

ITEMS RECOMMENDED BETWEEN ORDINARY MEETINGS (NOVEMBER 2020 – MARCH 2021)

SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>ADRENALINE</p> <p>I.M. injection 150 micrograms in 0.3 mL single dose syringe auto-injector</p> <p>I.M. injection 300 micrograms in 0.3 mL single dose syringe auto-injector</p> <p>I.M. injection 500 micrograms in 0.3 mL single dose syringe auto-injector</p> <p>Anapen®</p> <p>Allergy Concepts Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Acute allergic reaction with anaphylaxis</p>	<p>To request the Authority Required listing of an alternative brand of adrenaline auto-injector under the same conditions as other brands of adrenaline currently listed on the PBS and to request the Authority Required listing of a new strength of adrenaline auto-injector.</p>	<p>The PBAC recommended the General Schedule Authority Required listing of adrenaline auto-injectors Anapen 300®, Anapen 500® and Anapen 150 Junior® (Anapen Junior) for the treatment of acute allergic reaction with anaphylaxis. The PBAC recommended Anapen 300 and Anapen 500 on a cost-minimisation basis to EpiPen; and Anapen Junior to EpiPen Jr. The PBAC considered that the claim of non-inferior comparative effectiveness and safety was acceptable based on the advice in the TGA Delegate's Overview.</p> <p>The PBAC advised that the equi-effective doses should be consistent with PBAC's previous recommendation of Anapen 300 and Anapen Junior at its March 2010 meeting; and Anapen 500 at its November 2011 meeting. The PBAC advised that the equi-effective doses are:</p> <ul style="list-style-type: none"> • one Anapen 300 and one Anapen 500 and one EpiPen 300 and one Adrenaline Mylan 300 • one Anapen Junior and one EpiPen Jr and one Adrenaline Jr Mylan <p>The PBAC advised that under Section 101(4AACD) of the <i>National Health Act 1953</i>, in the Schedule of Pharmaceutical Benefits, Anapen 300 should be treated as equivalent at the pharmacy level (i.e. 'a' flagged in the Schedule) for the purpose of substitution for the treatment of acute allergic reaction with anaphylaxis with EpiPen 300 and Adrenaline Mylan 300; and Anapen Junior should be treated as equivalent at the pharmacy level (i.e. 'a' flagged in the Schedule) for the purpose of substitution for the treatment of acute allergic reaction with anaphylaxis with EpiPen Jr and Adrenaline Jr Mylan. The PBAC was satisfied that the differences in administration techniques of Anapen, EpiPen and Adrenaline Mylan would be appropriately managed. The PBAC advised that Anapen 500 should not be treated as equivalent at the pharmacy level (i.e. 'a' flagged in the Schedule) for the purpose of substitution for the treatment of acute allergic reaction with anaphylaxis with other adrenaline auto injectors as there are no other adrenaline auto injector products on the PBS with this strength. The PBAC reiterated that the substitutability of Anapen, EpiPen and Adrenaline Mylan would assist in the timely dispensing of adrenaline during shortages.</p>