5.33 TIOTROPIUM, Solution for oral inhalation 2.5 micrograms (as bromide monohydrate) per actuation (60 actuations), pack of 2 Spiriva® 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 (Spiriva® Respimat®) with 2 cartridges x 60 actuations (double pack) for the treatment of bronchospasm and dyspnoea associated with chronic obstructive pulmonary disease (COPD) and for the treatment of severe asthma under the same circumstances as the currently listed Spiriva Respimat with corresponding 60-day maximum dispensed quantities (MDQ).

2 Background

2.1 Spiriva Respimat is currently listed on the PBS as a Restricted Benefit for the long-term maintenance treatment of bronchospasm and dyspnoea associated with COPD and for the treatment of severe asthma in adults. Spiriva Respimat is also listed as an Authority Required (STREAMLINED) listing for the treatment of severe asthma in children aged six to seventeen years old.

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, Spiriva 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 pack to list only against the increased MDQ listings for the purpose of 60-day prescribing:

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

Registration status

2.8 Spiriva 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 Spiriva 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 Spiriva 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	№.of Rpts	Proprietary Name and Manufacturer
TIOTROPIUM					
tiotropium 2.5 microgram/actuation inhalation solution, 60 actuations	14499D	2	2	5	Spiriva Respimat
tiotropium 2.5 microgram/actuation inhalation solution inhaler 2 cartridges, 2 x 60 actuations	*NEW*	*1*	*1*	*5*	
Restriction Summary [NEW] / Treatment of Concept: [NEW]					
Concept ID (for internal Dept. use)	**Category / Program:** GENERAL – General Schedule (Code GE)				
	Prescriber type: ☒ Medical Practitioners ☒Nurse practitioners				
	Restriction type: ☒ Restricted benefit				
	Indication: Bronchospasm and dyspnoea associated with chronic obstructive pulmonary disease				
	Treatment Phase: Long-term maintenance treatment				
	Clinical criteria				
	The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient				
	Administrative Advice: The treatment must not be used in combination with a LAMA/LABA or SAMA				

	Administrative Advice: A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/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.

MEDICINAL PRODUCT medicinal product pack	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№.of Rpts**	**Proprietary Name and Manufacturer**
TIOTROPIUM					
tiotropium 2.5 microgram/actuation inhalation solution, 60 actuations	14323W	2	2	5	Spiriva Respimat
tiotropium 2.5 microgram/actuation inhalation solution inhaler 2 cartridges, 2 x 60 actuations	*NEW*	*1*	*1*	*5*	

Restriction Summary [NEW] / Treatment of Concept: [NEW]	
Concept ID (for internal Dept. use)	**Category / Program:** GENERAL – General Schedule (Code GE)
	Prescriber type: ☒Medical Practitioners ☒Nurse practitioners
	Restriction type: ☒ Restricted benefit
	Indication: severe asthma
	Clinical criteria
	The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient
	AND
	Clinical criteria:
	Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of: (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique
	AND
	Clinical criteria:
	The treatment must be used in combination with a maintenance combination of an inhaled corticosteroid (ICS) and a long acting beta-2 agonist (LABA) unless a LABA is contraindicated.
	Population criteria
	Patient must be at least 18 years of age
	Prescribing instructions: 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.
	Administrative Advice: Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

MEDICINAL PRODUCT medicinal product pack	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№.of Rpts**	**Proprietary Name and Manufacturer**
TIOTROPIUM					

tiotropium 2.5 microgram/actuation inhalation solution, 60 actuations	14531T	2	2	5	Spiriva Respimat
tiotropium 2.5 microgram/actuation inhalation solution inhaler 2 cartridges, 2 x 60 actuations	*NEW*	*1*	*1*	*5*	

Restriction Summary [NEW] / Treatment of Concept: [NEW]	
Concept ID (for internal Dept. use)	**Category / Program:** GENERAL – General Schedule (Code GE)
	Prescriber type: ☒Medical Practitioners ☒Nurse practitioners
	Restriction type / Method: ☒Authority Required – Streamlined
	Indication: severe asthma
	Clinical criteria
	The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient
	Treatment criteria
	Must be treated by a respiratory physician, paediatric respiratory physician, clinical immunologist, allergist, paediatrician or general physician experienced in the management of patients with severe asthma; or in consultation with one of these specialists
	Clinical criteria:
	Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented.
	AND
	Clinical criteria:
	Patient must have experienced at least one severe exacerbation prior to receiving PBS-subsidised treatment with this drug for this condition, which has required documented use of systemic corticosteroids in the previous 12 months while receiving optimised asthma therapy; or
	Patient must have experienced frequent episodes of moderate asthma exacerbations prior to receiving PBS-subsidised treatment with this drug for this condition.
	AND
	Clinical criteria:
	The treatment must be used in combination with a maintenance combination of an inhaled corticosteroid (ICS) and a long acting beta-2 agonist (LABA) unless a LABA is contraindicated.
	Population criteria
	Patient must be aged 6 to 17 years inclusive.
	Prescribing instructions: Optimised asthma therapy includes adherence to the maintenance combination of a medium to high dose ICS and a LABA. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative.
	Administrative Advice: Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).
	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: **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners

3.2 The submission requested an approved ex-manufacturer price (AEMP) equivalent to the current increased MDQ listings for Spiriva Respimat ($57.64).

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 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 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: $449.82

4.3 The estimated drug cost/patient/year would be $449.82, based on a dispensed price for maximum quantity (DPMQ) of $74.97 (i.e., each script provides 2 months of treatment - $74.97 x 6).

