

**5.34 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, pack of 2  
Spiolto® Respimat®  
BOEHRINGER INGELHEIM PTY LTD**

**1 Purpose of Submission**

- 1.1 The Committee Secretariat submission requested a General Schedule Authority Required (STREAMLINED) listing of a new pack size of tiotropium with olodaterol (Spiolto Respimat®) with 2 cartridges x 60 actuations (double pack) for the treatment of chronic obstructive pulmonary disease (COPD) under the same circumstances as the currently listed Spiolto Respimat with corresponding 60-day maximum dispensed quantities (MDQ).

**2 Background**

- 2.1 Spiolto Respimat is currently listed on the PBS as an Authority Required (STREAMLINED) listing for the treatment of COPD.
- 2.2 There are currently two packs available for this listing:
- A: single pack which contains one cartridge of tiotropium solution for inhalation and one re-usable Respimat inhaler device.
  - B: single refill pack which contains one cartridge of tiotropium solution for inhalation only.
- 2.3 As the current PBS listing is not explicit on whether an inhaler device is included in the pack, either pack can be dispensed under the same PBS item code for each indication at the pharmacist's discretion.
- 2.4 The current packs provide 60 actuations, which equates to a 30-day supply at the recommended dose of 2 actuations per day.
- 2.5 The re-usable Respimat inhaler can be used for up to six repeat prescriptions (six cartridges).
- 2.6 On 1 September 2024, Spiolto Respimat was listed with increased MDQs for the purpose of the 60-day prescribing policy. This means pharmacists can dispense two 'A' packs, two 'B' packs, or one 'A' and one 'B' pack at their discretion depending on whether a patient requires a new device (after six cartridges have been used).

2.7 The submission proposed listing a new double pack to list only against the item codes for increased MDQs the increased MDQs for the purpose of 60-day prescribing:

- C: Double pack 1 re-usable Respimat inhaler device and 2 cartridges of tiotropium with olodaterol solution for inhalation. All contents of the double pack are contained within the one outer carton.

### Registration status

2.8 Spiolto Respimat double pack was Therapeutic Goods Administration (TGA) registered on 17 May 2024.

### Previous PBAC consideration

2.9 At its December 2022 meeting, the PBAC recommended Spiolto Respimat as suitable for listing on the PBS with increased maximum dispensed quantities (MDQ).

2.10 The guidance for exclusion of a medicine/medicine group from the increased MDQ for chronic conditions, which was accepted by the PBAC at its December 2022 meeting, states that ‘Medicines must be PBS listed for 5 or more years, or generics of medicines which have been listed for 5 or more years, as severe but rare adverse effects frequently become evident during this period.’

2.11 Spiolto Respimat double pack has not been considered by the PBAC previously.

## 3 Requested listing

3.1 The submission requested the following new listing.

Add new medicinal product pack for the purpose of 60-day dispensing as follows:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Proprietary Name and Manufacturer
TIOTROPIUM + OLODATEROL					
tiotropium 2.5 microgram/actuation + olodaterol 2.5 microgram/actuation inhalation solution, 60 actuations	14530R	2	2	5	Spiolto Respimat
tiotropium 2.5 microgram/actuation + olodaterol 2.5 microgram/actuation inhalation solution inhaler 2 cartridges, 2 x 60 actuations	NEW	1	1	5	
<b>Restriction Summary [NEW] / Treatment of Concept: [NEW]</b>					
<b>Concept ID (for internal Dept. use)</b>	<b>Category / Program:</b> GENERAL – General Schedule (Code GE)				
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners				
	<b>Restriction Level / Method:</b> <input checked="" type="checkbox"/> Authority Required - Streamlined				
	<b>Indication:</b> Chronic obstructive pulmonary disease				
	<b>Clinical criteria</b>				
	The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient				
	<b>AND</b>				
	<b>Clinical criteria:</b>				

	Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); or
	Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); or
	Patient must have been stabilised on a combination of a LAMA and a LABA
	<b>Administrative Advice:</b> This product is not PBS-subsidised for the treatment of asthma.
	<b>Administrative Advice:</b> This product is not indicated for the initiation of bronchodilator therapy in COPD
	<b>Administrative Advice:</b> The treatment must not be used in combination with an ICS/LABA, LAMA, LABA, or SAMA
	<b>Administrative Advice:</b> A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.
	<b>Administrative Advice:</b> A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.
	<b>Administrative Advice:</b> A SAMA includes ipratropium
	<b>Administrative Advice:</b> Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.
	<b>Administrative Advice:</b> Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before “stepping up” a patient’s medication regimen.

