Australian Government
Services Australia

medicare

PBS

Psoriatic arthritis – risankizumab – initial grandfather authority application

Online PBS Authorities

You do not need to complete this form if you use the **Online PBS Authorities** system.

For more information and how to access the **Online PBS Authorities** system, go to **servicesaustralia.gov.au/hppbsauthorities**

When to use this form

Use this form to apply for **initial grandfather** PBS-subsidised risankizumab for patients 18 years or over with severe psoriatic arthritis who have received non-PBS-subsidised treatment with risankizumab for the same condition prior to **1 March 2025**.

Important information

Initial grandfather applications to start PBS-subsidised treatment can be made in real time using the **Online PBS Authorities** system or in writing and must include sufficient information to determine the patient's eligibility according to the PBS criteria.

Under no circumstances will phone approvals be granted for severe psoriatic arthritis **initial grandfather** authority applications.

The information in this form is correct at the time of publishing and may be subject to change.

Continuing treatment

This form is ONLY for **initial grandfather** treatment.

A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

For **continuing** PBS-subsidised treatment, a grandfathered patient must qualify under the continuing treatment criteria.

Treatment specifics

The assessment of the patient's response to the course of treatment must be conducted within the time frame specified in the restriction. Where a demonstration of response is not conducted within the required time frame, the patient will be deemed to have failed treatment with that particular PBS-subsidised biological medicine.

A patient who has experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal is not considered to have failed treatment with that particular PBS-subsidised biological medicine.

For more information

Go to **servicesaustralia.gov.au/healthprofessionals**

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Patient's details

1 Medicare card number

Ref no.

or

Department of Veterans' Affairs card number

2 Family name

First given name

3 Date of birth (DD MM YYYY)

4 Patient's weight

kg

Prescriber's details

5 Prescriber number

6 Family name

First given name

7 Business phone number (including area code)

Alternative phone number (including area code)

Conditions and criteria

To qualify for PBS authority approval, the following conditions must be met.

8 The patient, 18 years or over, is being treated by a:

- ☐ rheumatologist
- ☐ clinical immunologist with expertise in the management of psoriatic arthritis

9 Has the patient received non-PBS-subsidised treatment with this drug for this condition prior to **1 March 2025**?

- ☐ Yes
- ☐ No

10 Date the non-PBS-subsidised treatment commenced (DD MM YYYY)

11 Is the patient currently receiving treatment with this drug for this condition?

- ☐ Yes
- ☐ No

12 Prior to initiating non-PBS-subsidised treatment with this drug for this condition, the patient had failed to achieve an adequate response following a minimum of 3 months treatment with:

☐ Methotrexate, at a dose of at least 20 mg/week

and

☐ Sulfasalazine, at a dose of at least 2 g/day

or

☐ Leflunomide, at a dose up to 20 mg/day

13 If applicable, provide details of contraindications or intolerances to prior disease-modifying anti-rheumatic drugs (DMARD) treatment, including the degree of toxicity.

For details of the toxicity criteria, go to **servicesaustralia.gov.au/healthprofessionals**

Intolerances must be of a severity to necessitate permanent treatment withdrawal.

Methotrexate	Grade

Sulfasalazine	Grade

Leflunomide	Grade

MCA0PB375 2512

14 The patient has failed to achieve an adequate response to prior treatment demonstrated by:

☐ an elevated erythrocyte sedimentation rate (ESR) > 25 mm/hr

Baseline ESR level ____ mm/hr

Date of test (DD MM YYYY)

and/or

☐ an elevated C-reactive protein (CRP) > 15 mg/L

Baseline CRP level ____ mg/L

Date of test (DD MM YYYY)

or

☐ the requirement to demonstrate an elevated ESR or CRP could not be met due to

- ☐ treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent)

or

- ☐ treatment with a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent)

or

- ☐ provide an acceptable reason the patient could not demonstrate an elevated ESR or CRP level

and

☐ a total active joint count of at least 20 active (swollen and tender) joints

Baseline total active joint count

Date of assessment (DD MM YYYY)

or

☐ at least 4 active major joints from elbow, wrist, knee, ankle, shoulder and/or hip

Baseline active major joint count

Date of assessment (DD MM YYYY)

Where only one marker (ESR or CRP) has been provided at baseline, the same marker must be used for assessment for all continuing applications.

Where a patient has at least 4 active major joints and less than 20 total active joints at baseline, assessment of the major joints only will be used for all continuing applications.

15 Has the patient received non-PBS-subsidised treatment with this drug for this condition for at least 12 weeks?

Yes ☐ ***Go to 16***

No ☐ ***Go to 17***

16 The patient has demonstrated an adequate response to treatment evidenced by:

☐ an erythrocyte sedimentation rate (ESR) ≤ 25 mm/hr

ESR ____ mm/hr

Date of test (DD MM YYYY)

or

☐ an ESR reduced by at least 20% from baseline

Current ESR ____ mm/hr

Date of current ESR (DD MM YYYY)

and/or

☐ a C-reactive protein (CRP) level ≤ 15 mg/L

CRP ____ mg/L

Date of test (DD MM YYYY)

or

☐ a CRP reduced by at least 20% from baseline

Current CRP ____ mg/L

Date of current CRP (DD MM YYYY)

and

☐ a total active joint count of ≤ 10

Current total active joint count

Date of assessment (DD MM YYYY)

or

☐ a total active joint count reduced by at least 50% from baseline

Current total active joint count

Date of assessment (DD MM YYYY)

or

☐ a major joint count of ≤ 2

Current major joint count

Date of assessment (DD MM YYYY)

or

☐ a major joint count reduced by at least 50% from baseline

Current major joint count

Date of assessment (DD MM YYYY)

Checklist

17 The relevant attachments need to be provided with this form.

☐ Details of the proposed prescription(s).

Privacy notice

18 Personal information is protected by law (including the *Privacy Act 1988*) and is collected by Services Australia for the purposes of assessing and processing this authority application.

Personal information may be used by Services Australia, or given to other parties where the individual has agreed to this, or where it is required or authorised by law (including for the purpose of research or conducting investigations).

More information about the way in which Services Australia manages personal information, including our privacy policy, can be found at **servicesaustralia.gov.au/privacypolicy**

Prescriber's declaration

You do not need to **sign** the declaration if you complete this form using Adobe Acrobat Reader and return this form through Health Professional Online Services (HPOS) at **servicesaustralia.gov.au/hpos**

19 I declare that:

- I am aware that this patient must meet the criteria listed in the current Schedule of Pharmaceutical Benefits to be eligible for this medicine
- I have informed the patient that their personal information (including health information) will be disclosed to Services Australia for the purposes of assessing and processing this authority application
- I have provided details of the proposed prescription(s) and the relevant attachments as specified in the Pharmaceutical Benefits Scheme restriction
- the information I have provided in this form is complete and correct.

I understand that:

- giving false or misleading information is a serious offence.

☐ I have read, understood and agree to the above.

Date (DD MM YYYY) (you **must** date this declaration)

Prescriber's signature (**only** required if returning by post)

If returning by post, print and sign by hand.

Returning this form

Return this form, details of the proposed prescription(s) and any relevant attachments:

- **online** (no signature required), upload through HPOS at **servicesaustralia.gov.au/hpos**

  or

- by post (signature required) to

  Services Australia
  Complex Drugs Programs
  Reply Paid 9826
  HOBART TAS 7001

Reset form