

**5.26 RISANKIZUMAB,  
Injection 150 mg in 1 mL pre-filled pen and 150 mg  
in 1 mL pre-filled syringe,  
Skyrizi<sup>®</sup>,  
AbbVie Pty Ltd**

**1 Purpose of Submission**

- 1.1 The Category 4 submission requested General Schedule listings for new forms of risankizumab injection (Skyrizi<sup>®</sup>), that is, a 150 mg/1 mL pre-filled pen (PFP) and a 150 mg/1 mL pre-filled syringe (PFS), under the same circumstances as the currently listed risankizumab 75 mg/0.83 mL PFS.

**2 Background**

**Registration status**

- 2.1 Risankizumab is indicated for the treatment of moderate to severe plaque psoriasis in adults (18 years or older) who are candidates for phototherapy or systemic therapy. According to the Product Information, the recommended dose is 150 mg by subcutaneous injection at Week 0, Week 4 and every 12 weeks thereafter.
- 2.2 The 150 mg PFP and 150 mg PFS were listed on the Australian Register of Therapeutic Goods (ARTG) on 19 August 2021.

**Previous PBAC consideration**

- 2.3 At its July 2019 meeting, the PBAC recommended risankizumab (75 mg/0.83 mL PFS) for the treatment of severe chronic plaque psoriasis (CPP), which was listed on the PBS on 1 December 2019.

**3 Requested listing**

- 3.1 The submission requested listing risankizumab 150 mg PFP and 150 mg PFS under the same circumstances as the currently PBS-listed risankizumab 75 mg/0.83 mL PFS. As no changes to the restrictions were requested, they have not been reproduced.

Add new medicinal product packs as follows:

MEDICINAL PRODUCT Medicinal Product Pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
<b>Initial treatment</b>					Skyrizi
RISANKIZUMAB 150 mg/1 mL injection, 1 mL pen device	NEW	1	1	2	
RISANKIZUMAB 150 mg/1 mL injection, 1 mL syringe	NEW	1	1	2	
<b>Continuing treatment</b>					
RISANKIZUMAB 150 mg/1 mL injection, 1 mL pen device	NEW	1	1	1	
RISANKIZUMAB 150 mg/1 mL injection, 1 mL syringe	NEW	1	1	1	

3.2 The submission noted that at the July 2020 PBAC meeting, a PFP of guselkumab was recommended, including an update to the administrative advice to clarify that patients are not to be approved for concurrent use of guselkumab PFP and PFS. The submission considered that the same approach could apply to the administrative advice for risankizumab.

3.3 The pre-PBAC response considered the 150 mg PFP and 150 mg PFS should not be considered equivalent for the purposes of substitution (i.e. 'a' flagged in the Schedule). The different injection techniques present a risk of incorrect injecting of a dose if patients are dispensed a different presentation to what they were trained to use.

*For more detail on PBAC's view, see section 6 PBAC outcome.*

## 4 Comparator

4.1 The submission nominated risankizumab (two x 75 mg/0.83mL PFS) as the comparator and stated that this PBS-listed item will be substituted directly for the 150 mg PFP and 150 mg PFS. The PBAC agreed the comparator is appropriate.

*For more detail on PBAC's view, see section 6 PBAC outcome.*

## 5 Consideration of the evidence

5.1 The submission stated that there were three clinical trials included in the TGA submission to support registration of risankizumab 150 mg PFP and risankizumab 150 mg PFS (see Table 1 below). 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>M15-990</b>	Phase I bioequivalence bridging study conducted in healthy participants following a single dose administration of either 150 mg/mL in PFS or AI, or 2x 75mg/0.83 mL PFS.
<b>M15-999</b>	Phase 3 multicenter, randomised, double-blind, placebo-controlled evaluation of the same dose and dosing regimen as in the approved 75mg/0.83mL formulation in adult subjects with moderate to severe chronic plaque psoriasis.
<b>M16-005</b>	Phase 3 multicenter, single-arm, open-label study in adult patients with moderate to severe plaque psoriasis.

Source: Table 4, page 5 of submission

- 5.2 In consideration of the evidence for the 150 mg PFP and 150 mg PFS compared with the 75 mg/0.83 mL PFS, the TGA Evaluator concluded that bioequivalence was demonstrated (paragraph 5.2, page 7, Clinical Evaluation Report (CER) 2) and that, overall, the benefit-risk profile was favourable (paragraph 16.3, page 60, CER 2).
- 5.3 The TGA Delegate considered that the 150 mg PFS is bioequivalent to two 75 mg/0.83 mL PFS injections, and that the 150 mg PFS is bioequivalent to the 150 mg PFP.
- 5.4 The TGA Delegate concluded: “The sponsor has submitted acceptable data to support the registration of the 150 mg/mL pre-filled syringe and pen presentations.” (TGA Delegate’s Overview, page 10).

