

**6.16 RISANKIZUMAB,
Injection 150 mg in 1 mL pre-filled pen,
Injection 150 mg in 1 mL pre-filled syringe,
Injection 75 mg in 0.83 mL pre-filled syringe,
Skyrizi®,
AbbVie Pty Ltd**

1 Purpose of Submission

- 1.1 The Category 3 submission requested to extend the existing PBS listings for risankizumab 150 mg in 1 mL pre-filled pen (PFP), 150 mg in 1 mL pre-filled syringe (PFS) and 75 mg in 0.83 mL PFS for the treatment of severe chronic plaque psoriasis (CPP) to allow patients enrolled in the risankizumab open label extension trial (M15-997) to be grandfathered on to PBS-subsidised risankizumab.

2 Background

Registration status

- 2.1 Risankizumab is TGA registered for the treatment of moderate to severe plaque psoriasis in adults (18 years or older) who are candidates for phototherapy or systemic therapy.
- 2.2 The 75 mg PFS was listed on the Australian Register of Therapeutic Goods (ARTG) on 16 July 2019; the 150 mg PFP and 150 mg PFS were listed on the 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 CPP, which was listed on the PBS on 1 December 2019. The PBAC noted that a number of clinical trial patients were expected to transition to PBS-subsidised risankizumab in January 2022, and advised that an additional submission would be required closer to the date of trial completion to extend the grandfathering clause (paragraph 7.8, PSD, risankizumab July 2019).
- 2.4 At its November 2021 meeting, the PBAC recommended risankizumab 150 mg/1 mL PFP and PFS for the treatment of severe CPP. The 150 mg PFP and PFS are not yet listed on the PBS.

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

3 Requested listing

3.1 The submission requested the following new restriction to be added to the existing listings:

Add new restriction as follows:

3.2 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 |
|---|--------------------------|----------------|----------------|-------------|------------------|
| RISANKIZUMAB | | | | | |
| 75 mg/0.83 mL injection, 2 x 0.83 mL syringes | 11827L NEW | 1 | 2 | 1 | Skyrizi® |
| 150 mg/mL injection, 1 mL syringe | NEW | 1 | 1 | 1 | |
| 150 mg mg/mL injection pen device, 1 mL syringe | NEW | 1 | 1 | 1 | |

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| Create new prescribing rule with new Restriction Summary / Treatment of Concept: | |
| | Category / Program: GENERAL – General Schedule (Code GE) |
| | Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners |
| | Restriction: <input checked="" type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required – Telephone |
| | Administrative Advice: <i>No increase in the maximum quantity or number of units may be authorised.</i> |
| | Administrative Advice: <i>No increase in the maximum number of repeats may be authorised.</i> |
| | Administrative Advice: <i>Special Pricing Arrangements apply.</i> |
| | PBS Indication: Severe chronic plaque psoriasis |
| | Treatment phase: Grandfathered patients, Whole body (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) |
| | Treatment criteria: Must be treated by a dermatologist. |
| | Clinical criteria: Patient must have severe chronic plaque psoriasis where lesions had been present for at least 6 months from the time of initial diagnosis prior to initiating non-PBS subsidised treatment |
| | AND |
| | Clinical criteria: Patient must have previously received non-PBS subsidised treatment with this drug for this condition prior to [insert listing date] |

