PUBLIC SUMMARY DOCUMENT

Product: ACLIDINIUM BROMIDE, 400 microgram/actuation inhalation: powder for, 60 actuations, Bretaris® Genuair®
Sponsor: A.Menarini Australia Pty Ltd
Date of PBAC Consideration: March 2014

1. Purpose of Application

The submission proposed the inclusion of aclidinium bromide 400 µg on the Pharmaceutical Benefits Scheme (PBS) as a restricted benefit item for treatment of chronic obstructive pulmonary disease (COPD).

2. Background

Aclidinium bromide had not previously been considered by the PBAC.

3. Registration Status

The submission was made under TGA/PBAC Parallel Process. At the time of PBAC consideration, the Clinical Evaluation Report, TGA Delegate's Overview, and ACPM resolution were available.

Aclidinium bromide was TGA registered on 25 March 2014 and is indicated as a long-term maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).

4. Listing Requested and PBAC's View

Restricted benefit
Chronic obstructive pulmonary disease

The PBAC noted that the proposed restriction is consistent with that of the comparator, tiotropium, and the restriction recommended for glycopyrronium bromide at the November 2013 PBAC meeting.

Listing was requested on a cost-minimisation basis with tiotropium with a maximum quantity of one inhaler (60 actuations) with five repeats.

The PBAC noted that the listing as requested would allow use of aclidinium bromide for treatment of COPD as monotherapy, in combination with a long acting beta agonist (LABA) and in combination with a LABA and an inhaled corticosteroid (ICS).

Additionally, the PBAC noted that no forced expiratory volume in one second (FEV_1) cut-off levels were included in the proposed restriction, allowing use of aclidinium bromide in patients with any disease severity.

5. Clinical Place for the Proposed Therapy

Long acting muscarinic antagonists (LAMAs) such as aclidinium bromide, are recommended in the treatment algorithm for patients with moderate, severe and very severe COPD, and in some patients with mild COPD who may be experiencing high levels of breathlessness. LAMAs can be used either as monotherapy or in combination with a LABA as patients experience more breathlessness. Where patients experience frequent exacerbations then a bronchodilator with an ICS is currently recommended

The submission proposed that the PBS listing of aclidinium bromide would provide an alternative treatment choice for prescribers and could be used as monotherapy, in combination with a LABA or in combination with a LABA and an ICS.

The PBAC noted that the clinical management algorithm provided by the applicant was based on the Therapeutic Guidelines and the submission assumed that aclidinium bromide would be a substitute for tiotropium. The staged approach outlined in the submission was similar to the COPD-X Guidelines and the recommended Australian clinical management algorithm. However, unlike the guidelines, there were no FEV_1 cut-offs provided in the proposed clinical treatment algorithm.

6. Comparator

The submission nominated tiotropium as the comparator. The PBAC agreed that this was the appropriate comparator.

The PBAC recalled its November 2013 recommendation for glycopyrronium bromide for treatment of COPD and considered that glycopyrronium bromide may also be a relevant comparator.

7. Clinical Trials

The submission was based on one key six-week head-to-head randomised controlled trial comparing aclidinium bromide to tiotropium and placebo (n=414) and meta-analyses of an indirect comparison of aclidinium bromide and tiotropium using placebo as the common comparator.

Details of the published trials presented in the submission are shown in the table below.

Trial	Protocol title/ Publication title	Publication citation
Direct randomised trials		
LAS-39	A multiple dose, double-blind, double-dummy, placebo controlled, parallel clinical trial to assess the efficacy and safety or twice daily inhaled aclidinium bromide 400 µg compared to placebo and to tiotropium bromide in patients with stable moderate to severe chronic obstructive pulmonary disease (COPD).	Clinical study report M/34273/39. Almirall, Spain. 31 August 2012

