Australian Government
Services Australia

medicare

PBS

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

Online PBS Authorities

You do not need to complete this form if you use the **Online PBS Authorities** system to apply for **biosimilar** brands of adalimumab, etanercept and infliximab. 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 **changing** or **recommencing** PBS-subsidised biological medicines (**originator** brands) for patients 18 years or over 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 for **originator** brands must be in writing and must include sufficient information to determine the patient's eligibility according to the PBS criteria.

Applications for **biosimilar** brands of adalimumab, etanercept and infliximab, and **balance of supply** of all biological medicines 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 **change** or **recommencement** authority applications for **originator** brands.

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

Applications for **continuing** treatment with PBS-subsidised **originator** brands must be in writing and must include sufficient information to determine the patient's eligibility according to the PBS criteria.

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.

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

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 is being treated by a:

☐ rheumatologist

☐ clinical immunologist with expertise in the management of ankylosing spondylitis

11 Most recent biological medicine

Dates of the most recent treatment course

From (DD MM YYYY)

To (DD MM YYYY)

12 This application is for:

☐ adalimumab
☐ bimekizumab
☐ 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 medicine

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

MCA0PB251 2410

13 The patient is:

☐ **changing** from an alternate PBS-subsidised biological medicine 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.

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

☐ has received prior PBS-subsidised treatment with a biological medicine for this condition

and

☐ has had a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition

and

☐ will be submitting a new baseline.

▶ ***Go to 18***

15 The patient:

☐ has received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle

and

☐ has not already failed or ceased to respond to PBS-subsidised treatment with this drug (the biological medicine this application is for) for this condition during the current treatment cycle

and

☐ has not already failed or ceased to respond to PBS-subsidised treatment with 3 biological medicines 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 medicine

or

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

Provide details of the treatment and adverse reaction

or

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

If the patient is demonstrating a response	▶ ***Go to 17***
If the patient is providing a baseline	▶ ***Go to 21***
If the patient is not demonstrating a response and is not providing a new baseline	▶ ***Go to 23***
If the patient is changing from a biosimilar brand and:	
• demonstrating a response	▶ ***Go to 17***
• not demonstrating a response	▶ ***Go to 21***

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

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 evidenced by:

☐ a BASDAI score of

Date of assessment (DD MM YYYY)

and

☐ an erythrocyte sedimentation rate (ESR) level of

mm/hr

Date of test (DD MM YYYY)

and/or

☐ a C-reactive protein (CRP) level of

mg/L

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.

If the patient is changing from a biosimilar brand ▶ ***Go to 21***

All other applications ▶ ***Go to 23***

For a patient recommencing after a break > 5 years

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

☐ Grade II bilateral sacroiliitis

or

☐ Grade III unilateral sacroiliitis

19 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

20 The patient 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 baseline

21 The patient is:

☐ submitting a new baseline

or

☐ changing from a biosimilar brand and submitting the existing or a new baseline

22 The patient has:

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

Baseline BASDAI score

Date of assessment (DD MM YYYY)

and

☐ an elevated ESR > 25 mm/hr

Baseline ESR level

mm/hr

Date of test (DD MM YYYY)

and/or

☐ an elevated CRP > 10 mg/L

Baseline CRP level

mg/L

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 of **new baseline** BASDAI, ESR and/or CRP 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

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.

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.