

**14.03(k) GUSELKUMAB,
Solution for injection 100 mg in 1 mL pen device,
Tremfya[®],
Janssen-Cilag Pty Ltd.**

1 Purpose of Application

1.1 The Committee Secretariat submission sought PBS listing of a new pre-filled pen (PFP) form of guselkumab (Tremfya[®]) 100 mg under the same conditions as the existing pre-filled syringe (PFS) form.

2 Background

Registration status

2.1 Guselkumab PFP was TGA registered on 13 May 2020 for the treatment of adult patients (18 years or older) with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. The approval was based on demonstrated bioequivalence between the PFP and the PFS forms.

3 Requested listing

3.1 The submission requested the listing of guselkumab PFP under the same conditions as the currently PBS-listed guselkumab PFS.

Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Dispensed Price Max.Qty	Brand Name
GUSELKUMAB guselkumab 100 mg/mL injection, 1 mL pen device	NEW	1	1	2	\$3786.74 (published) \$ [REDACTED] (effective)	Tremfya
guselkumab 100 mg/mL injection, 1 mL syringe	11614G	1	1	2	\$3786.74 (published) \$ [REDACTED] (effective)	Tremfya

3.2 The current restriction does not prevent Services Australia from approving requests for concurrent use of the PFP and PFS. An Administrative Advice was proposed to clarify that patients are not to be approved for concurrent use, which would flow on to the current PFS restriction.

For more detail on PBAC's view, see section 6 PBAC outcome.

4 Comparator

4.1 The submission proposed a new form of guselkumab, and compared this to the currently listed form of the same drug. This comparator was appropriate, however in its July 2018 consideration of guselkumab PFS, the PBAC considered that any of the current PBS-listed bDMARDs for severe CPP could be an alternative therapy to

guselkumab. Guselkumab PFS was recommended on a cost-minimisation basis against the lowest cost biological agent available for severe CPP.

- 4.2 Further, at its November 2019 meeting, in its consideration of risankizumab, the PBAC considered that any of the listed biologics for CPP (which includes adalimumab, etanercept, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab) may be considered alternative therapies.
- 4.3 The PBAC therefore considered other relevant comparators may including adalimumab, etanercept, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab.

For more detail on PBAC's view, see section 6 PBAC outcome.

5 Consideration of the evidence

- 5.1 As a Committee Secretariat submission, a clinical evaluation was not performed.

Sponsor hearing

- 5.2 There was no hearing for this item as it was a Committee Secretariat submission.

Consumer comments

- 5.3 The PBAC noted that no consumer comments were received for this item.

Clinical claim

- 5.4 The submission claimed non-inferior comparative effectiveness and non-inferior comparative safety of guselkumab PFP compared with guselkumab PFS.
- 5.5 Bioequivalence, clinical efficacy and safety data of guselkumab PFP compared with guselkumab PFS was evaluated and accepted by the TGA.

Pricing considerations

- 5.6 The submission proposed no change to the published or effective prices of guselkumab and proposed for guselkumab PFP to be incorporated into the current Deed of Agreement for guselkumab PFS (with no change to the Special Pricing Arrangement).
- 5.7 While not a matter for PBAC, in its application the sponsor stated the 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 *National Health Act, 1953*.

Estimated PBS usage & financial implications

- 5.8 The submission proposed guselkumab PFP would only substitute for guselkumab PFS at the same effective price, and the listing would not grow the market, and subsequently there would be no net additional cost to the PBS.

For more detail on PBAC's view, see section 6 PBAC outcome.

6 PBAC Outcome

- 6.1 The PBAC recommended the listing of guselkumab 100mg pre-filled pen (PFP) for the treatment of severe chronic plaque psoriasis, under the same arrangements as the currently listed guselkumab pre-filled syringe (PFS).
- 6.2 The PBAC considered that guselkumab PFP and PFS were likely to be equivalent in efficacy and safety based on the TGA evaluation.
- 6.3 The PBAC considered that guselkumab PFP should be cost-minimised to the lowest cost biological agent available for severe CPP, noting that any of the current PBS listed bDMARDs for severe CPP could be an alternative therapy to guselkumab.
- 6.4 The PBAC considered it appropriate that an Administrative Advice note be included in the restriction, in order to prevent concurrent prescribing of both PFP and PFS forms of guselkumab, and that this should flow on to the existing PFS listing.
- 6.5 The PBAC noted the current PFS listing includes a grandfather restriction, and considered it appropriate for the new listing to include the same grandfather restriction.
- 6.6 The PBAC noted that its recommendation was on a cost-minimisation basis and advised 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.
- 6.7 The PBAC noted that this submission is not eligible for an Independent Review, as it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

- 7.1 Add new item:

Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Proprietary Manufacturer	Name and
GUSELKUMAB guselkumab 100 mg/mL injection, 1 mL pen device	NEW	1	1	2	Tremfya	Janssen-Cilag Pty Ltd

- 7.2 Attach the following restriction summaries to the new item (full restriction text not shown; refer to www.pbs.gov.au for full text):

Restriction summary 8874 (Initial 1, whole body)

Restriction summary 9873 (Initial 2, whole body)

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Restriction summary 8998 (Initial 3, whole body)
Restriction summary 8794 (Initial 1, face, hand, foot)
Restriction summary 9902 (Initial 2, face, hand, foot)
Restriction summary 8974 (Initial 3, face, hand, foot)
Restriction summary 9945 (Balance of supply)
Restriction summary 8936 (Continuing treatment, whole body)
Restriction summary 8956 (Continuing treatment, face, hand, foot)
Restriction summary 10332 (Grandfather listing, whole body)
Restriction summary 10287 (Grandfather listing, face, hand, foot)
Restriction summary 8975 (Balance of supply – Grandfather patient)
(Restriction summary numbers current as of July 2020)

7.3 Add the following ‘Note’ to each of the restriction summaries listed above:

new	Administrative Advice: Multiple forms/presentations of this drug are not to be prescribed as PBS-benefits simultaneously on an ongoing basis.
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This restriction may be subject to further review. Should there be any changes made to the restriction the Sponsor will be informed.

8 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.

9 Sponsor’s Comment

The sponsor had no comment.