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 GLYCOPYRRONIUM  Pressurised inhalation containing beclometasone dipropionate 100 micrograms with formoterol fumarate dihydrate 6 micrograms and glycopyrronium 10 micrograms (as bromide) per dose, 120 doses  Pressurised inhalation containing beclometasone dipropionate 200 micrograms with formoterol fumarate dihydrate 6 micrograms and glycopyrronium 10 micrograms (as bromide) per dose, 120 doses  Trimbow®  Chiesi Australia Pty Ltd  Category 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. |
| **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. |
| **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. |