Indirect comparison trials using placebo as a common comparator		
Aclidinium trials		
ACCORD	Efficacy and safety of aclidinium bromide at two dose levels (200 µg twice daily, 400 µg twice daily) vs. placebo when administered to patients with moderate to severe chronic obstructive pulmonary disease (COPD).	Clinical study report LAS-MD-33. Forest Research Institute, USA. 21 Jan 2011
ATTAIN	Efficacy and safety of aclidinium bromide at two dose levels vs. placebo when administered to patients with moderate to severe chronic obstructive pulmonary disease (COPD).	Clinical study report M/34273/34. Almirall, Spain. 12 April 2011
ACCORD II	A randomised, double-blind, placebo-controlled study evaluating the efficacy, safety and tolerability of 2 doses of aclidinium bromide compared with placebo for 12 weeks in patients with moderate to severe, stable chronic obstructive pulmonary disease followed by a 40-week evaluation of the higher aclidinium bromide dose.	Clinical study report LAS-MD-38 (Part A). Forest Research Institute, USA. 16 Mar 2011
Tiotropium trials		
Beeh	Efficacy of tiotropium bromide (Spiriva®) in patients with chronic obstructive pulmonary disease (COPD) of different severities.	Beeh KM, et al. Pneumologie. 2006;60:341-346.
Brusasco	Health outcomes following treatment for six months with once daily tiotropium compared with twice daily salmeterol in patients with COPD.	Brusasco V, et al. Thorax. 2003;58:399-404.
Casaburi	A long-term evaluation of once-daily inhaled tiotropium in chronic obstructive pulmonary disease.	Casaburi R, et al. Eur Respir J. 2002;19:217-224.
Covelli	Absence of electrocardiographic findings and improved function with once-daily tiotropium in patients with chronic obstructive pulmonary disease.	Covelli H, et al. Pharmacotherapy. 2005:25:1708-1718.
Freeman	Efficacy and safety of tiotropium in COPD patients in primary care – the SPiRiva Usual CarE (SPRUCE) study.	Freeman D, et al. Respiratory Research. 2007;8(45)
Johansson	Bronchodilator efficacy of tiotropium in patients with mild to moderate COPD.	Johansson G et al. Primary Care Respiratory Journal. 2008;17(3):169-175.
Niewoehner	Prevention of exacerbations of chronic obstructive pulmonary disease with tiotropium, a once-daily inhaled anticholinergic bronchodilator.	Niewoehner DE, et al. Ann Int Med. 2005;143:317-326.
SAFE	A randomised controlled trial to assess the efficacy of tiotropium in Canadian patients with chronic obstructive pulmonary disease.	Chan CKN, et al. Can Respir J. 2007;14:465-472.
SAFE-Portugal	Tiotropium improves FEV_1 in patients with COPD irrespective of smoking status.	Moita J, et al. Pulmonary Pharmacology and Therapeutics. 2008;21:146-151.
Sun	Evaluation of clinical effect and safety of tiotropium bromide in treating stable chronic obstructive pulmonary disease.	Sun LH, et al. Zhongguo Xinyao yu Linchuang Zazhi. 2007;26(5):328-331.
Tonnel	Effect of tiotropium on health-related quality of life as a primary efficacy endpoint in COPD.	Tonnel AB, et al. Int J of COPD. 2008;3(2):301-310.
UPLIFT	A 4-year trial of tiotropium in chronic obstructive pulmonary disease.	Tashkin DP, et al. N Engl J Med. 2008;359(15):1543-1554.
Verkindre	The effect of tiotropium on hyperinflation and exercise capacity in chronic obstructive pulmonary disease.	Verkindre C, et al. Respiration. 2006;73:420-427.

Meta-analyses tiotropium		
Karner	Tiotropium versus placebo for chronic obstructive pulmonary disease	Karner et al. Cochrane Database of Systematic Reviews 2012, Issue 7. Art No: CD009285
Systematic review and network analysis		
Karabis	Comparative efficacy of aclidinium versus glycopyrronium and tiotropium, as maintenance treatment of moderate to severe COPD patients: a systematic review and network analysis	Karabis et al. Int J of COPD 2013:8 405-423

COPD = chronic obstructive pulmonary disease; FEV1 = forced expiratory volume in one second; GOLD = Global Initiative for Chronic Obstructive Lung Disease

The key features of the direct and indirect randomised trials are presented in the table below.

