

Post-market Review of the use of biologics in the treatment of severe chronic plaque psoriasis

Plain language summary

Background

In December 2015, the PBAC recommended a Post-market Review (PMR) of the use of biologics for the treatment of severe chronic plaque psoriasis (the Review). The Minister for Health approved the Review's commencement on 7 April 2016.

The Review's purpose was to evaluate the use, safety, efficacy and cost-effectiveness ('value for money') of Pharmaceutical Benefits Scheme (PBS) listed biologics for the treatment of severe chronic plaque psoriasis (CPP). In line with the published PMR Framework, a Reference Group was established to provide independent expert clinical advice and there were a number of opportunities for stakeholder consultation and contribution to the Review.

The PBS listed medicines for the treatment of CPP included in the Review were:

- adalimumab
- etanercept
- infliximab
- ustekinumab
- secukinumab
- ixekizumab

Key Findings for each Term of Reference (ToR)

There were four ToRs to guide the Review. The key findings for each ToR follow:

ToR 1: Review current clinical guidelines for the treatment of severe chronic plaque psoriasis and compare to the Pharmaceutical Benefits Scheme (PBS) restrictions for use of biologics in this indication.

- The key clinical guidance documents of relevance to Australian practice were Baker 2013¹ and the Australasian College of Dermatologists (ACD) 2017² consensus statements.

¹ Baker C, Mack A, Cooper A, Fischer G, Shumack S, Sidhu S, et al. Treatment goals for moderate to severe psoriasis: an Australian consensus. [Erratum appears in Australas J Dermatol. 2014 Feb;55(1):94 Note: Soyer, Peter [corrected to Soyer, H Peter]]. Australasian Journal of Dermatology. 54(2):148-54..

² The Australasian College of Dermatologists. Treatment goals for psoriasis: The Australian Psoriasis Treatment Goals Project <https://www.dermcoll.edu.au/wp-content/uploads/ACD-Consensus-Statement-Treatment-goals-for-psoriasis-March-2017.pdf>2017

- The key differences between the PBS prescribing rules and the Australian consensus statements were that the PBS prescribing rules:
 - Required patients to trial at least three second-line therapies before being eligible for PBS-subsidised biologics, versus at least two recommended in the Australian consensus statements;
 - Required patients to have more severe CPP to be eligible for biologic therapy than was recommended in the Australian consensus statements. The consensus statements recommended that biologics be used to treat moderate-to-severe CPP; and
 - Did not account for the quality of life (QoL) impacts of CPP. The Australian consensus statements recommend the use of biologics in patients whose QoL was significantly impacted.

ToR 2: Review and evaluate recent clinical evidence on the efficacy and safety of biologics used in the treatment of severe chronic plaque psoriasis and compare to the evidence considered by Pharmaceutical Benefits Advisory Committee (PBAC) in previous sponsor submissions.

- The Review found that updated evidence on the efficacy and safety of biologics was generally consistent with that previously considered by the PBAC.
- The severity of CPP is measured by the Psoriasis Area and Severity Index (PASI) score. Scores range from 0 to 72, with higher scores indicating more severe disease. There was some variation in the efficacy and safety results between different biologics for severe CPP (PASI greater than 15).
- Overall, the efficacy of biologics compared to placebo showed that all PBS-listed biologics provide patients with clinically meaningful improvements in their psoriasis.
- There is very little data available for biologics in the moderate disease category (PASI greater than 10 but less than or equal to 15), even though the consensus from international and Australian guidelines was that biologics can and should be used in moderate CPP. The evidence available suggested that in the milder disease categories, response would be less than in those with more severe disease.

ToR 3: Review the utilisation of PBS biologics for the treatment of CPP including time on treatment and discontinuation from treatment, and compare this with that observed in the clinical trial evidence considered by the PBAC.

- The number of people affected with severe CPP (PASI greater than 15) in Australia was estimated to be around 19,000 in 2016.
- The number of patients being treated with biologics increased by over 60%, from 3,185 patients in the first quarter of 2014 to 5,144 patients in the last quarter of 2016. Ustekinumab was the most commonly used biologic, with 46% of patients being treated with this biologic in 2016.

- Commonwealth expenditure on biologics for CPP increased from approximately \$79 million in 2014 to approximately \$121 million in 2016 (PBS published prices).

ToR 4: Subject to the findings from Terms of Reference 1, 2 and 3, review the cost-effectiveness of biologics for severe chronic plaque psoriasis

- Considering the findings from Terms of Reference 1, 2 and 3, the Pharmaceutical Benefits Advisory Committee (PBAC) recommended a review of the cost-effectiveness ('value for money') of biologics for severe CPP under Term of Reference 4.
- The cost-effectiveness review (CER) found that biologics are less cost-effective (provide less 'value for money') in patients with less severe CPP compared to those currently eligible for PBS-subsidised biologics.

Outcomes

The PBAC considered the PMR report addressing ToRs 1-3 in April 2018 and the CER report in July 2020. The PBAC's recommendations to the Minister for Health from these meetings and the PMR report is available on the [Review webpage](#).