Australian Government
Services Australia

medicare

PBS

Non-radiographic axial spondyloarthritis – bimekizumab – 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 bimekizumab for patients with non-radiographic axial spondyloarthritis who have received non-PBS-subsidised treatment with bimekizumab for the same condition prior to **1 October 2024**.

Important information

Initial grandfather applications to start PBS-subsidised treatment can be made 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 non-radiographic axial spondyloarthritis **initial grandfather** authority applications.

A copy of the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) is provided for your convenience, but is not required to be submitted with this application.

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.

After an authority application for **initial grandfather** treatment has been approved, applications for **continuing** treatment with bimekizumab can be made in real time using the **Online PBS Authorities** system or by phone. Call 1800 700 270 Monday to Friday, 8 am to 5 pm, local time.

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 Dr Mr Mrs Miss Ms Other

Family name

First given name

3 Date of birth (DD MM YYYY)

Prescriber's details

4 Prescriber number

5 Dr Mr Mrs Miss Ms Other

Family name

First given name

6 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.

7 The patient is being treated by a:

- rheumatologist
- clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis

8 Has the patient previously received non-PBS-subsidised treatment with this biological medicine for this condition prior to **1 October 2024**?

Yes
No

9 Has the patient responded inadequately to biological medicine on 4 occasions within the current treatment cycle?

Yes
No

10 Prior to commencing non-PBS-subsidised treatment with this drug, was the condition diagnosed as non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria?

Yes
No

11 Prior to commencing non-PBS-subsidised treatment with this drug, was the condition radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis?

Yes
No

12 Prior to commencing non-PBS-subsidised treatment with this drug, the condition was:

- sacroiliitis with active inflammation on non-contrast Magnetic Resonance Imaging (MRI)

and/or

- sacroiliitis with oedema on non-contrast MRI.

13 Prior to commencing non-PBS-subsidised treatment with this drug, did the condition have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent)?

Yes
No

MCA0PB353 2503

14 Prior to commencing non-PBS-subsidised treatment with this drug, did the condition have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium)?

Yes ☐
No ☐

15 Prior to commencing non-PBS-subsidised treatment with this drug for this condition, the patient had the following conditions:

Tick all that apply

☐ enthesitis (heel)
☐ uveitis
☐ dactylitis
☐ psoriasis
☐ inflammatory bowel disease
☐ positive for Human Leukocyte Antigen B27 (HLA-B27).

16 Prior to commencing non-PBS-subsidised treatment with this drug for this condition, did the patient have chronic lower back pain and stiffness for 3 or more months that was relieved by exercise but not rest?

Yes ☐
No ☐

17 Prior to commencing non-PBS-subsidised treatment with this drug for this condition, did the patient fail to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total of 3 months?

Yes ☐ ***Go to 18***
No ☐ ***Go to 19***

18 Provide details of NSAID treatment

a) NSAID

Dose mg

From (DD MM YYYY)

To (DD MM YYYY)

b) NSAID

Dose mg

From (DD MM YYYY)

To (DD MM YYYY)

If the NSAID dose was less than the maximum recommended dose in the relevant Therapeutic Goods Administration (TGA) approved Product Information, state the reason why.

19 Provide details of contraindications or intolerances to NSAID prior therapy, 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.

20 The patient's failure to achieve an adequate response to NSAID treatment and concomitant exercise program was demonstrated by:

☐ a BASDAI score of at least 4 on a 0–10 scale

Baseline BASDAI score

Date of assessment (DD MM YYYY)

and

☐ an elevated C-reactive protein (CRP) > 10 mg/L

Baseline CRP level

Date of test (DD MM YYYY)

or

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

☐ treatment with prednisolone dosed at 7.5mg 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 CRP level.

The baseline BASDAI score and CRP level must have been determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment.

The BASDAI and CRP results must have been **no more than 4 weeks old** at the time of initiating non-PBS-subsidised treatment with this drug for this condition.

These **baseline** results will need to be provided for all continuing applications to demonstrate the patient's response.

21 Has the patient demonstrated an adequate response following at least 12 weeks of non-PBS-subsidised treatment with this drug for this condition?

Yes ☐
No ☐
Not applicable ☐ as the patient has not had 12 weeks of treatment to demonstrate a response ▶ *Go to 23*

22 The patient's adequate response is evidenced by:

☐ a BASDAI score reduced by at least 2 from baseline

Current BASDAI score

Date of assessment (no more than 4 weeks old) (DD MM YYYY)

and

☐ a CRP level ≤ 10 mg/L

Current CRP level

mg/L

Date of test (no more than 4 weeks old) (DD MM YYYY)

or

☐ a CRP level reduced by at least 20% from baseline

Current CRP level

mg/L

Date of test (no more than 4 weeks old) (DD MM YYYY)

or

☐ CRP exempt at baseline

Checklist

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

☐ Details of the proposed prescription(s).

Privacy notice

24 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**

25 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

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Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)

Place a mark on each line below to indicate your answer to each question as it relates to your **past week**.

1 How would you describe the overall level of fatigue/tiredness you have experienced?

None ⊢—|—|—|—|—|—|—|—|—|—|—⊣ Very severe
0 1 2 3 4 5 6 7 8 9 10

2 How would you describe the overall level of Ankylosing spondylitis neck, back or hip pain you have had?

None ⊢—|—|—|—|—|—|—|—|—|—|—⊣ Very severe
0 1 2 3 4 5 6 7 8 9 10

3 How would you describe the overall level of pain/swelling in joints other than your neck, back or hips that you have had?

None ⊢—|—|—|—|—|—|—|—|—|—|—⊣ Very severe
0 1 2 3 4 5 6 7 8 9 10

4 How would you describe the overall level of discomfort you have had from any areas tender to touch or pressure?

None ⊢—|—|—|—|—|—|—|—|—|—|—⊣ Very severe
0 1 2 3 4 5 6 7 8 9 10

5 How would you describe the overall level of morning stiffness you have had from the time you wake up?

None ⊢—|—|—|—|—|—|—|—|—|—|—⊣ Very severe
0 1 2 3 4 5 6 7 8 9 10

6 How long does your morning stiffness last from the time you wake up?

None ⊢—|—|—|—|—⊣ Very severe
0 ½ 1hr 1½ 2hr

Scoring the BASDAI

Measure each question from 'None' to the patient's mark in centimetres.

Add Q5 and Q6 and divide by 2 = A
Add Q1, Q2, Q3 and Q4 = B
Add A and B and divide by 5 = Score