietary Name and Manufacturer
SALBUTAMOL 2.5 mg/2.5 mL inhalation: solution, 2.5 mL ampoules, 20	1	1	0	Ventolin Nebules® GlaxoSmithKline Australia Pty Ltd

Category / Program	Prescriber Bag
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined

Name, Restriction, Manner of administration and fom	Max. Qty (Packs)	Max. Qty (Units)	No. of Rpts	Proprietary Name and Manufacturer
SALBUTAMOL 5 mg/2.5 mL inhalation: solution, 2.5 mL ampoules, 20	3	3	5	Ventolin Nebules® GlaxoSmithKline Australia Pty Ltd

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Condition:	Asthma Chronic obstructive pulmonary disease (COPD)
PBS Indication:	Asthma Chronic obstructive pulmonary disease (COPD)
Restriction Level / Method:	<input checked="" type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined
Clinical criteria:	Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.
Administrative Advice	Pharmaceutical benefits that have a 30 × 2 pack size and a 20 × 3 pack size are equivalent for the purposes of substitution.

Public Summary Document – November 2016 PBAC Meeting

Name, Restriction, Manner of administration and form	Max. Qty (Packs)	Max. Qty (Units)	No. of Rpts	Proprietary Name and Manufacturer
SALBUTAMOL 5 mg/2.5 mL inhalation: solution, 1 2.5 mL ampoules, 20	1	1	0	Ventolin Nebules® GlaxoSmithKline Australia Pty Ltd

Category / Program	Prescriber Bag
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required - Emergency <input type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined

9 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.

10 Sponsor's Comment

The sponsor had no comment.