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| | AND |
| | Patient must have a documented history of severe chronic plaque psoriasis |
| | Clinical criteria: Patient must have had a Psoriasis Area and Severity Index (PASI) score of greater than 15 prior to commencing treatment with this drug <i>for this condition</i> , |
| | AND |
| | Clinical criteria: Patient must have demonstrated a response to treatment following at least 12 weeks of non-PBS subsidised as specified in the criterion included in the restriction for continuing PBS-subsidised treatment with this drug <i>for this condition (whole body)</i> , |
| | AND |
| | Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); |
| | Clinical criteria: The treatment must be as systemic monotherapy (other than methotrexate), |
| | AND |
| | Clinical criteria: Patient must not receive more than 24 weeks of treatment under this restriction |
| | AND |
| | Population criteria: Patient must be aged 18 years or older. |
| | Prescriber Instructions: <i>An adequate response to treatment is defined as:</i> <i>A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.</i> |
| | <i>The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:</i> <i>(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.</i> <i>(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.</i> <i>(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.</i> |
| | Prescriber Instructions: The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes <i>the completed Psoriasis Area and Severity Index (PASI) calculation sheets including the date of the assessment of the patient's condition at baseline (prior to initiation of therapy with this drug); and the following:</i> (i) <i>details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy;</i> The most recent PASI assessment must be no more than 4 weeks old at the time of application. |

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| | <p>The most recent PASI assessment, demonstrating response, must be no more than 1 month old at the time of application.</p> <p>(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition at baseline (prior to initiation of therapy with this drug) and the most recent PASI assessment; and</p> <p>(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and</p> <p>(iii) the signed patient and prescriber acknowledgements.</p> <p>The most recent PASI assessment must be no more than 1 month old at the time of application.</p> <p>A patient may qualify for PBS subsidised treatment under this restriction once only</p> |
| | <p>Prescriber Instructions:</p> <p>A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria.</p> |
| | <p>Prescribing Instructions:</p> <p>This grandfather restriction will cease to operate from 14 months after the date specified in the clinical criteria.</p> |
| | <p>Administrative Advice</p> <p>Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</p> <p>Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au</p> <p>Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos</p> <p>Or mailed to: Services Australia Complex Drugs Reply Paid 9826 HOBART TAS 7001</p> |
| | <p>A PASI assessment of the patient's response to this initial PBS-subsidised course of therapy must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.</p> <p>It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.</p> <p>Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</p> <p>Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au</p> |

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| | <p>Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</p> <p>No increase in the maximum number of repeats may be authorised.</p> <p>No increase in the maximum number of units may be authorised.</p> <p>Special Pricing Arrangements apply.</p> |
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| Create new prescribing rule with new Restriction Summary / Treatment of Concept: | |
| | <p>Category / Program: GENERAL – General Schedule (Code GE)</p> |
| | <p>Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners</p> |
| | <p>Restriction: <input checked="" type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required – Telephone</p> |
| | <p>Administrative Advice: <i>No increase in the maximum quantity or number of units may be authorised.</i></p> |
| | <p>Administrative Advice: <i>No increase in the maximum number of repeats may be authorised.</i></p> |
| | <p>Administrative Advice: <i>Special Pricing Arrangements apply.</i></p> |
| | <p>PBS Indication: Severe chronic plaque psoriasis</p> |
| | <p>Treatment phase: Grandfathered patients, Face, hand, foot (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy)</p> |
| | <p>Treatment criteria: Must be treated by a dermatologist.</p> |
| | <p>Clinical criteria: Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where lesions have been present for at least 6 months from the time of initial diagnosis prior to initiating non-PBS subsidised treatment</p> |
| | <p>AND</p> |
| | <p>Clinical criteria: Patient must have previously received non-PBS subsidised treatment with this drug for this condition prior to [insert listing date]</p> |
| | <p>AND</p> |
| | <p>Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot,</p> |
| | <p>Clinical criteria: Patient must have had disease, prior to treatment with this drug <i>for this condition</i>, classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling were rated as severe or very severe; or (ii) the skin area affected was 30% or more of the face, palm of a hand or sole of a foot,</p> |
| | <p>AND</p> |
| | <p>Clinical criteria:</p> |

