

JULY 2020 PBAC MEETING – ITEMS AWAITING TGA OUTCOMES

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>EPINEPHRINE</p> <p>I.M Injection, 150 micrograms in 0.3 mL, pen device I.M Injection, 300 micrograms in 0.3 mL, pen device</p> <p>Symjepi®</p> <p>Emerge Health Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Acute allergic reactions including anaphylaxis</p>	<p>To request the Authority Required PBS listing of Symjepi® for the emergency treatment of allergic reactions.</p>	<p>The PBAC recommendation cannot be made public until the TGA outcome is known.</p>
<p>NIVOLUMAB + IPILIMUMAB</p> <p>Nivolumab: Injection concentrate for I.V. infusion 40 mg in 4 mL Injection concentrate for I.V. infusion 100 mg in 10 mL</p> <p>Opdivo®</p> <p>Ipilimumab: Injection concentrate for I.V. infusion 50 mg in 10 mL</p> <p>Yervoy®</p> <p>Bristol-Myers Squibb Australia Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Non-small cell lung cancer (NSCLC)</p>	<p>To request an extension to the current Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listings for nivolumab and ipilimumab to include the first-line treatment of patients with Stage IV NSCLC.</p>	<p>The PBAC recommendation cannot be made public until the TGA outcome is known.</p>