Australian Government
Services Australia

medicare

PBS

Non-radiographic axial spondyloarthritis – initial 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** PBS-subsidised biological medicines for patients with non-radiographic axial spondyloarthritis.

Important information

Initial 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.

Applications for **balance of supply** 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.

Under no circumstances will phone approvals be granted for non-radiographic axial spondyloarthritis **initial** authority applications.

Where the term 'biological medicine' appears, it refers to bimekizumab, certolizumab pegol, golimumab, secukinumab and upadacitinib. A patient is eligible for PBS-subsidised treatment with only one biological medicine at any one time.

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** treatment.

After an authority application for **initial** treatment has been approved, applications for **continuing** treatment 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 Family name

First given name

3 Date of birth (DD MM YYYY)

Prescriber's details

4 Prescriber number

5 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 This application is for:

- ☐ bimekizumab
- ☐ certolizumab pegol
- ☐ golimumab
- ☐ secukinumab (a **loading** dose regimen is intended)
- ☐ secukinumab (**no loading** dose regimen)
- ☐ upadacitinib

9 Has the patient previously received PBS-subsidised treatment with a biological medicine for this condition?

- Yes ☐
- No ☐

10 Is the condition non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria?

- Yes ☐
- No ☐

11 Is the condition radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis?

- Yes ☐
- No ☐

12 The condition is sacroiliitis with:

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

and/or

- ☐ oedema on non-contrast MRI

13 Does 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 ☐

MCA0PB255 2606

14 Does the condition have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium)?

Yes ☐
No ☐

15 The patient has one or more of the following conditions:
Tick all that apply

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

16 Has the patient had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest?

Yes ☐
No ☐

17 Has the patient failed 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***

Not applicable ☐ due to contraindication to NSAID treatment according to the relevant TGA-approved Product Information (PI)

Go to 20

Not applicable ☐ due to intolerance developed to NSAID treatment during the relevant period of use of a severity to necessitate permanent treatment withdrawal

Go to 21

18 Provide end date of prior NSAIDs treatment (DD MM YYYY) (Must be most recent end date. Use today's date for ongoing treatment.)

☐☐ ☐☐ ☐☐☐☐

19 Provide details of NSAIDs 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 is less than the maximum recommended dose in the relevant TGA-approved PI, state the reason why.

20 Provide details of the contraindication to NSAIDs treatment as it is written in the TGA-approved PI (use with caution is not considered a contraindication)

21 Provide the nature and severity of intolerances to NSAIDs treatment. Intolerances must be of a severity to necessitate permanent treatment withdrawal.

22 The patient's failure to achieve an adequate response to NSAID treatment and concomitant exercise program is 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

☐ other - provide an acceptable reason the patient could not demonstrate an elevated CRP level.

The baseline BASDAI score and CRP level must be determined at the completion of the 3 month NSAIDs (unless contraindicated) and exercise trial, but prior to ceasing NSAID treatment.

All measurements must be **no more than 4 weeks old** at the time of initial application.

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

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.

Reset form

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**
- 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 or 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 or 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