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| | Patient must have demonstrated a response to treatment following at least 12 weeks of non-PBS subsidised as specified in the criterion included in the restriction for continuing PBS subsidised treatment with this drug <i>for this condition (face, hand, foot),</i> |
| | AND |
| | Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot), |
| | Clinical criteria: The treatment must be as systemic monotherapy (other than methotrexate), |
| | AND |
| | Clinical criteria: Patient must not receive more than 24 weeks of treatment under this restriction |
| | AND |
| | Population criteria: Patient must be aged 18 years or older. |
| | Prescriber Instructions: <i>An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:</i> <i>(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or</i> <i>(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.</i> |
| | Prescriber Instructions: <i>The PASI assessment must be performed on the same affected area as assessed at baseline or prior to initiation of treatment with this drug.</i> |
| | <i>The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:</i> <i>(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.</i> <i>(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.</i> <i>(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.</i> |
| | Prescriber Instructions: The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes <i>the completed Psoriasis Area and Severity Index (PASI) calculation sheets demonstrating response and face, hand, foot area diagrams including the date of the assessment of the patient's condition at baseline (prior to initiation of therapy with this drug); and the following:</i> (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition at baseline (prior to initiation of therapy with this drug) and the most recent PASI assessment; and (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; |

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| | <p>The most recent PASI assessment must be no more than 4 weeks old at the time of application.</p> <p>(iii) the signed patient and prescriber acknowledgements.</p> <p>The most recent PASI assessment must be no more than 1 month old at the time of application.</p> <p>A patient may qualify for PBS-subsidised treatment under this restriction once only</p> |
| | <p>Prescribing Instructions: The most recent PASI assessment, demonstrating response, must be no more than 1 month old at the time of application.</p> |
| | <p>Prescriber Instructions: A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria.</p> |
| | <p>Prescribing Instructions: This grandfather restriction will cease to operate from 14 months after the date specified in the clinical criteria.</p> |
| | <p>Prescriber Instructions For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria.</p> |
| | <p>Administrative Advice: Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</p> <p>Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au</p> <p>Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos</p> <p>Or mailed to: Services Australia Complex Drugs Reply Paid 9826 HOBART TAS 7001</p> |
| | <p>A PASI assessment of the patient's response to this initial PBS-subsidised course of therapy must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.</p> <p>It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.</p> <p>Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</p> <p>Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au</p> |

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| <p>Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</p> <p>No increase in the maximum number of repeats may be authorised.</p> <p>No increase in the maximum number of units may be authorised.</p> <p>Special Pricing Arrangements apply.</p> |
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| Create new prescribing rule with new Restriction Summary / Treatment of Concept: | |
| | <p>Category / Program: GENERAL – General Schedule (Code GE)</p> |
| | <p>Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners</p> |
| | <p>Restriction: <input checked="" type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone</p> |
| | <p>Administrative Advice: No increase in the maximum quantity or number of units may be authorised.</p> |
| | <p>Administrative Advice: No increase in the maximum number of repeats may be authorised.</p> |
| | <p>Administrative Advice: Special Pricing Arrangements apply.</p> |
| | <p>PBS Indication: Severe chronic plaque psoriasis</p> |
| | <p>Treatment phase: Grandfathered patients, Face, hand, foot – Balance of Supply or Whole body – Balance of Supply</p> |
| | <p>Treatment criteria: Must be treated by a dermatologist.</p> |
| | <p>Clinical criteria: The treatment must be as systemic monotherapy (other than methotrexate),</p> |
| | <p>AND</p> |
| | <p>Clinical criteria: The treatment must provide no more than the balance of up to 24 weeks of treatment available under the above restriction.</p> |
| | <p>Administrative Advice: Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</p> <p>Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au</p> <p>Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos</p> <p>Or mailed to: Services Australia Complex Drugs Reply Paid 9826 HOBART TAS 7001</p> |

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

4 Consideration of the evidence

4.1 As a Category 3 submission, no evaluation of the clinical evidence was undertaken.

Sponsor hearing

4.2 There was no hearing for this item.

Consumer comments

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

Clinical Trials

4.4 The submission noted there are < 500 patients who will transition from the clinical trial M15-997, an open-label extension trial which recruited subjects from the four pivotal, randomised, double-blinded, active- or placebo-controlled studies which were previously considered by the PBAC in July 2019 (UltIMMa-1, UltIMMa-2, IMMvent and IMMhance). The < 500 patients will be completing their final treatment in M15-997 trial between April 2022 and May 2023.

