

6.11 CERTOLIZUMAB PEGOL 200 mg/mL injection, 2 x 1 mL syringes, Cimzia®, UCB Australia Pty Ltd

1 Purpose of Application

- 1.1 The minor submission sought to include an additional PBS item number for the loading dose in all currently PBS-listed indications for certolizumab.

2 Background

- 2.1 Certolizumab is currently PBS-listed for the treatment of ankylosing spondylitis, severe psoriatic arthritis, and severe active rheumatoid arthritis.
- 2.2 Based on the Product Information, a loading dose of 400 mg (given as 2 subcutaneous injections of 200 mg) at weeks 0, 2 and 4 is required for all three indications.
- 2.3 The current listings of certolizumab allow maximum quantity (MQ) packs of 1 pack of 2 syringes and 5 repeats. The patient would have to pay 6 co-payments for a 20-week treatment under the Initial treatment criteria. Three of the six co-payments would have been paid in the first month of treatment in order to administer the loading dose at weeks 0, 2 and 4.
- 2.4 The submission stated that a number of rheumatologists and patients through Med Advisor had approached the sponsor regarding the financial burden incurred by patients when initiating treatment with certolizumab.

For more detail on PBAC's view, see section 4 "PBAC outcome"

3 Requested listing

- 3.1 The submission requested that an additional PBS item number for the loading dose in the first month, with a requested MQ of 3 packs and nil repeats, be included in the current listings for certolizumab. This will allow patients to pay one co-payment instead of 3 in the first month of treatment.

For more detail on PBAC's view, see section 4 "PBAC outcome"

4 PBAC Outcome

- 4.1 The PBAC recommended that the loading doses at weeks 0, 2, and 4 should be allowed under one co-payment rather than under the 3 co-payments as currently required for the loading doses of secukinumab.
- 4.2 The PBAC noted that the change will result in patients having to pay one co-payment

for the first 3 loading doses, and another three co-payments, instead of the total of 6 co-payments as currently required, to complete the 20-week initial treatment.

- 4.3 The PBAC agreed that the current notes stating ‘No increase in the maximum quantity or number of units may be authorised’ and ‘No increase in the maximum number of repeats may be authorised’ should be replaced with a note stating “*Maximum quantity packs of up to 3 and nil repeats may be authorised for the purpose of the loading dose*”. The replacement is applied to all the Initial treatment restrictions under item codes 10137M, 10238W, and 3425G for certolizumab.

Outcome:

Recommended

5 Recommended listing

- 5.1 Amend existing listing as follows:

Replace the current notes stating ‘No increase in the maximum quantity or number of units may be authorised’ and ‘No increase in the maximum number of repeats may be authorised’ with the following note to all the Initial treatment restrictions under the item codes 10137M, 10238W, and 3425G for certolizumab.

Maximum quantity packs of up to 3 and nil repeats may be authorised for the purpose of the loading dose.

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.