Trial	N	Design	Duration	Risk of bias	Patient population COPD	Outcome
Direct randomised trial						
LAS-39	414	R, MC, MD, DB, DD, PC	6 wks	Low	Stable moderate-severe	Change in trough FEV_1 at week 6
Indirect comparison trials using placebo as common comparator						
Aclidinium trials						
ACCORD	561	R, MC, DB, PC	12 wks	Low	Moderate-severe	Change in trough FEV_1
ATTAIN	828	R, MC, DB, PC	24 wks	Low	Moderate-severe	Change in trough FEV_1
ACCORD II	544	R, MC, DB, PC	12/40 wks	Low	Moderate-severe	Change in trough FEV_1
Tiotropium trials						
Beeh	1,639	R, MC, DB, PC	12 wks	Low	COPD	Trough FEV_1; FVC
Brusasco	802	R, MC, DB, DD	24 wks	Low	Stable COPD	FEV_1; FVC; Exacerbations
Casaburi	921	R, MC, DB, PC	49 wks	Low	Stable COPD	FEV_1; FVC
Covelli	196	R, MC, DB, PC	12 wks	Unclear	COPD	Trough FEV_1
Freeman	395	R, MC, DB, PC	12 wks	Low	Stable COPD	Trough FEV_1
Johansson	224	R, MC, DB, PC	12 wks	Low	Mild-moderate	FEV_1 AUC_{0-2}, trough; FEV_1
Niewoehner	1,829	R, MC, DB, PC	26 wks	Low	Moderate-severe	Exacerbations
SAFE	913	R, MC, DB, PC	48 wks	Low	COPD	Trough FEV_1
SAFE-Portugal	311	R, MC, DB, PC	12 wks	Low	COPD	Trough FEV_1
Sun	60	R, DB, PC	12 wks	Unclear	Stable COPD	FEV_1; Symptom improvement
Tonnel	554	R, MC, DB, PC	39 wks	Low	COPD	SGRQ; FEV_1
UPLIFT	5,993	R, MC, DB, PC	4 yrs	Low	COPD	Trough FEV_1
Verkindre	100	R, MC, DB, PC	12 wks	Low	Moderate-severe	Trough FEV_1

AUC = area under the curve; COPD = chronic obstructive pulmonary disease; DB=double blind; DD = double dummy; FEV_1 = Forced expiratory volume in one second; FVC = forced vital capacity; MC = multi centre; MD = multiple dose; N = number in trial; PC = placebo controlled; R = randomised; SGRQ = St George's respiratory questionnaire; wks = weeks; yrs = years

The PBAC noted that no consumer comments were received for this item. The PBAC noted that there was no hearing for this item.

8. Results of Trials

The submission stated that the generally accepted minimum clinical important difference (MCID) in trough FEV_1 is 100 to 140 mL. This was based on the July 2011 PBAC Public Summary Document for indacaterol where the PBAC considered that differences less than 100 mL are non-significant. The submission therefore considered that differences less than 100 mL in trough FEV_1 are non-significant and support the conclusion of non-inferiority.

The clinically relevant outcome provided in the submission was trough FEV_1. In the direct trial, this was measured at six weeks and in the indirect comparison at 12 weeks.

The results of change from baseline in trough FEV_1 in the direct randomised trial (LAS-39) at week six for the intention to treat (ITT) population are presented in the table below.

	Statistic	Placebo (N=85)	Aclidinium (N=171)	Tiotropium (N=158)
Change from baseline at week 6				
	LS mean (SE)	-0.112 (0.024)	0.029 (0.018)	-0.009 (0.018)
Between-group difference				
Aclidinium/tiotropium vs. placebo	LSMD (95% CI)		**0.141 (0.083, 0.199)**	**0.102 (0.043, 0.161)**
Aclidinium vs. tiotropium	LSMD (95% CI)		0.038 (-0.010, 0.087)	

CI = confidence interval; FEV1 = forced expiratory volume in one second; LS = least squares; LSMD = least squares mean difference; N = number in trial arm; SE = standard error; Bold = statistically significant result

The PBAC noted that at six weeks, aclidinium bromide showed a statistically significant increase in adjusted mean change from baseline in pre-dose trough FEV_1 compared to placebo. When compared to tiotropium the change was not statistically significant.

The results of the indirect comparison of aclidinium bromide versus tiotropium, using placebo as the common reference, for change in trough FEV_1 at week 12 for the ITT population are presented in the table below.