Estimated PBS utilisation and financial implications

4.5 The submission requested no change to the Dispensed Price for Maximum Quantity (DPMQ) of risankizumab. The requested price was based on the DPMQ of risankizumab in January 2022.

4.6 The sponsor provided utilisation and cost modelling to confirm the estimated use and financial implications.

4.7 Table 1 presents the estimated extent of use, cost of risankizumab to the PBS and the net financial implications to the PBS. The financial impact to Services Australia will be determined by that agency as part of the post PBAC process.

Table 1: Estimated use and financial implications

| | 2022 | 2023 | 2024 | 2025 | 2026 | 2027 |
|---|------|------|------|------|------|------|
| Estimated extent of use | | | | | | |
| Number of grandfathered patients treated | 1 | 1 | 1 | 1 | 1 | 1 |
| Number of scripts dispensed ^a | 1 | 1 | 1 | 1 | 1 | 1 |
| Estimated financial implications of grandfathered patients of risankizumab | | | | | | |
| PUBLISHED PRICE | | | | | | |
| Cost to PBS (\$) | 2 | 2 | 2 | 2 | 2 | 2 |
| Less co-payments (\$) | 2 | 2 | 2 | 2 | 2 | 2 |

| | | | | | | |
|------------------------|---|---|---|---|---|---|
| Net cost to PBS (\$) | 1 | 1 | 1 | 1 | 1 | 1 |
| EFFECTIVE PRICE | | | | | | |
| Cost to PBS (\$) | 1 | 1 | 1 | 1 | 1 | 1 |
| Less co-payments (\$) | 1 | 1 | 1 | 1 | 1 | 1 |
| Net cost to PBS (\$) | 1 | 1 | 1 | 1 | 1 | 1 |

^a Assuming 4.35 scripts per patient per year as estimated by the submission. Assuming 0 RPBS scripts per year as estimated by the submission. Abbreviations: PBS = Pharmaceutical Benefits Scheme RPBS = Repatriation Pharmaceutical Benefits Scheme.

Source: Utilisation and Cost Model spreadsheet

The redacted values correspond to the following ranges:

¹ < 500

² \$0 to < \$10 million

- 4.8 The submission estimated that an additional < 500 patients would be supplied risankizumab over the first six years of listing. The static patient numbers from 2022 to 2027 reflect this cohort (Table 1).
- 4.9 The submission stated that the estimated net financial impact to the PBS for the grandfathered listing of risankizumab is \$0 to < \$10 million per year over six years at the effective price level.

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

5 PBAC Outcome

- 5.1 The PBAC recommended extension of the listing of risankizumab 75 mg in 0.83 mL PFS for the treatment of severe chronic plaque psoriasis (CPP) to allow access for patients enrolled in the risankizumab open label extension trial (M15-997) to be grandfathered on to PBS-subsidised risankizumab.
- 5.2 The PBAC noted that risankizumab 150 mg/mL PFP and 150 mg/mL PFS, which were recommended at its November 2021 meeting, are not currently listed on the PBS. The PBAC considered that, should risankizumab 150 mg/mL PFP and 150 mg/mL PFS list before the end of the grandfathering period, these listings should also include grandfather restrictions to allow for patients enrolled in risankizumab M15-997 to access to PBS-subsidised risankizumab 150 mg/mL.
- 5.3 The PBAC noted the estimated financial impact of \$0 to < \$10 million per year over six years at the effective price level.
- 5.4 The PBAC noted there are no grandfather restrictions in the current risankizumab PBS listing and considered the requested transition arrangements for patients to be grandfathered on from clinical trial M15-997 were appropriate.
- 5.5 The PBAC advised that because grandfathering of patients treated with risankizumab 75 mg/0.83 mL, 150 mg/mL PFP and 150 mg/mL PFS are not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over alternative therapies, 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.

