

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MAY 2023 PBAC MEETING**

The PBAC outcomes and recommendations are presented in alphabetical order by drug name.

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME	
<p>FLUTICASONE PROPIONATE</p> <p>Pressurised inhalation containing fluticasone propionate 50 micrograms per dose, 120 doses (CFC-free formulation)</p> <p>Axotide Junior® Flixotide Junior®</p> <p>GlaxoSmithKline Australia Pty Ltd</p> <p>(Change to PBS listing)</p>	<p>Asthma</p>	<p>To review the circumstances of the General Schedule Authority Required listing for patients under 6 years with asthma.</p>	<p>Recommended</p>	<p>The PBAC recalled its previous advice to amend the restrictions for fluticasone propionate 50 mcg metered dose inhaler had been provided in the context of the sponsor's request for Ministerial Discretion to avoid the 1 April 2023 catch-up statutory price reductions. The PBAC had been asked to provide advice as to whether there were any clinical alternatives available on the PBS and whether the delisting of the item would result in an unmet clinical need.</p> <p>At the time of its previous recommendation, the PBAC noted the relevant alternate therapies, beclomethasone and budesonide would remain available under the existing conditions. However, the PBAC noted that fluticasone propionate 50 mcg is the only metred aerosol for use in patients under 6 years of age and the only low dose metred aerosol registered for use in Australia by the Therapeutic Goods Administration. Therefore, the PBAC advised there was a clinical need to retain fluticasone propionate 50 mcg on the PBS for patients under 6 years of age due to the lack of clinical alternatives in this population. The PBAC noted the strong concerns that had been raised by clinicians and professional organisations regarding the restriction changes implemented on 1 April 2023.</p> <p>The PBAC acknowledged these concerns, including that the current listings may create difficulties in patient access, particularly for those in rural or remote areas, those unable to secure timely respiratory specialist appointments, and those who cannot afford private consultations or the private cost of the medicine. The PBAC noted this had not been the intended effect of its previous advice.</p> <p>Therefore, to reduce the impact on patient access, the PBAC recommended the following changes to the existing restrictions for fluticasone propionate 50 mcg:</p> <ul style="list-style-type: none"> • Remove existing restrictions on prescriber type, including the criterion that treatment must be initiated by a respiratory physician or paediatrician. • Amend the authority approval method from Authority Required (Telephone/Online) to Authority Required (STREAMLINED). • Allow patients who start and are stabilised on treatment before 6 years of age to continue PBS access beyond 6 years of age.

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			<p>The PBAC recommended that a review of utilisation be undertaken in two years to assess any impact on utilisation resulting from these changes.</p> <p>The PBAC recommended that fluticasone could return to an unrestricted listing if the price for patients aged 6 years and above were reduced as per the legislated 1 April 2023 catch up reduction. The PBAC considered that the cost-effectiveness of fluticasone propionate 50 mcg would be acceptable under these circumstances, where the price would be more consistent with the alternative therapies. While the PBAC considered an unrestricted listing would provide the greatest patient access and reduction in administrative burden for prescribers, it noted that accepting a price consistent with the legislated 1 April 2023 catch up reduction would be a commercial decision for the medicine's sponsor.</p>