

DECEMBER 2020 PBAC OUTCOMES – POSITIVE RECOMMENDATIONS

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>GLECAPREVIR + PIBRENTASVIR</p> <p>Tablet containing 100 mg glecaprevir with 40 mg pibrentasvir</p> <p>Maviret®</p> <p>AbbVie Pty Ltd</p> <p>Change to listing (Matters outstanding)</p>	<p>Chronic hepatitis C infection</p>	<p>To request an amendment to the Section 100 (Highly Specialised Drugs Program) and General Schedule Authority Required listings to reduce the duration of treatment from 12 weeks to 8 weeks for treatment naïve patients with chronic hepatitis C with compensated cirrhosis.</p>	<p>The PBAC recommended amending the listing of glecaprevir with pibrentasvir (GLE/PIB) to include an 8-week treatment option for the treatment of chronic hepatitis C (CHC) infection in patients who are treatment-naïve with compensated cirrhosis (TN/CC). The PBAC's recommendation was based on, among other matters, its assessment that an 8-week regimen of GLE/PIB in TN/CC patients achieves similar therapeutic outcomes to the currently PBS-listed 12-week regimen.</p> <p>In making this recommendation, the PBAC noted the TGA registration had now been finalised, which included retention of the 12-week regimen for the TN/CC population as an option for use at the discretion of the treating clinician. Consistent with its view expressed at its November 2020 meeting, the PBAC agreed that this regimen should be retained as an option and included as a footnote to the General Statement for simplicity.</p>
<p>SAPROPTERIN</p> <p>Powder for oral solution 500 mg Tablet (soluble) 100 mg</p> <p>Kuvan®</p> <p>Biomarin Pharmaceutical Australia Pty Ltd</p> <p>Change to listing (Matters outstanding)</p>	<p>Maternal phenylketonuria (MPKU)</p>	<p>Resubmission to request an Authority Required listing in combination with a phenylalanine (Phe)-restricted diet for the treatment of MPKU where a Phe-restricted diet does not adequately reduce blood Phe levels.</p>	<p>The PBAC recommended the Authority Required listing of sapropterin in combination with a phenylalanine (Phe)-restricted diet for the treatment of MPKU.</p> <p>The PBAC noted there is a high clinical need in a small patient population, and acknowledged the input received from individuals, organisations and health professionals in relation to the November 2020 submission. Further, the PBAC noted the strong consumer feedback describing the very high clinical need for access to sapropterin for any adult with PKU. The PBAC would welcome a major resubmission for this broader population.</p>