

## **5.29 SECUKINUMAB, Injection 300 mg in 2 mL pre-filled pen Injection 300 mg in 2 mL pre-filled syringe, Cosentyx<sup>®</sup>, Novartis Pharmaceuticals Australia Pty Limited**

### **1 Purpose of Submission**

- 1.1 The Category 4 submission requested General Schedule listings for two new forms of secukinumab injection (Cosentyx<sup>®</sup>): a 300 mg/2 mL pre-filled pen (PFP) and a 300 mg/2 mL pre-filled syringe (PFS) under the same circumstances as the current secukinumab 150 mg/mL PFP listing.

### **2 Background**

- 2.1 Secukinumab is currently 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 axial spondyloarthritis (axSpA).

#### ***Registration status***

- 2.2 Secukinumab 300 mg/2 mL PFP and 300 mg/2 mL PFS was registered on the Australian Register of Therapeutic Goods (ARTG) on 2 February 2022.
- 2.3 Secukinumab is TGA approved for:
- The treatment of moderate to severe plaque psoriasis in patients 6 years and older 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
  - The treatment of adult patients with active ankylosing spondylitis
  - 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.

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

### 3 Requested listing

- 3.1 The submission requested listing secukinumab 300 mg/2 mL PFP and 300 mg/2 mL PFS under the same circumstances as the currently PBS-listed secukinumab 150 mg PFP and 150 mg PFS. As no changes to the restrictions were requested, the restrictions have not been reproduced.
- 3.2 Secukinumab 300 mg/2 mL is requested for severe psoriatic arthritis, severe chronic plaque psoriasis and ankylosing spondylitis. The existing secukinumab 150 mg PFP/PFS listings have a fourth indication, axSpA, which will not apply to the 300 mg/2 mL forms.

Add new medicinal product packs as follows:

- 3.3 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 300 mg/2 mL injection, 1 x 2 mL syringe secukinumab 300 mg/2 mL injection, 1 x 2 mL pen device	NEW				Cosentyx®
Indication <b>Severe psoriatic arthritis</b>					
Initial Treatment	NEW	<del>4</del>	<del>4</del>	0	
<i>Initial Treatment Balance of Supply</i>	<i>NEW</i>	<i>1</i>	<i>1</i>	<i>2</i>	
Continuing Treatment <i>Continuing Treatment Balance of Supply</i>	NEW	1	1	5	
Indication <b>Severe chronic plaque psoriasis</b>					
Initial Treatment	NEW	<del>4</del>	<del>4</del>	<del>0</del> <sup>2</sup>	
<i>Initial Treatment Balance of Supply</i>	<i>NEW</i>	<i>1</i>	<i>1</i>	<i>2</i>	
Continuing Treatment <i>Continuing Treatment Balance of Supply</i>	NEW	1	1	5	
Indication <b>Ankylosing spondylitis</b>					
Initial Treatment	NEW	<del>4</del>	<del>4</del>	0	
<i>Initial Treatment Balance of Supply</i>	<i>NEW</i>	<i>1</i>	<i>1</i>	<i>2</i>	
Continuing Treatment <i>Continuing Treatment Balance of Supply</i>	NEW	1	1	5	

- 3.4 The submission requested the restriction wording to be copied from the current listings of secukinumab.
- 3.5 The Pre-PBAC response confirmed the requested indications for consideration were severe chronic plaque psoriasis, severe psoriatic arthritis and ankylosing spondylitis.

- 3.6 The Pre-PBAC response also confirmed that only pack size of 1 is requested for both listings of secukinumab 300 mg/2 mL PFP and 300 mg/2 mL PFS.

*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.

### **Clinical Trials**

- 4.3 The submission stated that there were two clinical trials included in the TGA submission to support registration of secukinumab 300 mg PFP and secukinumab 300 mg PFS (see Table 1 below).

- 4.4 As a Category 4 submission, no evaluation of the clinical evidence was undertaken.

