

**6.13 TIOTROPIUM WITH OLODATEROL,
Solution for oral inhalation containing tiotropium
2.5 micrograms (as bromide monohydrate) with
olodaterol 2.5 micrograms (as hydrochloride) per
dose, 60 doses
Spiolto® Respimat®,
Boehringer Ingelheim Pty Ltd**

1 Purpose of Application

- 1.1 The minor submission provided notification that the existing presentation of tiotropium with olodaterol solution for oral inhalation that has a non-reusable inhaler device is to be discontinued/phased out in early 2021 and replaced with (i) a presentation with a re-usable inhaler with dose counter and (ii) a presentation containing just the cartridge refill without the inhaler device. No changes to the listed drugs were otherwise proposed.

2 Background

- 2.1 Currently, Spiolto® Respimat® is formulated as a clear, colourless solution and stored inside an aluminium cylinder (cartridge) for use with the Respimat inhaler. Each pack consists of one Spiolto Respimat inhaler and one cartridge, delivering 60 metered actuations. The current Spiolto Respimat inhaler can only be used with a single cartridge. Once the cartridge is depleted, the Spiolto Respimat inhaler is irreversibly locked and cannot be removed; and is thus non-reusable. For ease of reference, the current Spiolto Respimat inhaler will be referred to as the Spiolto Respimat disposable inhaler for this public summary document and the new presentation (both single pack and single refill pack) will be referred to as Spiolto Respimat re-usable inhaler.
- 2.2 Spiolto Respimat disposable inhaler is currently listed on the PBS as an Authority Required (STREAMLINED) listing for Chronic Obstructive Pulmonary Disease (COPD) (PBS item code 10557P).
- 2.3 The submission stated that the inhalation solution remained the same. There were no changes to the product strength, the dose and dosing regimen or the labelled number of actuations per cartridge. The submission stated that only device components that had no impact on the aerosol performance of the Spiolto Respimat re-usable inhaler had been modified to allow the inhaler to be re-usable as well as improve patient handling and usability. The device components changed include the:
- dose indicator - enlarged in size and now attached to the cartridge instead of the Spiolto Respimat inhaler;

- reversible device lock – changed from irreversible to reversible in order to enable the Spiolto Respimat inhaler to be re-usable. The Spiolto Respimat re-usable inhaler is recommended for use with up to six cartridges, which allows patients to use the same inhaler for up to six months.
- 2.4 Assuming a PBS listing date of 1st March 2021, the submission stated wholesalers will cease supply of the Spiolto Respimat disposable inhaler effective 1st March 2021. The submission stated that only the Spiolto Respimat re-usable inhaler (both single pack and single refill pack) will be able to be distributed from 1st March 2021.

Registration status

- 2.5 Spiolto Respimat re-usable inhaler was TGA registered on 2 March 2020 for the same indication as Spiolto Respimat disposable inhaler.
- 2.6 The TGA Approval Letter dated 2 March 2020 stated that, while Spiolto Respimat re-usable inhaler is a separate and distinct good under subsection 16(1) of the Act, it is the same as the currently registered Spiolto Respimat disposable inhaler except for a new container type with dose indicator for use with the dedicated inhaler device provided as a procedure pack.

For more detail on PBAC's view, see section 6 PBAC outcome.

3 Requested listing

- 3.1 The submission requested the supply of Spiolto Respimat disposable and Spiolto Respimat re-usable inhaler (both the pack that contains the re-usable inhaler and the pack that contains the refill cartridge only) under the existing PBS item code for Spiolto Respimat without the addition of 2 new trade product packs to differentiate the 3 presentations on the PBS schedule. This was the submission's preferred option. The submission also proposed an alternative option should the use of 1 PBS item code not be possible. This alternative option was to add 1 new PBS item code (1 new code for the refill cartridge). The Secretariat proposed 3 separate codes and to mark all 3 presentations equivalent for the purposes of substitution (a-flag) as outlined below.
- 3.2 The option of PBS listing with two additional PBS item codes and 'a' flagging:

Public Summary Document – July 2020 PBAC Meeting

Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	Nº. of Rpts	Dispensed Price Max.Qty	Proprietary Name and Manufacturer
TIOTROPIUM + OLODATEROL tiotropium 2.5 microgram/actuation + olodaterol 2.5 microgram/actuation inhalation solution, 60 actuations	10557P	1	1	5	\$73.06	Spolto Respimat
tiotropium 2.5 microgram/actuation + olodaterol 2.5 microgram/actuation inhalation solution inhaler and cartridge, 60 actuations	NEW	1	1	5	\$73.06	Spolto Respimat
tiotropium 2.5 microgram/actuation + olodaterol 2.5 microgram/actuation inhalation solution cartridge, 60 actuations	NEW	1	1	5	\$73.06	Spolto Respimat