### **Pricing considerations**

- 5.5 The submission proposed the same published and effective prices for the 150 mg PFP and 150 mg PFS as the PBS-listed two pack of 75 mg PFS.
- 5.6 The submission requested no changes to the existing Special Pricing Arrangement for risankizumab in severe CPP.
- 5.7 The submission considered that the 150 mg PFP and 150 mg PFS should be cost-minimised to the existing PBS-listed risankizumab 75 mg PFS rather than the lowest cost comparator. The sponsor maintained this view in the pre-PBAC response.
- 5.8 Section 101(3B) of the Act stipulates that if the requested treatment is substantially more costly than alternative therapies, then the PBAC could only recommend listing at the higher price if it is satisfied that the treatment provides, for some patients, a significant improvement in efficacy or reduction of toxicity over the existing therapies. The advice provided by the PBAC applies to each medicine on a case by case basis.

### **Estimated PBS usage & financial implications**

- 5.9 With no expected changes to current utilisation, mark-up fees and co-payments, and with the same price and dosing schedule as the 75 mg PFS, the submission claimed nil net financial impact of listing the 150 mg PFP and 150 mg PFS.
- 5.10 The submission assumed that ■% of patients would move to the 150 mg PFP, while the remaining ■% would move to the 150 mg PFS.

- 5.11 In the pre-PBAC response, the sponsor confirmed the 75 mg strength would be discontinued in the future but did not specify a date.

### **Quality use of medicines**

- 5.12 The submission claimed that the availability of the 150 mg PFP and 150 mg PFS will reduce the burden for patients by halving the number of required injections.
- 5.13 The submission also claimed that the 150 mg PFP and 150 mg PFS may help to improve quality use of medicines by reducing the risk of under-dosing with the 75 mg PFS and will provide options to meet various patient preferences regarding choice of device.

*For more detail on PBAC's view, see section 6 PBAC outcome.*

### **Sponsor hearing**

- 5.14 There was no hearing for this item.

### **Consumer comments**

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

## **6 PBAC Outcome**

- 6.1 The PBAC recommended the listing of risankizumab 150 mg/1 mL PFP and 150 mg/1 mL PFS under the same circumstances as the currently listed risankizumab 75 mg/0.83 mL PFS.
- 6.2 The PBAC considered that risankizumab 150 mg PFP and PFS were likely to be equivalent in efficacy and safety when compared to risankizumab 75 mg/0.83 mL PFS based on the TGA evaluation.
- 6.3 Consistent with Section 101(3B) of the Act, the PBAC advised that risankizumab PFP and PFS should be cost-minimised to the lowest cost biological agent available for severe CPP, noting that any of the current PBS listed bDMARDs for severe CPP could be an alternative therapy to risankizumab. Relevant PBS-listed comparators include adalimumab, etanercept, guselkumab, infliximab, ixekizumab, Risankizumab, secukinumab, tildrakizumab and ustekinumab.
- 6.4 The PBAC considered the requested maximum quantities and repeats are appropriate as the 150 mg PFP and 150 mg PFS are intended to be used in place of the 75 mg PFS (two pack) (item codes: 11827L for initial treatment, and 11858D for continuing treatment).
- 6.5 The PBAC considered it appropriate to include administrative advice noting PFP and PFS are not to be prescribed concurrently. This should flow on to the existing 75 mg PFS listing.
- 6.6 The PBAC advised, under Section 101 (4AACD) of the Act, that risankizumab 150 mg PFP and risankizumab 150 mg PFS should not be considered equivalent for the purposes of substitution (i.e., 'a' flagged in the Schedule).

- 6.7 The PBAC considered that the listing the 150 mg PFP and 150 mg PFS would not result in any additional cost to government.
- 6.8 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because risankizumab 150 mg PFP and PFS are not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over risankizumab 75 mg PFS, 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.
- 6.9 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

**Outcome:**

Recommended

## 7 Recommended listing

- 7.1 Add new items:

MEDICINAL PRODUCT Medicinal Product Pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
<b>Initial treatment</b>					Skyrizi
RISANKIZUMAB 150 mg/1 mL injection, 1 mL pen device	NEW	1	1	2	
RISANKIZUMAB 150 mg/1 mL injection, 1 mL syringe	NEW	1	1	2	
<b>Continuing treatment</b>					
RISANKIZUMAB 150 mg/1 mL injection, 1 mL pen device	NEW	1	1	1	
RISANKIZUMAB 150 mg/1 mL injection, 1 mL syringe	NEW	1	1	1	

- 7.2 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):

**Initial treatment: Benefit Type 49329**

**Restriction summary 11155** (Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years))

**Restriction summary 11164** (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 10851** (Initial treatment - Initial 1, Face, hand, foot (new patient))

**Restriction summary 11156** (Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years))

**Restriction summary 11108** (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 10905** (Initial treatment - Initial 1, Whole body (new patient))

**Restriction summary 11092** (Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement 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 54136**

**Restriction summary 9985** (Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply)

**Restriction summary 10002** (Continuing treatment, Face, hand, foot)

**Restriction summary 12343** (Continuing treatment, Whole body)

(Restriction summary numbers current as of November 2021)

- 7.3 Add the following 'Note' to each of the item listed above in 7.1 and to be flowed on to 75 mg risankizumab PFS (11827L and 11858D):

new	<b>Administrative Advice:</b> Multiple forms/presentations of this drug are not to be prescribed as PBS-benefits simultaneously on an ongoing basis.
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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.***

## 8 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.

## 9 Sponsor's Comment

The sponsor had no comment.