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** |
| --- | --- | --- | --- |
| BECLOMETASONE WITH FORMOTEROL AND GLYCOPYRRONIUMPressurised inhalation containing beclometasone dipropionate 100 micrograms with formoterol fumarate dihydrate 6 micrograms and glycopyrronium 10 micrograms (as bromide) per dose, 120 dosesPressurised inhalation containing beclometasone dipropionate 200 micrograms with formoterol fumarate dihydrate 6 micrograms and glycopyrronium 10 micrograms (as bromide) per dose, 120 dosesTrimbow®Chiesi Australia Pty LtdCategory 2 submission(New PBS listing) | Asthma | To request a General Schedule Authority Required (STREAMLINED) listing for the maintenance treatment of asthma in adult patients not adequately controlled with a maintenance combination of a long-acting beta2-agonist and an inhaled corticosteroid who experienced one or more asthma exacerbations in the previous year. | Recommended | The PBAC recommended the Authority Required (Streamlined) listing for a fixed dose combination (FDC) of beclometasone (BEC) with formoterol (FOR) and glycopyrronium (GLY) for the maintenance therapy of severe asthma. Noting the TGA Delegate supported registration of BEC/FOR/GLY for this indication, the PBAC was satisfied the remaining outstanding issues relating to the application were satisfactorily resolved.The PBAC considered the cost of BEC/FOR/GLY should be no greater than the lowest price combination at approved ex-manufacturer price (AEMP) level of the PBS listed components of triple therapy that are available for asthma at comparable doses. |

**Submission category types**

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| **Category 1** | A request for PBS or NIP listing of one or more of the following: * A first in class medicine or vaccine, and/or a medicine or vaccine for a new population. OR
* A drug with a codependent technology that requires an integrated codependent submission to the PBAC and MSAC. OR
* A drug or designated vaccine with a TGA Provisional determination related to the proposed population.
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| **Category 2** | A request for PBS or NIP listing of a new medicine or new vaccine, a new indication of a currently listed medicine or vaccine, or to make material changes to a currently listed indication and do not meet the criteria for a Category 1 submission. |
| **Category 3** | Requests to change existing listings that do not change the population or cost-effectiveness of the medicine or vaccine that do not meet the criteria for a Category 4 submission. |
| **Category 4**  | A request for one or more of the following: * Listing of a new pharmaceutical item of a listed medicine.
* Consideration as an exempt item (Exempt item as per subsection 84AH of the *National Health Act 1953*).
* Including a listed medicine on the prescriber bag, or varying an existing prescriber bag listing.
* A change/new manner of administration of a listed medicine.
* A change to the maximum quantity and/or number of repeats of a listed medicine.
* A change or addition to the prescriber type(s) of a listed medicine.
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| **Committee Secretariat** | Application is not in Categories 1, 2, 3 or 4 and requests for one or more of the following:* New or varied listed drugs, medicinal preparations and designated vaccines that pose no greater risk
* Pharmaceutical benefits that can no longer be supplied early
* New brand of glucose indicator pharmaceutical item.
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