- 5.6 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 Grandfather treatment phase to PBS indication 8050 – severe chronic plaque psoriasis as follows:

| MEDICINAL PRODUCT Medicinal Product Pack | PBS item code | Max. qty packs | Max. qty units | No. of Rpts | Available brands |
|---|---------------|----------------|----------------|-------------|------------------|
| RISANKIZUMAB 75 mg/0.83 mL injection, 2 x 0.83 mL syringes | NEW | 1 | 2 | 1 | Skyrizi® |
| 150 mg/mL injection, 1 mL syringe | NEW | 1 | 1 | 1 | |
| 150mg mg/mL injection pen device, 1 mL syringe | NEW | 1 | 1 | 1 | |

| Create new prescribing rule with new Restriction Summary / Treatment of Concept: | |
|--|---|
| | Category / Program: GENERAL – General Schedule (Code GE) |
| | Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners |
| | Restriction: <input checked="" type="checkbox"/> Authority Required - In Writing |
| | Administrative Advice: No increase in the maximum quantity or number of units may be authorised. |
| | Administrative Advice: No increase in the maximum number of repeats may be authorised. |
| | Administrative Advice: Special Pricing Arrangements apply. |
| | PBS Indication: Severe chronic plaque psoriasis |
| | Treatment phase: Grandfathered patients, Whole body (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) |
| | Treatment criteria: Must be treated by a dermatologist. |
| | Clinical criteria: Patient must have severe chronic plaque psoriasis where lesions had been present for at least 6 months from the time of initial diagnosis prior to initiating non-PBS subsidised treatment |

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| | AND |
| | Clinical criteria: Patient must have previously received non-PBS subsidised treatment with this drug for this condition prior to [insert listing date] |
| | AND |
| | Clinical criteria: Patient must have had a Psoriasis Area and Severity Index (PASI) score of greater than 15 prior to commencing treatment with this drug for this condition, |
| | AND |
| | Clinical criteria: Patient must have demonstrated a response to treatment following at least 12 weeks of non-PBS subsidised treatment with this drug for this condition, |
| | AND |
| | Clinical criteria: The treatment must be as systemic monotherapy (other than methotrexate), |
| | AND |
| | Clinical criteria: Patient must not receive more than 24 weeks of treatment under this restriction |
| | AND |
| | Population criteria: Patient must be aged 18 years or older. |
| | Prescriber Instructions: An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. |
| | Prescriber Instructions: The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheets including the date of the assessment of the patient's condition at baseline (prior to initiation of therapy with this drug) and= (i) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; The most recent PASI assessment must be no more than 4 weeks old at the time of application. |
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| | Prescriber Instructions: A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria. |
| | Prescribing Instructions: This grandfather restriction will cease to operate from 14 months after the date specified in the clinical criteria. |
| | Administrative Advice |

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| | <p>Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</p> <p>Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au</p> <p>Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos</p> <p>Or mailed to: Services Australia Complex Drugs Reply Paid 9826 HOBART TAS 7001</p> |
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| Create new prescribing rule with new Restriction Summary / Treatment of Concept: | |
| | <p>Category / Program: GENERAL – General Schedule (Code GE)</p> |
| | <p>Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners</p> |
| | <p>Restriction: <input checked="" type="checkbox"/> Authority Required - In Writing</p> |
| | <p>Administrative Advice: No increase in the maximum quantity or number of units may be authorised.</p> |
| | <p>Administrative Advice: No increase in the maximum number of repeats may be authorised.</p> |
| | <p>Administrative Advice: Special Pricing Arrangements apply.</p> |
| | <p>PBS Indication: Severe chronic plaque psoriasis</p> |
| | <p>Treatment phase: Grandfathered patients, Face, hand, foot (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy)</p> |
| | <p>Treatment criteria: Must be treated by a dermatologist.</p> |
| | <p>Clinical criteria: Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where lesions have been present for at least 6 months from the time of initial diagnosis prior to initiating non-PBS subsidised treatment</p> |
| | <p>AND</p> |
| | <p>Clinical criteria: Patient must have previously received non-PBS subsidised treatment with this drug for this condition prior to [insert listing date]</p> |
| | <p>AND</p> |
| | <p>Clinical criteria: Patient must have had disease, prior to treatment with this drug for this condition, classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling were rated as severe or very severe; or (ii) the skin area affected was 30% or more of the face, palm of a hand or sole of a foot,</p> |

