| **DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION** | **DRUG TYPE AND USE** | **LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION** | **PBAC OUTCOME** |
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| 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. |