Category / Program: GENERAL – General Schedule (Code GE)
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners
Restriction Type / Method: <input checked="" type="checkbox"/> Authority Required - Streamlined
Condition: Chronic obstructive pulmonary disease
Indication: Chronic obstructive pulmonary disease
Clinical criteria:
Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA);
OR
Clinical criteria:
Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA)
OR
Clinical criteria:
Patient must have been stabilised on a combination of a LAMA and a LABA
Administrative Advice: This product is not PBS-subsidised for the treatment of asthma.
Administrative Advice: This product is not indicated for the initiation of bronchodilator therapy in COPD
Administrative Advice: The treatment must not be used in combination with an ICS/LABA, LAMA, LABA, or SAMA
Administrative Advice: A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.
Administrative Advice: A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.
Administrative Advice: A SAMA includes ipratropium
Administrative Advice:
Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.
Administrative Advice:
Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before “stepping up” a patient’s medication regimen.
Administrative Advice
<i>Pharmaceutical benefits that have the form tiotropium 2.5 microgram/actuation + olodaterol 2.5 microgram/actuation inhalation solution and tiotropium 2.5 microgram/actuation + olodaterol 2.5 microgram/actuation inhalation solution inhaler and cartridge and pharmaceutical benefits that have the form tiotropium 2.5 microgram/actuation + olodaterol 2.5 microgram/actuation inhalation solution cartridge are equivalent for the purposes of substitution.</i>

For more detail on PBAC’s view, see section 6 PBAC outcome.

4 Comparator

4.1 The submission did not nominate a comparator. However, the submission proposed a new re-usable inhaler presentation of tiotropium with olodaterol solution for oral

inhalation, and compared this to the currently listed tiotropium with olodaterol disposable inhaler of the same drug.

5 Consideration of the evidence

Sponsor hearing

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

Consumer comments

5.2 The PBAC noted and welcomed the input from organisations (1) via the Consumer Comments facility on the PBS website. The comments from the Lung Foundation described a range of benefits of treatment with the Spiolto Respimat re-usable inhaler including the ease-of-use and the reduced environmental footprint.

Clinical trials

5.3 As a minor submission, no clinical trials were presented in the submission.

Drug cost/patient/year: \$876.72

5.4 The submission stated the approved ex-manufacturer price of the Spiolto Respimat re-usable (both single pack and single refill pack) would be the same as the current Spiolto Respimat disposable inhaler (AEMP \$57.27).

5.5 The estimated drug cost per patient per year for Spiolto Respimat re-usable inhaler was \$876.72 based on the proposed dispensed price for maximum quantity (DPMQ \$73.06) and 12 scripts per year.

Estimated PBS usage & financial implications

5.6 The minor submission estimated there to be no financial implications to the PBS or changes in PBS usage as the submission expected Spiolto Respimat re-usable inhaler to only substitute for Spiolto Respimat disposable inhaler and both forms of tiotropium with olodaterol have the same price.

5.7 Although not a matter for the PBAC, the addition of two listings of the same drug/combination item to the Listing Instrument may have pricing implications under Division 3A of the National Health Act 1953.

Quality Use of Medicines

5.8 The submission stated a number of quality use of medicines activities were planned prior to PBS listing to inform healthcare professionals including prescribers, practice nurses and pharmacists of the change from Spiolto Respimat disposable to re-usable.

For more detail on PBAC's view, see section 6 PBAC outcome.

6 PBAC Outcome

- 6.1 The PBAC held no objections to the planned discontinuation of the existing Spiolto Respimat product and its replacement with an updated product whereby the inhaler device would be re-usable (for up to six cartridges) and the dose counter would be located on the cartridge rather than the inhaler device.
- 6.2 The PBAC noted the submission proposed the approved ex-manufacturer price (AEMP) of the Spiolto Respimat re-usable (both single pack and single refill pack) be the same as the currently listed Spiolto Respimat disposable inhaler AEMP.
- 6.3 The PBAC considered that due to the different contents of the proposed listings (one with inhaler and one without), it would be helpful to have them distinguished in the Schedule for clarity for patients, prescribers and pharmacists. However, the PBAC noted that the Department would take into consideration Australian Medicines Terminology, pharmaceutical item descriptions appearing in the legislative instruments and software vendor requirements before finalising the details of any new listings on the PBS.
- 6.4 The PBAC noted that no changes to the PBS eligibility criteria for the existing Spiolto Respimat listing were proposed.
- 6.5 The PBAC advised, under Section 101 (4AACD) of the National Health Act, should it be determined that new trade products be declared as available brands, that Spiolto Respimat re-usable inhaler (both single pack and single refill pack) and Spiolto Respimat disposable inhaler be considered equivalent for the purposes of substitution (i.e., 'a' flagged) to ensure a smooth transition from the existing product to the updated product. An administrative NOTE could be added to request that healthcare professionals ensure patients understand to use the cartridges with the correct device for the particular cartridge.
- 6.6 The PBAC noted the intention of the sponsor to delist Spiolto Respimat disposable inhaler from 1st March 2021, and considered that a formal request to delist Spiolto Respimat disposable inhaler would be required.
- 6.7 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

To be finalised.

8 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

9 Sponsor's Comment

The sponsor had no comment.