

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

1 Purpose of Application

- 1.1 The Category 4 submission requested an increase in the maximum quantity (from one to two) and to reduce the number of repeats (from five to two) for PBS listed secukinumab 150 mg injection for the continuing treatment phase of all of the currently listed PBS indications.

2 Background

Secukinumab is currently listed on the PBS as an Authority Required (non-immediate assessment) listing for the following indications:

- Ankylosing spondylitis
- Severe chronic plaque psoriasis
- Severe psoriatic arthritis
- Non-radiographic axSpA.

Registration status

- 2.1 Secukinumab is TGA registered for:
- The treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy
 - The treatment of adult patients with active psoriatic arthritis when the response to previous DMARD therapy has been inadequate, axial spondyloarthritis (axSpA) with or without radiographic damage
 - The treatment of adult patients with active ankylosing spondylitis, non-radiographic axSpA (axSpA without radiographic damage)
 - The treatment of adult patients with active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or MRI change, who have had an inadequate response to, or are intolerant to, NSAIDs.

Previous PBAC Considerations

- 2.2 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.
- 2.3 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.
- 2.4 At its July 2017 meeting, the PBAC did not recommend the submission's request to amend the maximum quantity and number of repeats of secukinumab for the continuing treatment of severe chronic plaque psoriasis. 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.
- 2.5 At the same meeting, the PBAC noted that the TGA approved Product Information (PI) 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 biological DMARDs and with usual practice for the supply of these medicines on the PBS.
- 2.6 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.
- 2.7 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.
- 2.8 The July 2017 PBAC recommendation to amend ixekizumab's pack size listing has not yet been implemented.

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

3 Requested listing

The submission requested amending the maximum quantity and number of repeats as follows:

Suggested additions are in italics and deletions are in strikethrough.

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
SECUKINUMAB					
secukinumab 150 mg/mL injection, 2 x 1 mL pen devices	10425Q	4 2	2 4	5 2	Cosentyx
Continuing treatment Indication: Severe chronic plaque psoriasis		Max.qty (packs) multiplier = 1 Repeat increases: nil			

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
SECUKINUMAB					
secukinumab 150 mg/mL injection, 1 mL pen device	10895K	4 2	4 2	5 2	Cosentyx
Continuing treatment Indication: Severe psoriatic arthritis		Max.qty (packs) multiplier = 1 Repeat increases: nil			

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
SECUKINUMAB					
secukinumab 150 mg/mL injection, 2 x 1 mL pen devices	10899P	4 2	2 4	5 2	Cosentyx
Continuing treatment Indication: Severe psoriatic arthritis		Max.qty (packs) multiplier = 1 Repeat increases: nil			

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
SECUKINUMAB					
secukinumab 150 mg/mL injection, 1 mL pen device	10906B	4 2	4 2	5 2	Cosentyx
Continuing treatment Indication: Ankylosing spondylitis		Max.qty (packs) multiplier = unlimited Repeat increases: unlimited			

3.1 The current maximum quantity and number of repeats for secukinumab are consistent with the PBAC Guidelines such that “for a chronic-use therapy, demonstrate that the maximum quantity/amount is consistent with the likely use of the proposed medicine for one month of therapy between each dispensing by the pharmacist”. The difference in the duration of treatment provided by a single dispensing for secukinumab and ixekizumab arises because of the interaction between the pack size and the dosing regimen.

3.2 The submission’s request to amend the maximum quantity and the number of repeats for secukinumab is inconsistent with the PBAC Guidelines because it will provide two months’ supply per prescription. The submission stated that amending the PBS-listed maximum quantity of ixekizumab without undue delay would be an acceptable alternative to amending the maximum quantity of secukinumab.

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.

Consumer comments

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

Estimated PBS utilisation and financial implications

4.3 The submission claimed that the co-payment differences between secukinumab and ixekizumab are inconsistent with PBS policy and PBAC guidelines.

4.4 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). Based on these figures, the submission calculated that the total co-payment costs per year for a general patient on secukinumab would be \$465.60 compared with \$268.45 for a general patient on ixekizumab.

