

**6.5 Golimumab, 50 mg/0.5 mL injection, 1x 0.5 mL, syringe
Simponi®;**

**Infliximab, 100 mg injection, 1x 100 mg vial,
Remicade®;**

**Ustekinumab 45 mg/0.5 ml injection, 1x 0.5 ml vial,
Stelara®; Janssen-Cilag Pty Ltd.**

1 Purpose of application

- 1.1 To request an amendment to the second and subsequent continuing treatment authorities for infliximab, golimumab and ustekinumab for all of the PBS-reimbursed indications from a complex written authority to a telephone authority.
- 1.2 The submission also requested that the Department of Human Services provide electronic PBS authority application forms for electronic completion and record keeping purposes.

2 Requested listing

- 2.1 The sponsor's pre-PBAC response provided a proposed revised wording for the severe chronic plaque psoriasis (whole body) restriction as an example. This proposed written Authority applications for the initial and first continuing prescriptions, and telephone Authority for subsequent prescriptions.

For more detail on PBAC's view, see section 7 "PBAC outcome"

3 Background

- 3.1 The current PBS reimbursed indications for golimumab, infliximab and ustekinumab are summarised in the table below.
- 3.2 Golimumab and ustekinumab are listed under Section 85, while infliximab is listed under the Section 100 (Highly Specialised Drugs Program).

Table 1 PBS reimbursed indications for the Janssen biologic drugs

Indication	Infliximab	Golimumab	Ustekinumab
Severe active rheumatoid arthritis	Yes	Yes	No
Ankylosing spondylitis	Yes	Yes	No
Severe active psoriatic arthritis	Yes	Yes	No
Severe chronic plaque psoriasis	Yes	No	Yes
Severe Crohn's disease	Yes	No	No
Complex refractory fistulising Crohn's disease	Yes	No	No
Paediatric Crohn's disease	Yes	No	No
Acute severe ulcerative colitis ^a	Yes	No	No
Moderate to severe ulcerative colitis ^b	Positive PBAC recommendation at March 2014 meeting	No	No

^a This indication is already Authority Required (Streamlined) for a Public Hospital

^b All continuing treatment was recommended as a telephone Authority Required item.

- 3.3 The submission proposed changing restriction to the biologics to reduce administrative burden for clinicians, the Department of Human Services and to facilitate continuity of treatment. The proposal is limited to patients who have already received initial and continuing therapy.
- 3.4 In March 2014, the PBAC recommended infliximab for the treatment of moderate to severe ulcerative colitis. The PBAC also recommended telephone Authority Required listing for *all* continuing authorities but initial treatment remained as a complex written Authority required item. In a separate minor submission for consideration by the PBAC in July 2014, the sponsor requested the PBAC consider making the first continuation script a complex written authority for consistency with this request for golimumab and ustekinumab.

4 Clinical place for the proposed therapy

- 4.1 The submission did not propose any change to the place in therapy of these agents.

5 Comparator

- 5.1 The submission did not propose a comparator.

6 PBAC consideration of the evidence

Sponsor hearing

- 6.1 There was no hearing for this item.

Consumer comments

- 6.2 The PBAC noted and welcomed the input from, health care professionals (1) and organisations (1) via the Consumer Comments facility on the PBS website. The comments described a range of benefits of the proposed change including improve workload for prescribers, a simplification of the Authority process and reduced administrative burden for the Department of Human services.

For more detail on PBAC's view, see section 7 "PBAC outcome"

Clinical trials

- 6.3 No clinical data were presented in the submission.

Economic analysis

- 6.4 No formal economic analysis was presented in the submission.

Estimated PBS usage & financial implications

- 6.5 The pre-PBAC response claimed that the proposed change would not alter the treated population or the response criteria, and that therefore there would be no financial implications to the PBS. The pre-PBAC response further noted that the proposed change would only permit telephone Authority approvals once patients had been treated for between 40 weeks (for golimumab) and 52 weeks (with ustekinumab) before being able to access ongoing treatment via a telephone Authority. The sponsor therefore claimed that the proposed change would still target patients in whom treatment with these drugs has been established to be cost-effective.

For more detail on PBAC's view, see section 7 "PBAC outcome"

7 PBAC Outcome

- 7.1 The PBAC deferred the submission, noting that this matter would be considered in the context of the Post Market Review of PBS Authorities. The PBAC agreed that the points raised by the sponsor merited further exploration, but considered that addressing these in a consolidated fashion in the context of the Review would be the most efficient approach. In reaching this conclusion, the PBAC noted that changes such as those proposed in the submission may appropriately be flowed on to other listings.
- 7.2 The PBAC noted that the current listings allow patients to switch to other agents for the same indication under specific circumstances. The PBAC foreshadowed that should it recommend changes such as those proposed in the submission, it considered that it would be appropriate for written applications to be required when switching to another agent.

Outcome:

Deferred

8 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final

PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

9 Sponsor's Comment

Janssen is committed to working with the PBAC in the context of the Post-Market Review of Authority Required PBS Listings to reduce the administrative burden for prescribers of PBS subsidised biologics and safeguard continuity of treatment for patients.