

6.14 SECUKINUMAB

Injection 150 mg in 1 mL pre-filled pen, Cosentyx[®], Novartis Pharmaceuticals Australia Pty Ltd

1 Purpose of Application

- 1.1 The minor submission requested a change to the maximum quantity and number of repeats per script of secukinumab for continuing treatment of severe chronic plaque psoriasis. The changes were requested to reduce the total number of patient co-payments per script to three to be consistent with the current PBS listing of ixekizumab for the same indication.

2 Requested listing

- 2.1 The minor submission requested amending the maximum quantity and number of repeats for continuing treatment of severe chronic plaque psoriasis as outlined below. The requested changes are shown in *italics* and deletions are in ~~strikethrough~~.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Manufacturer	Name and
SECUKINUMAB secukinumab 150 mg/mL injection, 2 x 1 mL injection devices	42	52	\$1585.75	Cosentyx®	Novartis Pharmaceuticals Australia Pty Ltd

3 Background

- 3.1 Secukinumab was recommended by the PBAC for the treatment of severe chronic plaque psoriasis that is refractory to treatment with non-biological disease modifying anti rheumatic drugs (DMARDs) at its March 2015 meeting.
- 3.2 At its July 2016 meeting, the PBAC recommended ixekizumab for the same indication. The PBAC advised that ixekizumab should be treated as interchangeable on an individual patient basis with adalimumab, etanercept and secukinumab according to S101(3BA) advice.

- 3.3 The maintenance dose for secukinumab is 300 mg every four weeks (beginning in week four of treatment). The current secukinumab restriction for the continuing treatment of severe chronic plaque psoriasis provides a maximum quantity of one pack containing a maximum quantity of two units of 150 mg/mL injections and five repeats per script. Each prescription therefore supplies approximately one month (four weeks) of continuing treatment.
- 3.4 The maintenance dose for ixekizumab is 80 mg every four weeks (beginning in week 16 of treatment). The current ixekizumab restriction for the same indication provides a maximum quantity of one pack containing a maximum quantity of two units of 80 mg/mL injections and two repeats per script. Accordingly, each dispensing supplies approximately two months (eight weeks) of treatment.

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

4 Consideration of the 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.

Patient co-payment costs per year

- 4.3 The submission noted that the current PBS restriction for secukinumab for the continuing treatment of severe chronic plaque psoriasis does not authorise increases in the maximum quantity or number of repeats. The minor submission claimed that for some patients, this raises affordability issues.
- 4.4 The minor submission stated that over one year, a patient on secukinumab continuing treatment for severe chronic plaque psoriasis would be required to pay 12 co-payments compared with 6.5 co-payments for patients on ixekizumab. Based on these figures, the minor submission calculated that the total co-payment costs per year for a general patient on secukinumab would be \$465.60 compared with \$252.30 for a general patient on ixekizumab. This is summarised in Table 1.

Table 1: Total patient co-payment costs of secukinumab versus ixekizumab continuing therapy for severe chronic plaque psoriasis

	Number of patient co-payments per year	Total co-payment costs per year (general patient)	Total co-payment costs per year (concessional patient)
48 weeks per year			
secukinumab	12	\$465.60	\$75.60
ixekizumab	6	\$232.80	\$37.80
difference	6	\$232.80	\$37.80
52 weeks per year			
secukinumab	13	\$504.40	\$81.90
ixekizumab	6.5	\$252.20	\$40.95
difference	6.5	\$252.20	\$40.95

General patient co-payment: \$38.80, concessional patient co-payment: \$6.30

- 4.5 The requested amendment for a maximum quantity of two injections with two repeats for secukinumab continuing treatment would reduce the number of patient co-payments to six per year (based on 48 weeks per year; 6.5 based on 52 weeks per year).

Estimated PBS usage & financial implications

- 4.6 While the requested amendment to the maximum quantity and number of repeats for the secukinumab listing to reduce the number of patient co-payments results in a cost to the PBS, the minor submission did not include any estimates for this cost.

For more detail on PBAC’s view, see section 5 “PBAC outcome.”

5 PBAC Outcome

- 5.1 The PBAC did not recommend the minor submission’s request to amend the maximum quantity and number of repeats per prescription of secukinumab for the continuing treatment of severe chronic plaque psoriasis.
- 5.2 The PBAC noted that the intention of the request was to align the maximum quantity and number of repeats of the secukinumab listing to that of ixekizumab, which currently provides two months’ supply per prescription. The PBAC noted that it is usual practice for drugs listed on the general schedule to have a maximum quantity per prescription that provides supply for one months’ treatment. The PBAC therefore considered that the current maximum quantity of one injection with five repeats for secukinumab for this indication and treatment phase should remain unchanged.

- 5.3 The PBAC noted that in contrast to other PBS subsidised biological disease modifying anti rheumatic drugs (bDMARDs) for severe chronic plaque psoriasis, the medicinal product pack for ixekizumab contains two injections, which allows for two months' treatment for a single PBS prescription.
- 5.4 The PBAC noted that the TGA approved Product Information for ixekizumab indicates it is also available in a pack size of one injection. The PBAC recommended amending the maximum quantity of the PBS listing for ixekizumab from two to one injection, to align the ixekizumab listing for severe chronic plaque psoriasis with the PBS listings of other bDMARDs and with usual practice for the supply of these medicines on the PBS.
- 5.5 The PBAC noted that the submission is not eligible for an Independent Review because it is a request to modify an existing listing.

Outcome:

Rejected

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.