- 3.2 The submission requested an approved ex-manufacturer price (AEMP) equivalent to the current increased MDQ listings for Spiolto Respimat (\$114.54).
- 3.3 The submission requested that the new double pack replace the single pack listing for increased MDQ purposes, and the current increased MDQ listing for the single pack be removed from the PBS. The submission did not propose a-flagging the single pack to the double pack.
- 3.4 The Secretariat noted if a-flagging between the pack sizes was permitted, there would be risk of a significant financial impact to the Government through broken pack fees where the double pack could be used to substitute for single packs on the 30-day listings. An option to address this risk could be to add an administrative note as follows to indicate substitution can only occur where two single packs are being used to substitute for a double pack, however an administrative note does not form part of the legal text in the legislative instrument:
- Administrative Advice:**  
*Pharmaceutical benefits that have the form tiotropium 2.5 microgram/actuation inhalation solution, 2 x 60 actuations and pharmaceutical benefits that have the form tiotropium 2.5 microgram/actuation inhalation solution, 60 actuations are equivalent for the purposes of substitution when dispensing 2 cartridges at one time.*
- 3.5 The pre-PBAC response did not support ‘a’ flagging between the different pack sizes (i.e., single pack under 30-day listing and double pack under 60-day listing) because this would reduce the risk of pharmacists splitting the double pack into separate single packs and charging broken pack fees. The pre-PBAC response stated that the intent of the broken pack fees is to compensate pharmacists for the additional work involved in dispensing medications in quantities that are not pre-packaged by the

manufacturer. The pre-PBAC response (p1) stated that given Spiriva Respimat is available as a single pack, there is no reason for pharmacists to split the double pack in order to supply as two single packs under the 30-day listing.

- 3.6 The pre-PBAC response stated it would be reasonable for the double pack to be the only listed pack size against the 60-day MDQ listing as feedback from pharmacists indicated that it would be a more practical and convenient way of fulfilling 60-day prescriptions and would streamline the supply process for pharmacists and minimise potential confusion when selecting the correct product combination for patients. The pre-PBAC response stated that there are potential safety benefits for patients, including minimising the risk of double dosing from being supplied two single inhaler packs (each containing a separate inhaler device) and the potential risk of missing therapy should two cartridge packs be supplied but the patient no longer has their inhaler device to administer the medicine.

## **4 Consideration of the evidence**

### ***Sponsor hearing***

- 4.1 There was no hearing for this item.

### ***Consumer comments***

- 4.2 The PBAC noted and welcomed the input from one organisation via the Consumer Comments facility on the PBS website. The Lung Foundation Australia described a number of benefits of 60-day prescribing for people with COPD including reduced costs associated with prescriptions and travel, particularly for those in rural and remote regions. The Lung Foundation Australia concluded that it was supportive of the expansion of initiatives such as the 60-day Prescription Program that lower out-of-pocket medicine costs for people living with a lung condition and reduce inequities in access to medications.

### ***Drug cost/patient/year: \$823.86***

- 4.3 The estimated drug cost/patient/year would be \$823.86, based on a dispensed price for maximum quantity (DPMQ) of \$137.31 (i.e., each script provides 2 months of treatment - \$137.31 x 6).

**Table 1: Financial implications**

	<b>Single Pack</b>	<b>Double Pack</b>
Pack Qty for 60-day supply	2	1
AEMP	\$57.27	2 * \$57.27 = \$114.54
Wholesaler Mark-up	0.0752 * \$57.27 = \$4.31	0.0752 * \$114.54 = \$8.61
PtP	\$57.27 + \$4.31 = \$61.58 <sup>1</sup>	\$114.54 + \$8.61 = \$123.16
Pharmacy Mark-up	\$5.78	\$5.78
Dispensing fee	\$8.37	\$8.37
DPMQ	\$61.58 * 2 + \$5.78 + \$8.37 = \$137.31	\$123.16 * 1 + \$5.78 + \$8.37 = \$137.31
Cost difference	<b>\$0</b>	

Source: p6 of the submission main body

Prices based on Pharmaceutical Benefits Schedule June 2024

Abbreviations: AEMP = approved ex-manufacturer price; DPMQ = dispensed price maximum quantity; PtP = price to pharmacy; Qty = quantity

Single Pack contains 1 x cartridge with or without an inhaler device, double Pack contains 2 x cartridge with an inhaler device

### ***Estimated PBS usage and financial implications***

4.4 The submission estimated there would be nil net financial impact to the PBS/RPBS for the listing of Spiolto Respimat double pack as a new pharmaceutical item over six years beyond the overall financial implications of the increased MDQ policy. The submission noted there is no cost difference between supply of 1 x Double Pack compared to 2 x single packs as shown in Table 1.