**Table 1: Trials and associated reports presented in the submission**

Trial ID	Protocol title/ Publication title
<b>CAIN457A2323 (ALLURE)</b>	52-week, Phase 3 double blind, multicentre, randomised, placebo controlled, parallel-group trial in 214 adults with moderate to severe plaque-type psoriasis, subjects were randomised to treatment with secukinumab 300 mg (2 mL PFS or 2 x 1 mL PFS) or placebo for 12 weeks.
<b>CAIN457A2325 (MATURE)</b>	52-week, Phase 3 double blind, multicentre, randomised, placebo-controlled, parallel-group trial in 122 adults with moderate to severe plaque-type psoriasis, in which subjects were randomised to treatment with secukinumab 300 mg (2 mL AI or 2 x 1 mL PFS) or placebo for 12 weeks.

*Source: page 5 of main body submission*

- 4.5 In consideration of the evidence for the new 300 mg PFP and 300 mg PFS, compared with 150 mg/mL PFS, the TGA Evaluator concluded that efficacy was generally consistent between the 300 mg/2 mL form (PFP and PFS) and 2 x 150 mg/1 mL PFS in the treatment of moderate to severe plaque-type psoriasis. In addition, 300 mg PFP and PFS were well tolerated, there were no major adverse events, and injection site reactions were similar between the two forms. There were no new or unexpected safety signals for the 300 mg PFP and PFS compared to the 150 mg PFS. The TGA Evaluator also noted that there was no formal bioequivalence study; the ALLURE and MATURE studies had used historical data only.

### **Estimated PBS utilisation and financial implications**

- 4.6 With no expected changes to current utilisation, mark-up fees and co-payments, and with the same price and dosing schedule as the 150 mg PFP, the submission claimed that the net financial impact of listing the 300 mg PFP and PFS on the PBS would be nil.

- 4.7 The submission requested listing of 300 mg PFP and 300 mg PFS approved ex-manufacturer price (AEMP) of \$1,316.56 on the basis of equivalence to the AEMP of \$658.28 for 2 x secukinumab 150 mg PFS. The proposed DPMQ is \$1,403.69 (max quantity 1 pack) or \$5,427.50 (max quantity 4 packs).
- 4.8 Secukinumab is currently subject to a Special Pricing Arrangement. The above prices are based on published pricing, and would need to be subject to the same rebate arrangements.

### **Quality use of medicines**

- 4.9 The submission claimed that the availability of the 300 mg PFP and 300 mg PFS will reduce the burden for patients by halving the number of required injections and would also improve treatment adherence.
- 4.10 The submission also claimed that the 300 mg PFP and 300 mg PFS would provide options to meet various patient preferences regarding choice of device.

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

## **5 PBAC Outcome**

- 5.1 The PBAC recommended the listing of secukinumab 300 mg in 2 mL PFP and 300 mg in 2 mL PFS for the treatment of severe chronic plaque psoriasis, severe psoriatic arthritis and ankylosing spondylitis. The PBAC also noted that the existing secukinumab 150 mg PFP listings have a fourth indication, non-radiographic axial spondyloarthritis, which will not apply to the 300 mg/2 mL forms.
- 5.2 The PBAC noted that listing of the 300 mg forms of secukinumab would be at the same price per mg as the currently listed 150 mg form of secukinumab.
- 5.3 The PBAC noted the TGA evaluator's view that secukinumab 300 mg PFP and PFS were likely to be equivalent in efficacy and safety when compared to secukinumab 2 x 150 mg PFP.
- 5.4 The PBAC noted that the listing of secukinumab 300 mg PFP and 300 mg PFS would not result in any additional cost to government.
- 5.5 The PBAC noted the Sponsor's claim that the secukinumab 300 mg/2 mL PFP and 300 mg/2 mL PFS listings would reduce injection burden for some patients, as the new forms could be used in place of 2 x secukinumab 150 mg PFP.
- 5.6 The PBAC recalled that, at its November 2021 meeting, it recommended secukinumab for the treatment of paediatric patients with severe chronic plaque psoriasis. The PBAC noted that, should its November 2021 recommendation progress to listing, the paediatric chronic plaque psoriasis indication should also apply to secukinumab 300 mg/2 mL PFP and 300 mg/2 mL PFS.
- 5.7 The PBAC advised, under Section 101(4AACD) of the Act, that secukinumab 300 mg PFP and secukinumab 300 mg PFS should be considered equivalent for the purposes

of substitution (i.e., 'a' flagged in the Schedule with a NOTE stating pharmaceutical benefits of one form and pharmaceutical benefits of another form are equivalent for the purposes of substitution).