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| | AND |
| | Clinical criteria: Patient must have demonstrated a response to treatment following at least 12 weeks of non-PBS subsidised treatment with this drug for this condition, |
| | AND |
| | Clinical criteria: The treatment must be as systemic monotherapy (other than methotrexate), |
| | AND |
| | Clinical criteria: Patient must not receive more than 24 weeks of treatment under this restriction |
| | AND |
| | Population criteria: Patient must be aged 18 years or older. |
| | Prescriber Instructions: An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. |
| | Prescriber Instructions: The PASI assessment must be performed on the same affected area as assessed at baseline or prior to initiation of treatment with this drug. |
| | Prescriber Instructions: The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheets demonstrating response and face, hand, foot area diagrams including the date of the assessment of the patient's condition at baseline (prior to initiation of therapy with this drug); and the following : (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy] The most recent PASI assessment must be no more than 4 weeks old at the time of application. |
| | |
| | Prescriber Instructions: A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria. |
| | Prescribing Instructions: This grandfather restriction will cease to operate from 14 months after the date specified in the clinical criteria. |
| | Prescriber Instructions |

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| | For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria. |
| | <p>Administrative Advice: Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</p> <p>Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au</p> <p>Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos</p> <p>Or mailed to: Services Australia Complex Drugs Reply Paid 9826 HOBART TAS 7001</p> |

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| Create new prescribing rule with new Restriction Summary / Treatment of Concept: | |
| | <p>Category / Program: GENERAL – General Schedule (Code GE)</p> |
| | <p>Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners</p> |
| | <p>Restriction: <input checked="" type="checkbox"/> Authority Required - In Writing</p> |
| | <p>Administrative Advice: No increase in the maximum quantity or number of units may be authorised.</p> |
| | <p>Administrative Advice: No increase in the maximum number of repeats may be authorised.</p> |
| | <p>Administrative Advice: Special Pricing Arrangements apply.</p> |
| | <p>PBS Indication: Severe chronic plaque psoriasis</p> |
| | <p>Treatment phase: Grandfathered patients, Face, hand, foot – Balance of Supply or Whole body – Balance of Supply</p> |
| | <p>Treatment criteria: Must be treated by a dermatologist.</p> |
| | <p>Clinical criteria: The treatment must be as systemic monotherapy (other than methotrexate),</p> |
| | <p>AND</p> |
| | <p>Patient must have received insufficient therapy with this drug for this condition under the Grandfathered treatment, Whole body restriction to complete 24 weeks treatment; OR</p> |
| | <p>Patient must have received insufficient therapy with this drug for this condition under the Grandfathered treatment, Face, hand, foot restriction to complete 24 weeks treatment</p> |
| | <p>AND</p> |
| | <p>Clinical criteria: The treatment must provide no more than the balance of up to 24 weeks of treatment available under the above restriction.</p> |

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| <p>Administrative Advice: Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</p> <p>Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au</p> <p>Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos</p> <p>Or mailed to: Services Australia Complex Drugs Reply Paid 9826 HOBART TAS 7001</p> |
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- 6.2 The following wording will need to be added to the Explanatory notes for Severe chronic plaque psoriasis: *‘Grandfather patients (risankizumab only). A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to [insert listing date] and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction’.*

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.