

ITEMS RECOMMENDED BETWEEN ORDINARY MEETINGS (JULY 2020 – NOVEMBER 2020)

SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>INDACATEROL + GLYCOPYRRONIUM + MOMETASONE</p> <p>Capsule containing powder for oral inhalation mometasone furoate 80 micrograms with indacaterol 150 micrograms (as acetate) with glycopyrronium 50 micrograms (as bromide) (for use in Breezhaler)</p> <p>Capsule containing powder for oral inhalation mometasone furoate 160 micrograms with indacaterol 150 micrograms (as acetate) with glycopyrronium 50 micrograms (as bromide) (for use in Breezhaler)</p> <p>Energair Breezhaler®</p> <p>Novartis Pharmaceuticals Australia Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Asthma</p>	<p>To request an Authority Required (STREAMLINED) listing for the treatment of patients with severe asthma who are inadequately controlled on a long acting beta agonist in combination with an inhaled corticosteroid (LABA/ICS).</p>	<p>The PBAC recommended the Authority Required (Telephone/Electronic/Emergency) listing of mometasone furoate (MF), with indacaterol acetate (IND), and glycopyrronium (GLY) fixed dose combination (FDC) for maintenance therapy of severe asthma. Noting the TGA has registered both medium dose MF/IND/GLY and high dose MF/IND/GLY for this indication, the PBAC was satisfied the remaining outstanding issues relating to this application were satisfactorily resolved.</p> <p>The PBAC considered that medium and high dose MF/IND/GLY should be priced no higher than the lowest cost combination of respective medium and high dose ICS/LABA plus LAMA combinations.</p>