

5.16 ADALIMUMAB

Injection 40 mg in 0.8 mL vial, Humira[®], AbbVie Pty Ltd

1 Purpose of Application

- 1.1 The minor submission requested the listing of a new 40 mg vial form of adalimumab with the same Authority Required listings as for the currently listed forms of adalimumab (cartridge and syringe forms).

2 Requested listing

- 2.1 The submission requested the same listings as for the currently listed 40 mg cartridge and syringe forms of adalimumab.
- 2.2 The sponsor has requested the same dispensed price for maximum quantity (DPMQ) as the currently listed forms of adalimumab 40mg.

3 Background

- 3.1 Adalimumab (Humira[®] 40 mg in vial) is TGA registered for the same indications as the currently PBAC listed forms of adalimumab. The Product Information for adalimumab was updated in October 2016.
- 3.2 Adalimumab (pre-filled syringe) was recommended by the PBAC at the December 2003 PBAC meeting. The pre-filled pen presentation was recommended by the PBAC for the currently listed indications at the March 2007 meeting.

4 Consideration of the evidence

Consumer comments

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

Current situation

- 4.2 The basis for listing presented in the minor submission was that the new form will offer an alternative to the currently available presentations for adalimumab, providing flexibility and choice for patients and clinicians.

- 4.3 The PBAC considered that the submission did not provide convincing evidence of clinical need for the vial presentation, given that adalimumab is given subcutaneously as part of a fixed-dose regimen and the currently available pre-filled syringe and cartridge presentations provide a ready-prepared and convenient delivery system. In contrast, the vial will require additional preparation before administration.
- 4.4 Although not a matter for the PBAC, the PBAC noted that the 40 mg vial form of adalimumab is bioequivalent to the currently listed 40 mg syringe and pre-filled pen forms, and the listing of a new bioequivalent form of adalimumab will trigger a 16% statutory price reduction under s99ACB of the *National Health Act 1953*. The drug adalimumab will also move into the F2 formulary and be subject to price disclosure.

Estimated PBS usage & financial implications

- 4.5 The minor submission estimated that the new form of adalimumab will be cost neutral for the government as it is expected to directly substitute for the 2 pack 40mg cartridge and syringe presentations at the same price as for the currently listed 40 mg forms of adalimumab.
- 4.6 The PBAC noted that although not a matter for PBAC, the listing of a new form of adalimumab at this time has the potential to result in the loss of some of the savings to government that would have occurred under Section 5 of the 2017 Strategic Agreement between the Commonwealth and Medicines Australia. Given that Commonwealth expenditure on adalimumab exceeded \$330 million in the 2015-16 financial year¹, the quantum of any savings lost is likely to be significant.

Risk Share Arrangements

- 4.7 The submission requested that the same special pricing arrangements apply to the 40 mg vial presentation as to the currently listed forms.
- 4.8 Although not a matter for the PBAC, the listing of the 40 mg vial form of adalimumab will cause the drug to move into the F2 formulary, and special pricing arrangements are not usually applied to F2 medicines.

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

¹ <http://www.pbs.gov.au/info/statistics/pbs-expenditure-prescriptions-30-june-2016>

5 PBAC Outcome

- 5.1 The PBAC recommended the listing of adalimumab injection (40 mg in 0.8 mL vial) with the same restrictions as the currently listed forms of adalimumab cartridge and syringe on a cost-minimisation basis.
- 5.2 In making this recommendation, the PBAC noted that although the application for the vial form of adalimumab met the requirements for a positive PBAC recommendation, the evidence that there is a clinical need for a vial presentation of adalimumab is not convincing, and there is potential for this listing to result in a considerable loss of savings to government.
- 5.3 The PBAC considered that the adalimumab vial form and the other two PBS-listed forms of adalimumab should be considered equivalent for the purposes of substitution (i.e., 'a' flagged in the Schedule). The PBAC considered that although each form has a different injection delivery device and method, the dispensing pharmacist would be able to provide the necessary patient education and training.
- 5.4 The PBAC noted that adalimumab currently has a special pricing arrangement and that the listing of the 40 mg vial form would trigger the drug adalimumab to move to the F2 formulary. Special pricing arrangements are not usually applied to drugs in the F2 formulary.
- 5.5 Consistent with the existing arrangements, the PBAC advised that adalimumab is not suitable for prescribing by nurse practitioners.
- 5.6 The PBAC also advised that the vial form of adalimumab should not be exempt from the Early Supply Rule as the PBAC previously considered that adalimumab should not be exempt from the early supply rule.
- 5.7 The PBAC noted that this submission is not eligible for Independent Review as it received a positive recommendation.

Outcome:

Recommended

Recommended listing

Add new item for the same indications as the currently listed cartridge and syringe forms of adalimumab

The list of item codes under the cartridge form are:

10400J
10413C
10420K
10955N
10961X
5282B
5284D
8965W
8966X
9099X
9100Y
9101B
9102C
9103D
9104E
9190Q
9191R
9426D
9428F
9663N
9680L

6 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.

7 Sponsor's Comment

The sponsor had no comment.

Addendum to the July 2017 PBAC Minutes:

12.14 ADALIMUMAB

**Injection 40 mg in 0.8 mL vial,
Humira[®], AbbVie Pty Ltd**

8 Purpose of Reconsideration

- 8.1 In its consideration of an additional form of another biological disease modifying anti-rheumatic drug (bDMARD), tocilizumab, at the July 2018 PBAC meeting, the PBAC discussed substitution at the pharmacy level of different injection devices of the same drug(s). Concern was raised regarding different administration techniques between devices and risks of improper administration if patients were not appropriately trained in the use of the device (item 5.26, tocilizumab July 2018 Public Summary Document refers). The PBAC considered the pre-filled syringe and auto-injector forms of the tocilizumab should not be considered equivalent for the purposes of substitution (i.e., 'a' flagged in the Schedule).

9 PBAC Outcome

- 9.1 In advising that the two different self-administered injectable forms of tocilizumab should not be considered equivalent for the purposes of substitution ('a' flagged), the PBAC considered it was appropriate to rescind its July 2017 advice on brand equivalence for the vial, pre-filled syringe and auto-injector forms of adalimumab.

10 Context for Decision

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11 Sponsor's Comment

The sponsor had no comment.