Outcome	Aclidinium trials		Tiotropium trials		Indirect estimate MD (95% CI)
	N trials (n)	MD (95% CI)	N trials (n)	MD / OR (95% CI)	
Change in trough FEV1 (L); MD	3 a (1,276)	0.10 (0.07, 0.13) I2 = 32%	10 b (5,675)	0.11 (0.09, 0.14) I2 = 64%	-0.01 (-0.05, 0.03)

CI = confidence interval; FEV1 = forced expiratory volume in one second; MD = mean difference; N = number of trials; n= number in meta-analysis; Bold = statistically significant outcome
a ACCORD, ATTAIN and ACCORD II
b Beeh, Casaburi, Covelli, Freeman, Johansson, Niewoehner, SAFE, SAFE-Portugal, Sun and Verkindre

At week 12, both aclidinium bromide and tiotropium resulted in statistically significant increases compared to placebo in adjusted mean change from baseline in pre-dose FEV_1. The indirect estimate was not statistically significant.

The PBAC noted that the increase in FEV_1 for aclidinium bromide compared to placebo was smaller in the indirect comparison than the direct trial. The PBAC also noted that the meta-analyses performed for the indirect comparison indicated that there was heterogeneity between the aclidinium bromide trials (I^2 = 32%) as well as the tiotropium trials (I^2 = 64%).

The results from the additional indirect comparisons at 12 and 24 weeks provided similar outcomes as the indirect comparison for trough FEV_1 at 12 weeks, with no statistically significant differences between aclidinium bromide and tiotropium, using placebo as the common comparator.

The submission presented single arm long-term follow up data from the ACCORD (LAS-36) and ACCORD II (LAS-38B) trials, and provided a naïve comparison with tiotropium trials that report results at 52 weeks. Efficacy results for aclidinium bromide and tiotropium at 52 weeks are presented in the table below.

	Aclidinium trials		**Tiotropium trials**			
	LAS-36	**LAS-38B**	**Casaburi**	**Dusser**	**Powrie**	**UPLIFT**
N	448	289	921	1,010	142	5,993
Efficacy						
≥ 1 exacerbation (%)	26.1%	23.1%	36.0%	49.9%	43.5%	NR
Change form baseline in trough FEV1 (L)	0.069	0.048	0.11	NR	0.04	0.09
Change from baseline in SGRQ (units)	-5.68	-6.82	-3.18	NR	NR	-5.26

FEV1 = forced expiratory volume in one second; N = number in trial; NR = not reported; SGRQ = St George's respiratory questionnaire

The submission claimed that based on the naïve indirect comparison, aclidinium bromide appears to produce superior results for COPD exacerbations and St George's respiratory questionnaire (SGRQ) outcomes, and similar results for change in trough FEV_1. The submission stated that these results support the claim of non-inferiority.

Overall, the PBAC accepted that treatment with aclidinium bromide resulted in neither a statistically significant, nor clinically relevant, difference in change in FEV_1 compared to tiotropium.

With regard to comparative harms, there were no statistically significant differences in the occurrence of adverse events or serious adverse events between aclidinium bromide and tiotropium and the incidence of anticholinergic events was low in all treatment arms. The most common adverse events that led to discontinuation from the trials were COPD exacerbations and dyspnoea. The most common treatment-emergent adverse events were headache, nasopharyngitis, COPD exacerbation and cough.

The PBAC noted that two patients treated with aclidinium bromide and two patients treated with tiotropium reported a treatment-emergent cardiac disorder. Although the incidence of cardiac adverse events was low, the PBAC noted that the European Medicines Agency lists aclidinium bromide as a medicinal product under additional monitoring to closely monitor for cardiovascular effects. The PBAC also noted that a trial to evaluate the risk of major adverse cardiac events with aclidinium bromide in patients with COPD is scheduled for completion in

2017, but was somewhat reassured by a study[1] of the impact of tiotropium when added to ICS and LABA therapy in COPD on mortality and exacerbations.

A safety issue not measured in the trials was the potential for patients to be prescribed a higher than recommended dose of LAMA. A predicted versus actual utilisation review of indacaterol conducted by the Drug Utilisation Sub Committee (DUSC) highlighted the potential for confusion and incorrect dosing of fixed dose combination (FDC) products. The DUSC analysis showed that 20.8% of patients who initiated indacaterol between December 2011 and November 2012 were also taking, and continued to take, an ICS/LABA concomitantly (i.e. these patients added indacaterol to an ICS/LABA); there is no clinical evidence to support the safety or efficacy of using two LABAs. The PBAC agreed with the Economics Sub-Committee (ESC) that the introduction of a third single-agent LAMA could further increase the risk of confusion and incorrect and double-dosing of COPD medicines. The use of inappropriately high doses of LAMA would lead to an unknown but likely increased risk of harm.

