

## **6.15 SECUKINUMAB**

### **150 mg/mL injection, 2 x 1 mL injection devices, Cosentyx®, Novartis Pharmaceuticals Australia Pty Ltd**

#### **1 Purpose of Application**

- 1.1 The minor submission sought to amend the current PBS restriction for secukinumab to allow an increase in maximum quantity to cover the loading dose required at weeks 0, 1, 2 and 3 in the first month of treatment.

#### **2 Background**

- 2.1 Secukinumab was recommended for listing at the March 2015 PBAC meeting for the treatment of chronic plaque psoriasis, and was listed on 1 September 2015
- 2.2 Based on the Product Information, a loading dose of 300 mg (given as 2 subcutaneous injections of 150 mg) at weeks 0, 1, 2 and 3 is required, followed by monthly maintenance dosing of 300 mg starting at week 4.
- 2.3 The current listing of secukinumab allows maximum quantity (MQ) packs of 1 pack of 2 syringes and 6 repeats (rpts). The patient would need to pay 7 co-payments for a 16 - week treatment under the Initial treatment criteria. Four of the seven co-payments would have been paid in the first month of treatment in order to administer the loading dose at weeks 0, 1, 2 and 3.

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

#### **3 Requested listing**

- 3.1 The submission requested splitting the supply under the initial treatment criteria into 2 phases. Phase 1 has a MQ of 5 packs and nil repeats for the loading doses in the first month; and phase 2 has a MQ of 1 pack and 1 rpts for the remainder of the supply under the criteria. The patients would only have to pay 4 co-payments instead of 7; and 1 co-payment instead of 4 in the first month of therapy.

*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, 1, 2 and 3 should be allowed under one co-payment rather than under the 4 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 4 loading doses and another three co-payments, instead of the total of 7 co-payments as currently required, to complete the 16-week initial treatment.

- 4.3 The PBAC did not consider the submission's request to allow five weeks of treatment under one co-payment appropriate, as this would include week 4 that does not require a loading dose as according to the Product Information.
- 4.4 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 4 and nil repeats may be authorised for the purpose of the loading dose*". The replacement is applied to all the Initial treatment restrictions under the item code 10494H for secukinumab.

**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 code 10494H:

*Maximum quantity packs of up to 4 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.