

March 2009 PBAC OUTCOMES – Results of Independent Review

Drug and Form	Listing Requested By Sponsor	Sponsor's Reasons For Seeking Review	Results Of Independent Review	PBAC Outcome and Comments
<p>IMIQUIMOD, cream 50 mg per g (5%), 250 mg single use sachets, 12, Aldara[®] iNova Pharmaceuticals (Aust) Pty Ltd</p> <p><u>TGA INDICATION:</u> For treatment of solar (actinic) keratosis on the face and the scalp, and primary treatment of confirmed superficial basal cell carcinoma where surgery is considered inappropriate, and the treatment of external genital and peri-anal warts (Condyloma acuminata) in adults.</p>	<p><u>Authority Required</u> Solar keratosis on the face or scalp in a patient with normal immune function who has multiple clinically evident solar keratosis lesions and requires topical drug treatment as field therapy.</p> <p>NOTE: The patient or carer must be able to understand and administer the imiquimod dosing regimen. No applications for increased maximum quantities and/or repeats will be authorised.</p>	<p>The issues upon which review is sought are:</p> <ol style="list-style-type: none"> 1. Is there value in treating solar keratosis ? 2. Is there certainty of imiquimod's comparative effectiveness? 3. Is there a safety issue with imiquimod as a true field therapy? 4. Is imiquimod a cost-effective therapy for solar keratosis? 	<p>The Independent Review concluded that “the superiority of imiquimod over its active comparators 5-fluorouracil (5-FU) and cryotherapy has not been established and at best it can be considered a non-inferior treatment for solar keratosis. Accordingly, we have conducted a cost-minimisation analysis. This analysis shows that imiquimod is significantly more expensive than the two relevant comparators, 5-FU and cryotherapy”.</p>	<p>The PBAC noted the findings of the Independent Review and considered that the Review provided no new basis for the Committee to reconsider its recommendation made at the July 2008 meeting.</p>
			<p>Sponsor's comments:</p>	<p>The sponsor has no comment.</p>