

MAY 2020 PBAC MEETING – POSITIVE RECOMMENDATIONS

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>METHOXSALEN</p> <p>Solution for blood fraction, 20 microgram per mL, 10 mL</p> <p>Uvadex®</p> <p>Terumo BCT Australia Pty Limited</p> <p>New listing (Major Submission)</p>	<p>Erythrodermic cutaneous T-cell lymphoma</p>	<p>To consider the deferred request for a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for the treatment of patients with advanced stage, erythrodermic cutaneous T-cell lymphoma under certain conditions, as part of treatment with integrated, closed system, extracorporeal photopheresis.</p>	<p>The PBAC recommended the Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing of methoxsalen, delivered as part of an extracorporeal photopheresis (ECP) service for the treatment of refractory erythrodermic stage III-IVa T4 M0 cutaneous T-cell lymphoma (CTCL), either as monotherapy or in combination with peginterferon alfa-2a. The PBAC was satisfied that ECP involving methoxsalen provides, for some patients, a significant reduction in toxicity over the nominated comparators (methotrexate, interferon alfa, vorinostat, and brentuximab vedotin).</p> <p>The PBAC noted that MSAC accepted the claim of superiority for safety and non-inferiority for efficacy between ECP involving methoxsalen and the nominated comparators, and that the evidence is unlikely to improve in the context of this rare cancer. Further, the PBAC noted MSAC's advice that ECP involving methoxsalen is likely cost-effective taking into account the high clinical need and the small number of patients.</p>