9. Clinical Claim

The submission described aclidinium bromide as non-inferior in terms of effectiveness and non-inferior in terms of safety compared to tiotropium.

The PBAC noted the following concerns raised in the Commentary and the ESC advice:

- that patients in the clinical trials may be different to the likely PBS population (LAS-39 excluded patients with upper respiratory tract infections and recent exacerbations of COPD),
- LAS-39 was not designed to study non-inferiority and was only six weeks in duration,
- no data were presented for use of aclidinium bromide in combination with a LABA or a LABA+ICS, and
- the evidence for trough FEV_1 at 12 weeks being derived from an indirect comparison where the tiotropium analyses had high levels of heterogeneity.

On balance, however, the PBAC considered that the data presented supported the submission's claim of non-inferior comparative efficacy and comparative safety of aclidinium bromide over tiotropium.

10. Economic Analysis

The submission presented a cost-minimisation analysis using a comparison of drug costs only. The equi-effective doses were estimated as aclidinium bromide 400 µg twice daily and tiotropium 18 µg once daily, based on the trials presented.

The PBAC considered that a cost-minimisation analysis was the correct approach based on the evidence presented.

[1] Short PM et al. The Impact of Tiotropium on Mortality and Exacerbations When Added to Inhaled Corticosteroids and Long-Acting B-Agonist Therapy in COPD. CHEST 2012; 141(1): 81-86

The PBAC noted that the submission proposed a lower dispensed price for maximum quantity (DPMQ) for aclidinium bromide 400 µg compared to the current DPMQ for tiotropium 18 µg. The PBAC noted that unlike tiotropium, the price for aclidinium bromide incorporates the cost of the included inhaler device, whereas patients prescribed tiotropium are required to purchase an inhaler device separately.

11. Estimated PBS Usage and Financial Implications

The submission used a market share approach to estimate utilisation and financial implications of aclidinium bromide and tiotropium over a five-year time horizon.
The number of aclidinium prescriptions per year was estimated in the submission to be more than 200,000 in Year 5. The listing of aclidinium bromide was estimated to result in a total net saving to the PBS/RPBS of between $10 and $30 million over the first five years, due to the predicted substitution only from tiotropium and the lower DPMQ of aclidinium bromide compared to tiotropium.

The market growth rate for LAMAs was based on PBS prescribing data for tiotropium over the period July 2007 to June 2013, where growth increased on average by 6% per year. The submission assumed, given the maturity of the market, that growth would remain constant over the forward estimate period. The PBAC agreed with the DUSC that this may not be reasonable. The DUSC noted that the most recent GOLD guidelines reiterate the risks associated with long-term use of inhaled corticosteroids (pneumonia and increased fracture risk) and emphasise that these medicines should not be prescribed outside of their indications. The DUSC considered that it was possible that this advice might delay transition of COPD patients to treatment with ICS/LABA and thus expand the use of LAMAs. The PBAC noted the results of a sensitivity analysis investigating the effect of a 20% increase in aclidinium bromide scripts with no change in the number of tiotropium scripts (i.e., an increase in the overall market) showed that listing of aclidinium bromide would result in a net cost to the PBS of less than $100,000 over five years.

The submission assumed an increasing market share from Year 1 to Year 5 of listing, modelled on patterns observed for indacaterol. The DUSC considered that the initially low uptake estimated may be reasonable, given that aclidinium bromide may be the third single agent LAMA to be PBS-subsidised, and that twice daily dosing of aclidinium bromide may be less favourable than once daily dosing of tiotropium and glycopyrronium.

The PBAC noted the sponsor's willingness to discuss options for a risk-sharing arrangement for aclidinium bromide, due to there being residual uncertainty relating to uptake and usage. The PBAC recalled it had recommended a risk share agreement (RSA) be put in place to mitigate larger than predicted market growth and the risk of leakage into the mild COPD market in its consideration of the submission for glycopyrronium bromide in November 2013.

With regard to the quality use of medicines (QUM), the PBAC shared the DUSC's concerns that there was a risk in the PBS-listing of a third LAMA that a combination of LAMA agents may be inadvertently used together. Further, the PBAC agreed with the DUSC's concerns that the trade names and proliferation of inhalers may potentially be confusing for both prescribers and patients. The DUSC highlighted that using two LAMAs together could present significant clinical risk, which may lead to increased use of other medicines to treat

side effects. A recent DUSC analysis (October 2013) of indacaterol utilisation showed that co-administration of COPD therapies is common, with many patient supplied a combination of medicines that is not consistent with COPD treatment guidelines. However, the DUSC noted that aclidinium bromide is provided as a preloaded inhaler, diminishing the risk of patients using the incorrect inhaler device for their medicine.