- 5.8 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because secukinumab 300 mg PFP and PFS are not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over secukinumab 150 mg PFP, or not expected to address a high and urgent unmet clinical need given the presence of an alternative therapy, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2009* for Pricing Pathway A were not met.
- 5.9 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

**Outcome:**

Recommended

## **6 Recommended listing**

- 6.1 Add new items:

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MEDICINAL PRODUCT Medicinal Product Pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
SECUKINUMAB secukinumab 300 mg/2 mL injection, 1 x 2 mL syringe secukinumab 300 mg/2 mL injection, 1 x 2 mL pen device	NEW				Cosentyx®
Indication <b>Severe psoriatic arthritis</b>					
Initial Treatment	NEW	4	4	0	
Initial Treatment Balance of Supply	NEW	1	1	2	
Continuing Treatment Continuing Treatment Balance of Supply	NEW	1	1	5	
Indication <b>Severe chronic plaque psoriasis</b>					
Initial Treatment	NEW	4	4	0	
Initial Treatment Balance of Supply	NEW	1	1	2	
Continuing Treatment Continuing Treatment Balance of Supply	NEW	1	1	5	
Indication <b>Ankylosing spondylitis</b>					
Initial Treatment	NEW	4	4	0	
Initial Treatment Balance of Supply	NEW	1	1	2	
Continuing Treatment Continuing Treatment Balance of Supply	NEW	1	1	5	

6.2 Attach the following restriction summaries to the new items (full restriction text not shown; refer to [www.pbs.gov.au](http://www.pbs.gov.au) for full text):

**Severe psoriatic arthritis**

**Initial Treatment: Benefit type 49431**

Restriction summary 11268 Initial treatment - Initial 1 (new patient)

Restriction summary 9112 Initial treatment – Initial 2 (change or recommencement of treatment after a break in in biological medicine of less than 5 years)

Restriction summary 9061 Initial treatment – Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Initial Treatment Balance of Supply: Benefit type 45968**

Restriction summary 9106 Initial treatment – Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Continuing Treatment: Benefit type 49447**

Restriction summary 11208 Continuing treatment

Restriction summary 9121 Continuing treatment - balance of supply

**Severe chronic plaque psoriasis**

**Initial Treatment: Benefit type 49356**

Restriction Summary 11087 Initial treatment - Initial 1, Whole body (new patient)

**Restriction Summary 11140** Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

**Restriction Summary 11088** Initial treatment – Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)

**Restriction Summary 11146** Initial treatment - Initial 1, Face, hand, foot (new patient))

**Restriction Summary 11106** Initial treatment – Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

**Restriction Summary 11121** Initial treatment – Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

**Initial Treatment Balance of Supply: Benefit type 45455**

**Restriction summary 8788** Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Continuing Treatment: Benefit type 49486**

**Restriction summary 11209** Continuing treatment, Whole body

**Restriction summary 11271** Continuing treatment, Face, hand, foot

**Restriction summary 8829** Continuing treatment – Whole body or Face, hand, foot - balance of supply

**Ankylosing spondylitis**

**Initial Treatment: Benefit type 46344**

**Restriction Summary 9530** Initial treatment - Initial 1, Whole body (new patient)

**Restriction Summary 9412** Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Restriction Summary 9427** Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Initial Treatment Balance of Supply: Benefit type 46451**

**Restriction summary 9535** Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Continuing Treatment: Benefit type 46301**

**Restriction summary 9508** Continuing treatment

**Restriction summary 9415** Continuing treatment - balance of supply

6.3 Add the following ‘Note’ to each of the item listed above in 7.1:

new	<p><b>Administrative Advice:</b>                  Pharmaceutical benefits that have the form secukinumab 300 microgram/2 mL injection, 2mL pen device and pharmaceutical benefits that have the form secukinumab 300 microgram/2 mL injection, 2 mL pre-filled syringe are equivalent for the purposes of substitution.</p>
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**This restriction may be subject to further review. Should there be any changes made to the restriction the Sponsor will be informed.**

**7 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.

## **8 Sponsor's Comment**

The sponsor had no comment.