4.5 The difference in co-payments are summarised in Table 1.

Table 1: Patient co-payment costs of secukinumab versus ixekizumab (12 months of continuing treatment)

	Tx duration/ Script	Scripts/Year	Co-payment	
			General patients	Concessional patients
Secukinumab	4 weeks	12	\$495.60	\$79.20
Ixekizumab	8 weeks	6.5	\$268.45	\$42.90
Difference	4 weeks less /script	5.5	\$227.15	\$36.30

Source: Submission main body

Tx = Treatment

4.6 The requested amendment to the maximum quantity and number of repeats for the secukinumab listing to reduce the number of patient co-payments would result in a net cost to the PBS/RPBS. The submission did not include any financial estimates to support this amendment.

4.7 The submission claimed that patients who trialled secukinumab prior to ixekizumab were more likely to remain on ixekizumab. This was based on the analysis of switching patterns using a 10% Medicare sample database. The PBAC considered that this was a small sample size and did not accurately reflect the current market.

4.8 In its Pre-PBAC response, the sponsor provided financial estimates for the impact to the PBS and Repatriation PBS (RPBS) of amending the current maximum quantity and number of repeats for secukinumab. Additionally, the sponsor also estimated the financial impact for amending the current maximum quantity of ixekizumab from two packs to one pack per prescription. This is presented in Table 2.

Table 2: Expected impact to the PBS/RPBS of the proposed change in MQ in Yrs 1-6 of listing

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Total
Secukinumab							
PBS scripts ¹	55,990	58,790	61,730	64,817	68,058	71,461	
Avg co-payment ²	\$27.63	\$27.63	\$27.63	\$27.63	\$27.63	\$27.63	
Co-payment revenue	\$1,546,968	\$1,624,331	\$1,705,561	\$1,790,853	\$1,880,400	\$1,974,422	\$10,522,535
Change in cost to PBS/RPBS if MQ=2	\$773,484	\$812,165	\$852,780	\$895,426	\$940,200	\$987,211	\$5,261,267
Ixekizumab							
PBS scripts	14,960	17,204	18,924	20,438	21,460	22,533	
Avg co-payment	\$30.20	\$30.20	\$30.20	\$30.20	\$30.20	\$30.20	
Co-payment revenue	\$451,720	\$519,478	\$571,413	\$617,129	\$647,988	\$680,388	\$3,488,116
Change in cost to PBS/RPBS if MQ=1	-\$451,720	-\$519,478	-\$571,413	-\$617,129	-\$647,988	-\$680,388	-\$3,488,116

MQ = Maximum quantity

¹ Using historical annual growth rates in PBS script volumes for 'Continuing treatment' PBS items for each drug since listing projected for Years 1-6 (2022-2027) of the proposed change to the listing; projections reflect current maximum quantity for each drug

² Calculated from 'Continuing treatment' PBS scripts for each drug for calendar year 2020 by patient category, using 2021 co-payment levels

4.9 The submission estimated a cost to the PBS of \$5.3 m in the first six years of the changed listing for secukinumab with the proposed maximum quantity of two injections.

4.10 The submission estimated a saving to the PBS of \$3.5 m in the first six years of the changed listing for ixekizumab with the proposed maximum quantity to one injection.

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

5 PBAC Outcome

5.1 The PBAC did not recommend increasing the maximum quantity from one to two or reducing the number of repeats from five to two of the PBS listed secukinumab 150 mg injection for the continuing treatment phase of the following PBS indications:

- Ankylosing spondylitis
- Severe chronic plaque psoriasis
- Severe psoriatic arthritis
- Non-radiographic axSpA.

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 as per PBAC Guidelines and that the current maximum quantity and number of repeats for secukinumab are consistent with the PBAC Guidelines.

5.3 The PBAC noted the submission claimed that the different maximum quantity

between secukinumab and ixekizumab may incentivise prescribers and patients to choose ixekizumab over secukinumab. The PBAC considered that choice of treatment would be largely driven by individual patient characteristics related to clinical suitability to a particular drug and clinician familiarity with the drug.

- 5.4 The PBAC considered that the current maximum quantity of one injection with five repeats for secukinumab for all its current PBS indications should remain unchanged.
- 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:

Not recommended

6 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

7 Sponsor's Comment

The sponsor had no comment.