The DUSC also noted newly emerging data that shows that there may be a role for LAMAs in the treatment of asthma, when used in conjunction with an ICS (with or without a LABA), although this has not yet been fully determined.

In view of the above-mentioned issues, the PBAC referred the matter of QUM of COPD treatments to NPS MedicineWise and requested they produce information and education for prescribers in relation to this matter.

12. PBAC Outcome

The PBAC recommended listing of aclidinium bromide as a restricted benefit for chronic obstructive pulmonary disease with a maximum quantity of one pack with five repeats. Listing was recommended at the price proposed in the submission, with the PBAC noting the lower DPMQ offered for aclidinium bromide compared with tiotropium. The trial-based equi-effective doses are aclidinium bromide 400 µg twice daily and tiotropium 18 µg once daily.

The PBAC accepted that tiotropium is the appropriate comparator but also considered that glycopyrronium bromide (recommended at the November 2013 PBAC meeting) may also be a relevant comparator.

Based on the data provided, the PBAC accepted that treatment with aclidinium bromide resulted in changes in FEV_1 that were comparable to those associated with tiotropium. Differences in effect on FEV_1 were neither statistically significant, nor clinically relevant. The PBAC considered that the data provided adequately supported the submission's claim that aclidinium bromide is non-inferior in terms of comparative effectiveness and comparative safety to tiotropium.

The PBAC noted that no trial data were presented for use of aclidinium bromide in combination with a LABA or a LABA+ICS. The PBAC noted the sponsor's advice in its pre-PBAC response that patients in the aclidinium bromide trials were permitted to continue treatment with ICS provided that doses were equivalent to 10 mg prednisone per day or 20 mg every other day and stable for at least 4 weeks prior to study entry. Results for the sub-population analyses of the pooled studies ATTAIN and ACCORD-I for the mean change from baseline to week 12 in trough FEV_1 showed no statistically significant differences in the adjusted mean treatment differences between aclidinium bromide and placebo based on concomitant use of ICS. The PBAC also noted the sponsor's claim in the pre-PBAC response that there is no pharmacological reason to suggest that aclidinium bromide treatment could not be combined for co-administration with other agents for COPD. The PBAC recalled that in its November 2013 consideration of glycopyrronium bromide, the studies that best supported the non-inferiority claim were the trials presented for monotherapy, and thus listing was recommended with the same restriction as that requested for aclidinium bromide.

The PBAC considered that a cost-minimisation economic analysis was the appropriate approach based on the evidence presented for non-inferiority. The PBAC noted that the submission proposed a lower dispensed price for maximum quantity (DPMQ) for aclidinium bromide 400 µg than the current DPMQ for tiotropium 18 µg. The PBAC accepted the proposed price for aclidinium bromide.

The PBAC noted the sponsor's willingness to discuss options for a risk-sharing arrangement for aclidinium bromide, due to there being residual uncertainty relating to uptake and usage. The PBAC recalled it had recommended a risk share agreement (RSA) be put in place to mitigate larger than predicted market growth and the risk of leakage into the mild COPD market in its consideration of the submission for glycopyrronium bromide in November 2013.

The PBAC recommended that the Safety Net 20 Day Rule should apply.

The PBAC advised that aclidinium bromide is suitable for inclusion in the PBS medicines for prescribing by nurse practitioners within collaborative arrangements.
The PBAC advised the Minister that under Section 101 3BA of the *National Health Act,* aclidinium bromide should be treated as interchangeable on an individual patient basis with tiotropium and glycopyrronium bromide.

Outcome:
Recommended

Recommendation:
Add new item:

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer	
Aclidinium Inhalation: powder for, 400 microgram/actuation, 60 actuations	1	5	Bretaris®	A. Menarini Australia Pty Ltd

Condition:	Chronic obstructive pulmonary disease
Restriction:	Restricted Benefit

13. 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.

14. Sponsor's Comment

The sponsor is pleased with the decision and the availability on the PBS of a new treatment for COPD.