

7.06 GUSELKUMAB, Injection 100 mg in 1 mL single use pre-filled pen, Tremfya[®], Janssen-Cilag Pty Ltd

1 Purpose of Application

- 1.1 The minor resubmission requested the PBAC reconsider its July 2020 recommendation so that guselkumab 100 mg pre-filled pen (PFP) is cost-minimised against the guselkumab 100 mg pre-filled syringe (PFS) rather than against the lowest cost biological disease modifying antirheumatic drugs (bDMARDs).

2 Background

Previous PBAC consideration

- 2.1 At its July 2020 meeting, the PBAC recommended listing guselkumab 100 mg PFP, under the same arrangements as the currently listed guselkumab PFS, on a cost-minimisation basis against the lowest cost bDMARDs available for severe chronic plaque psoriasis (CPP).
- 2.2 The PBAC considered that any of the current PBS-listed bDMARDs for severe CPP could be an alternative therapy to guselkumab and that other relevant comparators may include adalimumab, etanercept, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab (guselkumab, Public Summary Document (PSD), July 2020).

For more detail on PBAC's view, see section 5 PBAC outcome.

3 Comparator

- 3.1 The Sponsor disagreed with the July 2020 PBAC recommendation that the other current PBS-listed bDMARDs for severe CPP are relevant comparators for guselkumab PFP, stating that guselkumab PFP will primarily replace the PBS-listed guselkumab PFS.
- 3.2 The resubmission argued that guselkumab PFS is the appropriate comparator for guselkumab PFP because it is the same drug, manner of administration, and dosage as the PFS, and the PFP form would only replace the guselkumab PFS in clinical practice and would not change the utilisation of any other bDMARDs for severe CPP. The PBAC recalled its consideration in July 2018 and July 2020 that any of the current PBS-listed bDMARDs for severe CPP could be an alternative therapy to guselkumab. The PBAC further recalled that PFS was recommended on a cost-minimisation basis against the lowest cost biological agent available for severe CPP.

3.3 The resubmission provided a summary of previous PBAC considerations of new PFP or auto-injector presentations of bDMARDs for which a subcutaneous injection presentation was already listed (Table 1). The resubmission argued that in each of these cases the PBAC recommended on the basis that the new form would only replace the existing form of the same medicine, without reference to the potential replacement of other medicines. The PBAC noted that none of these cases were considered for the treatment of CPP.

Table 1: Summary of previous PBAC considerations of new biological forms discussed in the resubmission

Medication	Discussion
certolizumab pegol auto-injector/pre-filled pen (PFP)	<p>The PBAC considered the certolizumab PFS on 3 separate occasions prior to March 2017, and in all three instances, the PBAC recommended PBS listing of the certolizumab PFS on a cost-minimisation basis with adalimumab.</p> <p>At its March 2017 meeting, the PBAC recommended PBS listing of the certolizumab PFP with the same conditions as the listed PFS presentation and cost-minimised to the PFS presentation (certolizumab pegol PSD, March 2017).</p>
tocilizumab auto-injector	<p>Tocilizumab PFS was initially recommended at the March 2016 PBAC meeting on a cost-minimisation basis with the lowest cost biologic.</p> <p>At its July 2018 meeting, the PBAC recommended a new subcutaneously administered presentation of tocilizumab, an auto-injector for the treatment of severe active RA, under the same conditions as the listed PFS and cost-minimised to the PFS presentation (tocilizumab PSD, July 2018).</p>
mepolizumab PFP and PFS and benralizumab PFP	<p>Mepolizumab vial was first recommended in March 2016 on a cost minimisation basis with omalizumab. Subsequently, benralizumab PFS was recommended in March 2018 on a cost-minimisation basis with mepolizumab.</p> <p>At its March 2020 meeting, the PBAC recommended the PBS listing of two new presentations of mepolizumab, a PFP and PFS, on a cost-minimisation basis to the mepolizumab vial (mepolizumab PSD, March 2020). At the same meeting, the PBAC recommended a new presentation of benralizumab PFP on a cost-minimisation basis with benralizumab PFS (benralizumab PSD, March 2020).</p>

Source: guselkumab resubmission, pg. 2-4.

3.4 The *National Health Act 1953* (the Act), Section 101(3B) stipulates that if the requested treatment is substantially more costly than alternative therapies, then the PBAC could only recommend listing at the higher price if it is satisfied that the treatment provides, for some patients, a significant improvement in efficacy or reduction of toxicity over the existing therapies. The advice provided by the PBAC applies to each medicine on a case by case basis. In this case, the PBAC considered guselkumab PFP did not satisfy the criteria for a price higher than the lowest cost of other available PBS-listed bDMARDs for the treatment of CPP.

For more detail on PBAC’s view, see section 5 PBAC outcome.

4 Consideration of the evidence

Sponsor hearing

4.1 There was no hearing for this item.

Consumer comments

4.2 The PBAC noted the input from the Australasian College of Dermatologists that the listing of guselkumab PFP will enable more patients to self-inject and reduce the need for regular eight weekly visits to their doctor for patients who are unable to use the currently PBS-listed guselkumab PFS.

Estimated PBS usage & financial implications

4.3 The minor resubmission maintained there to be no financial implications to the PBS or changes in PBS usage as guselkumab PFP is expected to only substitute for guselkumab PFS.

4.4 While not a matter for PBAC, in its July 2020 application the sponsor stated the guselkumab PFP should be considered a ‘new presentation’ of an existing brand of guselkumab and not trigger a statutory price reduction, under section 99ACB(3A) of the Act. The Minister’s delegate considered the sponsor’s request and considered that guselkumab PFP is a new presentation. As such, if the listing of guselkumab PFP occurs prior to 1 February 2024, it will not trigger a 25% first new brand reduction.

For more detail on PBAC’s view, see section 5 PBAC outcome.

5 PBAC Outcome

5.1 The PBAC reaffirmed its recommendation at its July 2020 meeting that guselkumab 100 mg pre-filled pen (PFP) be listed, under the same arrangements as the currently listed guselkumab pre-filled syringe (PFS), on a cost-minimisation basis against the lowest cost PBS-listed biological disease-modifying antirheumatic drugs (bDMARDs) for the treatment of severe chronic plaque psoriasis (CPP).

5.2 The PBAC maintained its July 2020 recommendation that any of the current PBS-listed bDMARDs for severe CPP could be an alternative therapy to guselkumab and that other relevant comparators may include adalimumab, etanercept, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab (guselkumab, Public Summary Document (PSD), July 2020).

5.3 The PBAC noted that to recommend listing guselkumab PFP at the higher price it would need to be satisfied that the treatment provides, for some patients, a significant improvement in efficacy or reduction of toxicity over the existing therapies. In this case, the PBAC considered that guselkumab PFP did not meet these criteria to be listed at a price higher than the lowest cost of PBS-listed bDMARDs for the treatment of severe CPP. The PBAC noted that there is not a high clinical need for a PFP for CPP given there are multiple agents available on the PBS for CPP.

- 5.4 The PBAC maintained its view from July 2020 that because guselkumab PFP is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over guselkumab PFS, or not expected to address a high and urgent unmet clinical need given the presence of an alternative therapy, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2009* for Pricing Pathway A were not met.
- 5.5 The PBAC noted that this submission is not eligible for an Independent Review.

Outcome:

Rejected

6 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

7 Sponsor's Comment

The sponsor had no comment.