

## **5.13 CERTOLIZUMAB PEGOL Injection 200 mg in 1 mL single dose auto-injector Cimzia<sup>®</sup>, UCB Australia Pty Ltd**

### **1 Purpose of Application**

- 1.1 The minor submission requested the same Authority Required listings for Cimzia<sup>®</sup> injection (certolizumab pegol, 200 mg/mL injection 1 mL single use pre-filled syringe) be applied to the new pre-filled pen form of the drug.

### **2 Requested listing**

- 2.1 The submission requested the same restriction wording for the treatment of severe active rheumatoid arthritis, severe psoriatic arthritis (PsA) and active ankylosing spondylitis as the current listing of certolizumab pegol.
- 2.2 The sponsor has requested the same DPMQ as the currently listed Cimzia<sup>®</sup> pre-filled syringes.

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

### **3 Background**

- 3.1 Cimzia<sup>®</sup> pre-filled pen is TGA registered for the same indications as the pre-filled syringe. The product information for certolizumab pegol was updated in November 2016.

### **4 Consideration of evidence**

#### ***Sponsor hearing***

- 4.1 There was no hearing for this item as it was a minor submission.

#### ***Consumer comments***

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

#### ***Estimated PBS usage & financial implications***

- 4.3 As a minor submission, there was no economic comparison.
- 4.4 The basis for listing presented in the minor submission was that patients preferred auto-injection devices over prefilled syringes.
- 4.5 The PBAC noted that a special pricing arrangement currently applies to Cimzia<sup>®</sup> pre-

filled syringes for the severe PsA indication. This arrangement would also apply to the new form listed under this particular indication.

4.6



4.7 The sponsor claimed that there may be a 10% uptake from other bDMARDs of each current indication (i.e. rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis). The submission presented potential savings across all these indications. However, the evaluation of these financial estimates was not undertaken in this minor submission.

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

## **5 PBAC Outcome**

5.1 The PBAC recommended the Authority Required listing of Cimzia® injection (pre-filled pen) with the same conditions as the pre-filled syringe form of the drug on a cost-minimisation basis.

5.2 The PBAC considered that Cimzia® pre-filled syringes and Cimzia® pre-filled pen should not be considered equivalent for the purposes of substitution (i.e., 'a' flagged in the Schedule) due to the different injection methods required.

5.3 The PBAC noted its previous advice, under Section 101(3BA) of the *National Health Act 1953*, that certolizumab and the other bDMARDs for the treatment of PsA, adalimumab, etanercept, golimumab and infliximab, should be treated as interchangeable on an individual patient basis (Certolizumab pegol Public Summary Document November 2014 PBAC).

5.4 Consistent with the existing arrangements for the currently available form, the PBAC advised that certolizumab is not suitable for prescribing by nurse practitioners.

5.5 The PBAC advised that Safety Net Early supply rule does not currently apply to this drug.

5.6 The PBAC noted that this submission is not eligible for Independent Review as it received a positive recommendation.

### **Outcome:**

Recommended

## **6 Recommended listing**

### 6.1 Add new item:

The same restriction wording for the treatment of severe active rheumatoid arthritis, severe psoriatic arthritis (PsA) and active ankylosing spondylitis as the current listing of certolizumab pegol for the Cimizia® injection (pre-filled pen) as the pre-filled syringe form of the drug.

## **7 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.

## **8 Sponsor's Comment**

The sponsor had no comment.