JULY 2020 PBAC OUTCOMES – OTHER MATTERS

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
Matters relating to the Post-market Review (PMR) of the use of biologics for the treatment of chronic plaque psoriasis (CPP): Cost-effectiveness Review (CER) ETANERCEPT INFLIXIMAB ADALIMUMAB USTEKINUMAB SECUKINUMAB IXEKIZUMAB GUSELKUMAB TILDRAKIZUMAB RISANKIZUMAB (All listed brands)	CPP	To consider the findings from the CER of biologics for CPP recommended by PBAC in April 2018 following consideration of the PMR. http://www.pbs.gov.au/info/reviews/post-market-biologics This review assesses the cost-effectiveness of biologics in the eligible population under the current Authority Required PBS restrictions for severe CPP and the proposed population presenting with moderate to severe CPP.	The PBAC considered the CER of biologics for the treatment of CPP, the DUSC and ESC advice, the pre-PBAC responses and other feedback from stakeholders and the PMR reference group. The PBAC recalled that in April 2018, based on the findings from Terms of Reference 1, 2 and 3 of the PMR of biologics for the treatment of severe CPP, the Committee recommended a review of the cost-effectiveness of biologics for severe CPP under Term of Reference 4. The PBAC requested a CER to consider the additional PBS populations treated with biologics that meet the eligibility criteria of a baseline Psoriasis Area and Severity Index (PASI) of ≥12 to ≤15 and a Dermatology Life Quality Index (DLQI) >10. Where possible this analysis should also consider the inclusion of the 'OR DLQI > 10' population in addition to those who meet the combined eligibility requirement of a baseline PASI of ≥12 to ≤15 and a DLQI >10. The PBAC noted that the incremental cost-effectiveness ratio (ICER) for the PASI >15 subgroup was between $15,000- 45,000 and the ICER for the PASI ≥12 to ≤15 subgroup was between $105,000 – 200,000. The PBAC noted that the ICERs in the two populations were highly sensitive to the utility values applied in the CER, and considered the ICER for the PASI ≥12 population to be unacceptably high. The PBAC noted the DUSC advice that the estimates for the additional population (with baseline PASI ≥12 to ≤15) treated with a biologic were high and uncertain. In addition, a significant price reduction would be required for the proportion of use in this population (baseline PASI ≥12 to ≤15) relative to those treated under the current PBS indication (PASI >15) specific price in order to maintain the same ICER (cost-effectiveness) across both populations. As a result, the PBAC did not recommend expanding the PBS restrictions for CPP to include patients with a baseline PASI score of ≥12 to ≤15. The PBAC noted that it was open to submissions from Sponsors to extend the PBS listings for any of the biologics used to treat CPP to the

			PASI ≥12 to ≤15 OR DLQI >10 population at a cost-effective price at any time.