Australian Government
Services Australia

medicare

PBS

Ankylosing spondylitis – bimekizumab – initial grandfather authority application

When to use this form

Use this form to apply for **initial grandfather** PBS-subsidised bimekizumab for patients 18 years or over with ankylosing spondylitis 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 must be 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 ankylosing spondylitis **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.

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, 18 years or over, is being treated by a:

☐ rheumatologist

☐ clinical immunologist with expertise in the management of ankylosing spondylitis

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

No ☐

Yes ☐

9 The condition is radiologically (plain X-ray) confirmed:

☐ Grade II bilateral sacroiliitis

or

☐ Grade III unilateral sacroiliitis

10 Provide details of the radiological report confirming the condition:

Name of the radiology report provider

Date of the radiology report (DD MM YYYY)

Unique identifying number/code that links the radiology report to the patient

11 Prior to commencing non-PBS-subsidised treatment with this drug for this condition, the patient had **at least 2** of the following:

☐ low back pain and stiffness for 3 or more months that was relieved by exercise but not by rest

and/or

☐ limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least **1** on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI)

and/or

☐ limitation of chest expansion relative to normal values for age and gender.

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12 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 period of 3 months?

No ☐

Yes ☐ 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 TGA-approved Product Information, state the reason why.

13 If applicable, 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.

14 Prior to commencing non-PBS-subsidised treatment with this drug for this condition, the patient failed to achieve an adequate response to NSAID treatment and concomitant exercise program 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 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) > 10 mg/L

Baseline CRP level mg/L

Date of test (DD MM YYYY)

If applicable, provide the reason the patient could not demonstrate an elevated ESR or CRP level.

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

All measurements must have been **no more than 4 weeks old** at the time of initiating non-PBS-subsidised treatment with this drug for this condition.

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

15 Has the patient been treated with this drug for this condition for 16 weeks or longer?

No ☐ ***Go to 17***

Yes ☐ ***Go to 16***

16 The patient has demonstrated an adequate response to the non-PBS-subsidised treatment with this drug for this condition evidenced by:

☐ a BASDAI score reduced by at least 2 from baseline

BASDAI score

Date of assessment (DD MM YYYY)

and

☐ an ESR level ≤ 25 mm/hr or reduced by at least 20% from baseline

ESR level

mm/hr

Date of test (DD MM YYYY)

and/or

☐ a CRP level ≤ 10 mg/L or reduced by at least 20% from baseline

CRP level

mg/L

Date of test (DD MM YYYY)

Checklist

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

☐ Details of the proposed prescription(s).

☐ A completed Ankylosing spondylitis – exercise program self certification form.

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

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Ankylosing spondylitis – exercise program self certification

Patient's declaration

I declare that:

- I have undertaken a minimum exercise program, as detailed below, in conjunction with appropriate non-steroidal anti-inflammatory drug (NSAID) therapy, over the entire 3 month period immediately before this application.
- I have performed stretch and range of motion exercises for a minimum of 5 times per week, **and either**
- an aerobic exercise of at least 20 minutes duration on at least 3 different occasions per week, **or**
- a group exercise class at least once per week.

Indicate by ticking the relevant exercise undertaken in the following table ☑

Week commencing (DD MM YYYY)		Stretch and motion exercise (5 x per week)						Aerobic activity (3 x per week)				Group exercise (1 x per week)
	Wk 1	☐	☐	☐	☐	☐	and either	☐	☐	☐	or	☐
	Wk 2	☐	☐	☐	☐	☐		☐	☐	☐		☐
	Wk 3	☐	☐	☐	☐	☐		☐	☐	☐		☐
	Wk 4	☐	☐	☐	☐	☐		☐	☐	☐		☐
	Wk 5	☐	☐	☐	☐	☐		☐	☐	☐		☐
	Wk 6	☐	☐	☐	☐	☐		☐	☐	☐		☐
	Wk 7	☐	☐	☐	☐	☐		☐	☐	☐		☐
	Wk 8	☐	☐	☐	☐	☐		☐	☐	☐		☐
	Wk 9	☐	☐	☐	☐	☐		☐	☐	☐		☐
	Wk 10	☐	☐	☐	☐	☐		☐	☐	☐		☐
	Wk 11	☐	☐	☐	☐	☐		☐	☐	☐		☐
	Wk 12	☐	☐	☐	☐	☐		☐	☐	☐		☐

Patient's full name

Patient's signature

If returning by post, print and sign by hand.

Date (DD MM YYYY)

Prescriber's declaration

I declare that:

- I have instructed the patient in an adequate exercise program.

Prescriber's full name

Prescriber's signature

If returning by post, print and sign by hand.

Date (DD MM YYYY)

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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 = BASDAI score

BASDAI prepared by the Pharmaceutical Benefits Branch, Australian Government Department of Health and Aged Care, 15 July 2004. Reproduced and extracted from: Garrett, Sarah et al. (1994) A New Approach to Defining Disease Status in Ankylosing Spondylitis: The Bath Ankylosing Spondylitis Activity Index. Journal of Rheumatology, 21 (12), 2286–2291, with the permission of the copyright holder.