### ***Quality use of medicines***

4.5 The submission stated the proposed listing offers several Quality Use of Medicines (QUM) benefits such as minimising patient confusion and reducing the risk of medication misuse compared to the supply of two separate single packs.

4.6 The submission stated if patients were to receive two A packs (each containing an inhaler device and cartridge), there is a possibility that patients may load both inhaler devices and inadvertently take a double dose of the medication. It claimed the risk of double-dosing is significantly minimised with the double pack as there is only one inhaler device in the pack, thereby allowing only one cartridge to be loaded into the inhaler at any given time. The submission stated several QUM activities are being planned to inform healthcare professionals including medical practitioners and pharmacists of the proposed double pack listing and that existing QUM initiatives will continue for healthcare professionals and patients to ensure correct use and inhaler technique. The PBAC noted it is the responsibility of the dispensing pharmacist to ensure patients are provided with the appropriate number of inhaler devices and are counselled on the safe use of their medication.

4.7 The submission stated the listing of the double pack would result in an overall decrease in the number of inhalers that patients need to discard annually resulting in reduced waste and landfill. This decrease may not be realised in practice, and the listing may instead result in an increase to the number of discarded inhalers. The double pack listing will mean patients will receive a new inhaler every two months, whereas inhalers are re-usable for up to six months. The current MDQ listing should

not result in any unnecessary discarding of inhalers if pharmacists dispense pack A only when required after 5 repeats.

- 4.8 The pre-PBAC response reaffirmed that the proposed listing for the double pack would offer significant QUM benefits such as minimising patient confusion and reducing the risk of medication misuse compared to the supply of two separate single packs. The pre-PBAC response stated that given the current 60-day listing requires the supply of two single packs, it is highly likely that patients are being supplied two inhaler device packs, which can increase the possibility of medication misadventure arising from patients inadvertently loading both inhaler devices and taking a double dose of medication. The pre-PBAC response reaffirmed that several QUM activities have been planned to communicate the 60-day listing to healthcare professionals including medical practitioners and pharmacists (pg 3, pre-PBAC response).

## **5 PBAC Outcome**

- 5.1 The PBAC recommended the General Schedule Authority Required (STREAMLINED) listing of a new pack size of tiotropium with olodaterol (Spiolto Respimat®) with 2 cartridges x 60 actuations for the treatment of chronic obstructive pulmonary disease (COPD) under the same circumstances as the currently listed Spiolto Respimat with corresponding 60-day maximum dispensed quantities (MDQ). The PBAC's recommendation was based on, among other matters, its assessment that the cost-effectiveness of 1 x double pack of Spiolto Respimat would be acceptable if it were cost-minimised against 2 x single packs of Spiolto Respimat.
- 5.2 The PBAC noted that the submission requested that the double pack be the only listed pack size for the 60-day MDQ listing, with the single pack remaining listed against only the 30-day prescription listings. The PBAC recalled that at its December 2022 meeting, Spiolto Respimat was recommended as suitable for listing on the PBS with increased MDQs. The PBAC noted that the single pack was subsequently listed against the increased MDQs for the purpose of the 60-day prescribing policy on 1 September 2024.
- 5.3 The PBAC noted that the submission did not request a-flagging or substitution between the single and double pack sizes. The PBAC also noted that if a-flagging between the pack sizes was permitted, there would be the potential for a significant financial impact to the Government through broken pack fees, where the double pack would be used to substitute for single packs on the 30-day listings. The PBAC noted that the use of an administrative note to indicate substitution can only occur where two single packs are being used to substitute for a double pack does not form part of the legislated text. The PBAC also noted that the pre-PBAC response did not believe 'a' flagging between the different pack sizes was appropriate, and that listing only the double pack against the 60-day MDQ listing would be a more practical and convenient way of fulfilling 60-day prescriptions and would streamline the supply process for pharmacists and minimise potential confusion.

