Australian Government
Services Australia

medicare

PBS

Ankylosing spondylitis – change, recommencement or demonstration of response authority application

When to use this form

Use this form to apply for **changing** or **recommencing** PBS-subsidised biological agents for patients aged 18 years or older with ankylosing spondylitis.

This form can also be used for **demonstrating a response** to the current PBS-subsidised treatment before temporarily stopping treatment.

Important information

Authority applications 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.

Call charges may apply.

Under no circumstances will phone approvals be granted for ankylosing spondylitis **change** or **recommencement** authority applications.

Where the term 'biological agent' appears, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and upadacitinib.

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 **changing** or **recommencing** treatment or **demonstrating a response** to treatment before temporarily stopping treatment.

After a written authority application for **first continuing** treatment has been approved, **subsequent continuing** treatments with PBS-subsidised biosimilar brands of biological agents are Authority Required (Streamlined) and do not require authority approval from Services Australia for the listed quantity and repeats.

Section 100 arrangements for infliximab i.v. only

This item is available to a patient who is attending:

- an approved private hospital, **or**
- a public hospital

and is:

- a day admitted patient
- a non-admitted patient, **or**
- a patient on discharge.

This item is not available as a PBS benefit for in-patients of a public hospital.

The hospital name and provider number must be included in this authority form.

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 agent.

A patient who has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered to have failed treatment with that particular PBS-subsidised biological agent.

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)

4 Patient's current weight

kg

Prescriber's details

5 Prescriber number

6 Dr ☐ Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other

Family name

First given name

7 Business phone number (including area code)

Alternative phone number (including area code)

Hospital details

8 Hospital name

This hospital is a:

☐ public hospital

☐ private hospital

9 Hospital provider number

Conditions and criteria

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

10 The patient, aged 18 years or older, is being treated by a:

☐ rheumatologist

☐ clinical immunologist with expertise in the management of ankylosing spondylitis

11 Most recent biological agent

Dates of the most recent treatment course

From (DD MM YYYY)

To (DD MM YYYY)

12 This application is for:

☐ adalimumab

☐ certolizumab pegol

☐ etanercept

☐ golimumab

☐ infliximab i.v.

☐ ixekizumab

☐ secukinumab

☐ tofacitinib

☐ upadicitinib

▶ *Go to 14*

or

☐ infliximab s.c. with i.v. loading ▶ *Go to 13*

or

☐ **demonstrating a response** to the current PBS-subsidised treatment before temporarily stopping treatment with this biological agent

Demonstration of response can be submitted when recommencing treatment. ▶ *Go to 17*

13 The patient is:

☐ **changing** from an alternate PBS-subsidised biological agent and an authority prescription for at least 2 i.v. doses of infliximab at weeks 0 and 2 is attached

or

☐ **recommencing** PBS-subsidised infliximab after a treatment break and an authority prescription for 1 i.v. dose of infliximab at week 0 is attached.

MCA0PB251 2308

14 The patient:

☐ is **changing** PBS-subsidised biological treatment for this condition after a break **< 5 years** (including **no break**)

and

☐ will be submitting a new baseline

or

☐ will be using the previous baseline

▶ *Go to 15*

or

☐ is **recommencing** PBS-subsidised biological treatment for this condition after a break **< 5 years**

and

☐ the demonstration of response from the time of cessation is provided with this application

or

☐ the demonstration of response was submitted to Services Australia at the time of treatment cessation

and

☐ will be submitting a new baseline

or

☐ will be using the previous baseline

▶ *Go to 15*

or

☐ is **recommencing** PBS-subsidised biological treatment for this condition after a break **> 5 years**

and

☐ will be submitting a new baseline

and

☐ has previously received PBS-subsidised biological treatment for this condition.

▶ *Go to 18*

15 The patient:

☐ has previously received PBS-subsidised treatment with a biological agent for this condition in this treatment cycle

and

☐ has not failed or ceased to respond to PBS-subsidised treatment with this biological agent (the agent being applied for today) for this condition in this treatment cycle

and

☐ has not already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this treatment cycle since **1 October 2021**.

16 The patient:

☐ has **failed** to demonstrate or sustain a response to the most recent PBS-subsidised biological agent

or

☐ has experienced a **serious adverse reaction** of a severity necessitating permanent withdrawal of the most recent PBS-subsidised biological agent.

Give details of treatment and adverse reaction

or

☐ has **demonstrated or sustained an adequate response** to the most recent PBS-subsidised biological agent.

If the patient is demonstrating a response	▶ *Go to 17*
If the patient is providing a new baseline	▶ *Go to 19*
If the patient is not demonstrating a response and is not providing a new baseline	▶ *Go to 20*

For a patient demonstrating a response (to current or previous biological agent)

The response assessment should be conducted while still on treatment, but **no later than 4 weeks** following cessation of treatment.

17 The patient has demonstrated an adequate response to treatment confirmed by:

☐ a BASDAI score of:

Date of score (DD MM YYYY)

and

☐ erythrocyte sedimentation rate (ESR) level of:

Date of test (DD MM YYYY)

and/or

☐ C-reactive Protein (CRP) level of:

Date of test (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.

▶ *Go to 20*

For a patient recommencing after a break > 5 years

18 The patient:

☐ has documented radiographically (plain x-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis

Date of the radiological report (DD MM YYYY)

and has at least **2** of the following:

☐ low back pain and stiffness for 3 or more months that is 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 one 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.

For a patient submitting a new baseline

19 The patient has:

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

Baseline BASDAI score

Date of score (DD MM YYYY)

and

☐ an elevated ESR > 25 mm/hr

Baseline ESR level

Date of test (DD MM YYYY)

and/or

☐ an elevated CRP > 10 mg/L

Baseline CRP level

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

If the requirement to demonstrate an elevated ESR or CRP cannot be met, state the reason why.

Checklist

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

☐ The completed authority prescription form(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

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 the completed authority prescription form(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.

Prescriber's signature

On completion, print and sign by hand.

Date (DD MM YYYY)

Returning this form

Return this form and any supporting documents:

- **online**, upload this form, the authority prescription form(s) and any relevant attachments through Health Professional Online Services (HPOS) at **servicesaustralia.gov.au/hpos**

or

- by post, send this form, the authority prescription form(s) and any relevant attachments to:

Services Australia
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

Reset form Print form

Australian Government
Services Australia

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PBS

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

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.