

Non-radiographic axial spondyloarthritis – initial authority application

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 must be 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 a written 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

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

No

Yes

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?

No

Yes

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?

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

18 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.

19 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

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 NSAID 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

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

Details of the proposed prescription(s).

Privacy notice

21 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

22 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)



Returning this form

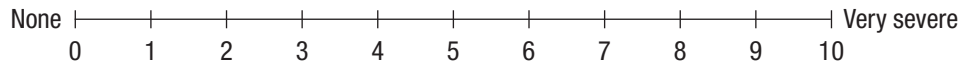
Return this form, details of the proposed prescription(s) and any relevant attachments:

- **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

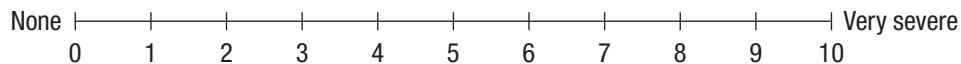
Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)

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

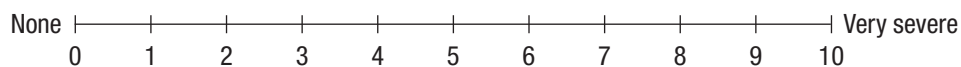
1 How would you describe the overall level of fatigue/tiredness you have experienced?



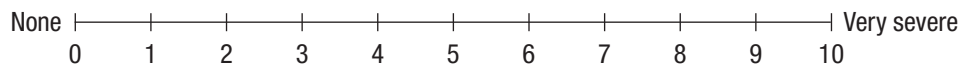
2 How would you describe the overall level of Ankylosing spondylitis neck, back or hip pain you have had?



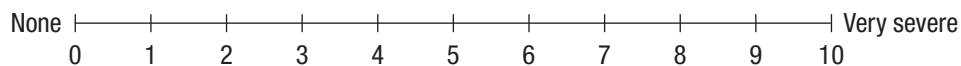
3 How would you describe the overall level of pain/swelling in joints other than your neck, back or hips that you have had?



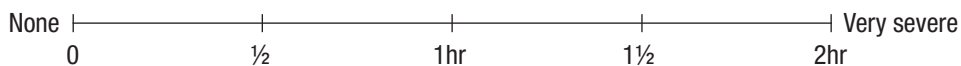
4 How would you describe the overall level of discomfort you have had from any areas tender to touch or pressure?



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



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



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

BASDAI prepared by the Pharmaceutical Benefits Branch, Australian Government Department of Health, 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.