

JULY 2016 PBAC OUTCOMES – SUBSEQUENT DECISIONS NOT TO RECOMMEND

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	TGA INDICATION	CURRENT PBS LISTING	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>ADALIMUMAB</p> <p>40 mg/0.8 mL injection, 2 x 0.8 mL cartridges 40 mg/0.8 mL injection, 2 x 0.8 mL syringes 40 mg/0.8 mL injection, 6 x 0.8 mL cartridges 40 mg/0.8 mL injection, 6 x 0.8 mL syringes</p> <p>Humira®</p> <p>AbbVie Pty Ltd</p> <p>Change to listing</p> <p>(Minor Submission)</p>	<p>Adalimumab is indicated for reducing signs and symptoms in moderate to severe rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, enthesitis-related arthritis, psoriatic arthritis, Crohn's Disease, ulcerative colitis, chronic plaque psoriasis, active ankylosing spondylitis and hidradenitis suppurativa.</p>	<p>Adalimumab is currently listed for severe Crohn disease, severe active juvenile idiopathic arthritis, complex refractory fistulising Crohn disease, ankylosing spondylitis, severe chronic plaque psoriasis, severe active rheumatoid arthritis and severe psoriatic arthritis.</p> <p>For more details see the PBS Schedule.</p>	<p>Re-submission for Authority Required listing for the treatment of moderate to severe hidradenitis suppurativa (HS).</p>	<p>The PBAC did not recommend adalimumab for PBS listing for moderate to severe HS on the basis of an unfavourable and uncertain estimate of the incremental cost effectiveness ratio.</p>
			<p>Comparator: best supportive care (BSC)</p>	<p>Accepted.</p>
			<p>Clinical claim: superior efficacy and inferior safety of adalimumab compared with BSC</p>	<p>The PBAC considered that the claim of superior comparative effectiveness was adequately supported by the data for the first 12 weeks of treatment. The PBAC noted that the requested listing restricted continuing treatment to those patients who are responding to adalimumab. The sponsor provided updated results of an open label extension study in the pre-PBAC response. The PBAC noted that this was new evidence for the minor submission which was provided a week before the meeting and therefore it had not been formally evaluated. While the PBAC considered that the claim of superior comparative effectiveness may be reasonable beyond 12 weeks, the PBAC did not accept the modelled benefit extending over 20 years when most patients discontinued treatment within 3.5 years.</p> <p>The PBAC accepted the claim of inferior safety.</p>
			<p>Economic claim: cost-utility analysis of adalimumab versus BSC</p>	<p>Not accepted. The PBAC did not accept the extrapolation of incremental benefit beyond discontinuation of treatment which meant that the overall cost effectiveness was considered to be uncertain.</p>

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			Sponsor's comments:	AbbVie is committed to working with physicians, patients and the PBAC to make Humira available for patients who suffer with hidradenitis suppurativa in this area of recognised high unmet need.