Table 1: Financial implications

	Single Pack	Double Pack
Pack Qty for 60-day supply	2	1
AEMP	$28.82	2 * $28.82 = $57.64
Wholesaler Mark-up	0.0752 * $28.82 = $2.17	0.0752 * $57.64 = $4.34
PtP	$28.82 + $2.17 = $30.99	$57.64 + $4.33 = $61.98
Pharmacy Mark-up	$4.62	$4.62
Dispensing fee	$8.37	$8.37
DPMQ	$30.99 * 2 + $4.62 + $8.37 = $74.97	$61.98 * 1 + $4.62 + $8.37 = $74.97
Cost difference	**$0**	

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 the Spiriva 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 the single pack size 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 (p3) reaffirmed that several QUM activities have been planned to communicate the 60-day listing to healthcare professionals including medical practitioners and pharmacists.

5 PBAC Outcome

5.1 The PBAC recommended the General Schedule Authority Required (STREAMLINED) listing of a new pack size of tiotropium (Spiriva® Respimat®) with 2 cartridges x 60 actuations for the treatment of bronchospasm and dyspnoea associated with chronic obstructive pulmonary disease (COPD) and for the treatment of severe asthma under the same circumstances as the currently listed Spiriva 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 Spiriva Respimat would be acceptable if it were cost-minimised against 2 x single packs of Spiriva 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, Spiriva 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 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 Spiriva Respimat ($57.64). 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 Spiriva Respimat double pack was reasonable.

5.7 The PBAC noted 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 its recommendation was on a cost-minimisation basis and advised that, because 1 x double pack of Spiriva Respimat is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over 2 x single packs of Spiriva 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					
					Spiriva Respimat
tiotropium 2.5 microgram/actuation inhalation solution inhaler 2 cartridges, 2 x 60 actuations	*NEW*	*1*	*1*	*5*	
Restriction Summary [15752] / Treatment of Concept: [15753]					
Concept ID (for internal Dept. use)	**Category / Program:** GENERAL – General Schedule (Code GE)				
	Prescriber type: ☒ Medical Practitioners ☒Nurse practitioners				
	Restriction type:☒ Restricted benefit				
	Indication: Bronchospasm and dyspnoea associated with chronic obstructive pulmonary disease				
	Treatment Phase: Long-term maintenance treatment				
	Clinical criteria				
	The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient				
	Administrative Advice: The treatment must not be used in combination with a LAMA/LABA or SAMA				
	Administrative Advice: A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/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.				

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Proprietary Name and Manufacturer
TIOTROPIUM					
					Spiriva Respimat
tiotropium 2.5 microgram/actuation inhalation solution inhaler 2 cartridges, 2 x 60 actuations	*NEW*	*1*	*1*	*5*	

Restriction Summary [15674] / Treatment of Concept: [15566]	
Concept ID (for internal Dept. use)	**Category / Program:** GENERAL – General Schedule (Code GE)
	Prescriber type: ☒Medical Practitioners ☒Nurse practitioners
	Restriction type: ☒ Restricted benefit
	Indication: severe asthma
	Clinical criteria
	The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient
	AND
	Clinical criteria:
	Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of: (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique
	AND
	Clinical criteria:
	The treatment must be used in combination with a maintenance combination of an inhaled corticosteroid (ICS) and a long acting beta-2 agonist (LABA) unless a LABA is contraindicated.
	Population criteria
	Patient must be at least 18 years of age
	Prescribing instructions: 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.
	Administrative Advice: Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Proprietary Name and Manufacturer
TIOTROPIUM					
					Spiriva Respimat
tiotropium 2.5 microgram/actuation inhalation solution inhaler 2 cartridges, 2 x 60 actuations	*NEW*	*1*	*1*	*5*	

Restriction Summary [15720] / Treatment of Concept: [15754]	
Concept ID (for internal Dept. use)	**Category / Program:** GENERAL – General Schedule (Code GE)
	Prescriber type: ☒Medical Practitioners ☒Nurse practitioners
	Restriction type / Method: ☒Authority Required – Streamlined
	Indication: severe asthma

	Clinical criteria
	The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient
	Treatment criteria
	Must be treated by a respiratory physician, paediatric respiratory physician, clinical immunologist, allergist, paediatrician or general physician experienced in the management of patients with severe asthma; or in consultation with one of these specialists
	Clinical criteria:
	Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented.
	AND
	Clinical criteria:
	Patient must have experienced at least one severe exacerbation prior to receiving PBS-subsidised treatment with this drug for this condition, which has required documented use of systemic corticosteroids in the previous 12 months while receiving optimised asthma therapy; or
	Patient must have experienced frequent episodes of moderate asthma exacerbations prior to receiving PBS-subsidised treatment with this drug for this condition.
	AND
	Clinical criteria:
	The treatment must be used in combination with a maintenance combination of an inhaled corticosteroid (ICS) and a long acting beta-2 agonist (LABA) unless a LABA is contraindicated.
	Population criteria
	Patient must be aged 6 to 17 years inclusive.
	Prescribing instructions: Optimised asthma therapy includes adherence to the maintenance combination of a medium to high dose ICS and a LABA. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative.
	Administrative Advice: Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).
	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: **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners

6.2 Delist the single packs from the 60-day MDQ listing with a 12 month supply only period. Item codes to be delisted include: 14499D, 14323W and 14531T.

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

9 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.

10 Sponsor's Comment

The sponsor had no comment.