Australian Government
Services Australia

medicare

PBS

Ankylosing spondylitis – continuing authority application

Online PBS Authorities

Requesting PBS Authorities online provides an immediate assessment in real time.

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 **continuing** PBS-subsidised biological medicines for patients 18 years or over with ankylosing spondylitis.

Important information

Continuing authority applications can be made in real time 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 ankylosing spondylitis **continuing** authority applications.

Where the term 'biological medicine' appears, it refers to adalimumab, bimekizumab, 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 **continuing** treatment.

The patient remains eligible to receive **continuing** treatment providing they continue to sustain a response to treatment.

Applications for **continuing** treatment with PBS-subsidised **biosimilar** brands of adalimumab, etanercept and infliximab are **Authority Required (STREAMLINED)** and do not require authority approval from Services Australia for the listed quantity and repeats.

Continuing treatment with PBS-subsidised **infliximab s.c.** is **Authority Required (STREAMLINED)** and does not require authority approval from Services Australia for the listed quantity and repeats.

Section 100 arrangements for infliximab i.v.

This item is available to a patient who is attending:

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

and is a:

- day admitted patient
- non-admitted patient, **or**
- 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 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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Online PBS Authorities

You do not need to complete this form if you use the **Online PBS Authorities** system.

Go to **servicesaustralia.gov.au/hppbsauthorities**

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)

4 Patient's current weight

kg

Prescriber's details

5 Prescriber number

6 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 is being treated by a:

- ☐ rheumatologist
- ☐ clinical immunologist with expertise in the management of ankylosing spondylitis

11 This application is for the:

- ☐ **first continuing** treatment with:
  - ☐ adalimumab ☐ etanercept
  - ☐ infliximab i.v.

or

- ☐ **subsequent continuing** treatment with:
  - ☐ adalimumab ☐ etanercept
  - ☐ infliximab i.v.

or

- ☐ **continuing** treatment with:
  - ☐ bimekizumab ☐ certolizumab pegol
  - ☐ golimumab ☐ secukinumab
  - ☐ ixekizumab ☐ upadacitinib
  - ☐ tofacitinib

12 Has the patient received this drug (regardless of formulation) as their most recent course of PBS-subsidised biological medicine treatment for this condition?

- Yes ☐
- No ☐

13 Has the assessment of response been conducted following **a minimum of 12 weeks** of therapy and **no later than 4 weeks** from cessation of the most recent course of treatment?

- Yes ☐
- No ☐

MCA0PB074 2511

14 The patient has demonstrated an adequate response to treatment with this drug evidenced by:

☐ a BASDAI score (on a scale of 0-10) of ≤ 2

Responding BASDAI score

Date of response assessment (DD MM YYYY)

or

☐ a BASDAI score reduced by at least 2 units from baseline

Baseline BASDAI score

Responding BASDAI score

Date of response assessment (DD MM YYYY)

and

☐ an erythrocyte sedimentation rate (ESR) ≤ 25 mm/hr

Responding ESR mm/hr

Date of response assessment (DD MM YYYY)

or

☐ an ESR reduced by at least 20% from baseline

Baseline ESR mm/hr

Responding ESR mm/hr

Date of response assessment (DD MM YYYY)

and/or

☐ a C-reactive protein (CRP) ≤ 10 mg/L

Responding CRP mg/L

Date of response assessment (DD MM YYYY)

or

☐ a CRP reduced by at least 20% from baseline

Baseline CRP mg/L

Responding CRP mg/L

Date of response assessment (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.

Checklist

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

☐ Details of the proposed prescription(s).

Privacy notice

16 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**

17 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 = 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.