- 5.4 The PBAC advised that the double pack should be the only listed pack size for the 60-day MDQ listing, while the single pack should remain listed against only the 30-day prescription listings as requested by the sponsor. The PBAC noted that the single pack would be removed from the 60-day MDQ listing by the Department when implementing the double pack listing. The PBAC requested the Department work with the sponsor to minimise impacts on patients with existing MDQ prescriptions for the single packs who require a new prescription for the double pack, such as through the application of a Supply Only period.
- 5.5 The PBAC noted under section 85(7)(b) of the *National Health Act 1953*, circumstances determined for different pack quantities of the same pharmaceutical benefit must be the same and therefore both packs would need to be listed for standard MDQ circumstances as well as increased MDQ circumstances if they were determined under the same form. As such, the PBAC advised that listing the double pack as a new form would be appropriate.
- 5.6 The PBAC noted the submission requested an approved ex-manufacturer price (AEMP) equivalent to the current increased MDQ listings for Spiolto Respimat (\$114.54). The PBAC noted no cost difference between the supply of 1 x double pack compared to 2 x single packs and therefore considered that the estimated nil net financial impact to the PBS/RPBS over six years for the listing of the Spiolto Respimat double pack was reasonable.
- 5.7 The PBAC noted that the submission stated that the proposed listing offers several Quality Use of Medicines (QUM) benefits such as minimising patient confusion and reducing the risk of medication misuse compared to the supply of two separate single packs. The PBAC noted that the pre-PBAC response stated that given the current 60-day listing requires the supply of two single packs, it is highly likely that patients are being supplied two inhaler device packs, which can increase the possibility of medication misadventure arising from patients inadvertently loading both inhaler devices and taking a double dose of medication. The PBAC noted the pre-PBAC response reaffirmed that several QUM activities have been planned to communicate the new listing to healthcare professionals including medical practitioners and pharmacists.
- 5.8 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because 1 x double pack of Spiolto Respimat is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over 2 x single packs of Spiolto Respimat, or not expected to address a high and urgent unmet clinical need given the presence of an alternative therapy, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022* for Pricing Pathway A were not met.
- 5.9 The PBAC noted this submission is not eligible for an Independent Review because it received a positive recommendation.

**Outcome:**

Recommended

## 6 Recommended listing

6.1 Add new medicinal product pack for the purpose of 60-day dispensing as follows:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Proprietary Name and Manufacturer
TIOTROPIUM + OLODATEROL					
<i>tiotropium 2.5 microgram/actuation + olodaterol 2.5 microgram/actuation inhalation solution inhaler 2 cartridges, 2 x 60 actuations</i>	NEW	1	1	5	Spiolto RespiMAT
<b>Restriction Summary [15645] / Treatment of Concept: [15691]</b>					
<b>Concept ID (for internal Dept. use)</b>	<b>Category / Program:</b> GENERAL – General Schedule (Code GE)				
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners				
	<b>Restriction Level / Method:</b> <input checked="" type="checkbox"/> Authority Required - Streamlined				
	<b>Indication:</b> Chronic obstructive pulmonary disease				
	<b>Clinical criteria</b>				
	The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient				
	<b>AND</b>				
	<b>Clinical criteria:</b>				
	Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); or				
	Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); or				
	Patient must have been stabilised on a combination of a LAMA and a LABA				
	<b>Administrative Advice:</b> This product is not PBS-subsidised for the treatment of asthma.				
	<b>Administrative Advice:</b> This product is not indicated for the initiation of bronchodilator therapy in COPD				
	<b>Administrative Advice:</b> The treatment must not be used in combination with an ICS/LABA, LAMA, LABA, or SAMA				
	<b>Administrative Advice:</b> A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.				
	<b>Administrative Advice:</b> A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.				
	<b>Administrative Advice:</b> A SAMA includes ipratropium				
	<b>Administrative Advice:</b> Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.				
	<b>Administrative Advice:</b> Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before “stepping up” a patient’s medication regimen.				

6.2 Delist the single packs (item code 14530R) from the 60-day MDQ listings with a 12 month supply only period.

***These restrictions may be subject to further review. Should there be any changes made to the restriction the sponsor will be informed.***

## **7 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.

## **8 Sponsor's Comment**

The sponsor had no comment.