Australian Government
Medicare Australia

PBS

Ankylosing spondylitis
Initial PBS authority application
Supporting information

Important information

This form must be completed by a rheumatologist with expertise in the management of ankylosing spondylitis.

You must lodge this form for an adult patient starting **initial** PBS subsidised treatment with a Tumour Necrosis Factor alpha (TNFα) antagonist.

Where the term TNFα antagonist appears it only refers to adalimumab, etanercept, golimumab and infliximab. Patients are eligible for PBS subsidised treatment with only one TNFα antagonist at any time.

All applications must be in writing and must include sufficient information to determine the patient's eligibility according to the PBS criteria.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than one month following cessation of the most recent prior treatment.

The lodgement of this application must be made within one month of the date of the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) assessment and Erythrocyte Sedimentation Rate (ESR)/C-reactive Protein (CRP) blood tests.

The information on this form is correct at the time of publishing and is subject to change.

Section 100 arrangements – for infliximab

This item is only available to a patient who is attending:

- an approved private hospital
- a public participating hospital

  or
- a public hospital

and is either

- a day admitted patient
- a non-admitted patient

  or
- a patient on discharge

This is not a PBS benefit for in-patients of the hospital. The hospital provider number must be included on the application form.

Acknowledgements

The patient's and the prescriber's acknowledgements must be signed in front of a witness (over 18 years of age).

Authority prescription form

A completed authority prescription form must be attached to this form.

The medical indication section of the authority prescription form does not need to be completed when submitted with this form.

Phone approvals

Under no circumstance will phone approvals be granted for complete initial authority applications, or for treatment that would otherwise extend the treatment period.

Applications for continuing treatment

The assessment of the patient's response to an initial course of treatment must be made after a minimum of 12 weeks of treatment. Assessments before 12 weeks of treatment have been completed will not be considered.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than one month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment.

Assistance

If you need assistance completing this form or need more information call **1800 700 270** (call charges may apply) and select option 2, between 8.00 am and 5.00 pm EST, Monday to Friday or go to **www.medicareaustralia.gov.au > For health professionals > PBS > Specialised drugs (PBS) A-I > Ankylosing spondylitis**

Lodgement

Send the completed authority application form, a completed authority prescription form and all relevant attachments to:

Medicare Australia
Prior written approval of specialised drugs
Reply paid 9826
Hobart TAS 7001

Print in **BLOCK LETTERS**

Tick where applicable ☑

4154.14.07.10

Australian Government
Medicare Australia

PBS

Ankylosing spondylitis
Initial PBS authority application

Patient's details

1 Medicare/DVA card number

[ ][ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ] Ref no. [ ]

2 Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other ☐

Family name

First given name

3 Date of birth

/ /

Patient's acknowledgement

4 I acknowledge that PBS subsidised treatment with TNFα antagonists for ankylosing spondylitis will stop if:

- subsequent testing demonstrates that I have failed to demonstrate or sustain a response to treatment as detailed in the criteria
- I have failed three TNFα antagonist treatment courses for which I was eligible.

My prescriber has explained the nature of the ongoing monitoring and testing required in order to demonstrate an adequate response to therapy.

Patient's signature

Date

/ /

Prescriber's details

5 Prescriber number

6 Family name

First given name

7 Work phone number

( )

Alternative phone number

Fax number

( )

Prescriber's acknowledgement

8 **I have explained:**

- the circumstances governing PBS subsidised treatment with TNFα antagonists for ankylosing spondylitis
- the nature of the ongoing monitoring and testing required to demonstrate an adequate and sustained response to therapy.

I believe these to be understood and accepted by the patient.

Prescriber's signature

Date

/ /

Witness's acknowledgement

9 I have witnessed the signatures of **BOTH** the patient and the prescriber.

Witness's full name (over 18 years of age)

Witness's signature

Date

/ /

TNFα antagonist details

10 Which TNFα antagonist is this application for?

☐ adalimumab ☐ golimumab
☐ etanercept ☐ infliximab

For infliximab only:

Patient's current weight

kg

Hospital name

Hospital provider number

Conditions and criteria

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

The patient:

☐ is an adult with severe active ankylosing spondylitis

and

☐ has signed the patient's acknowledgement

and

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

and

has at least **two** of the following:

☐ low back pain and stiffness for three 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

and

☐ has failed to achieve an adequate response following a minimum of three months of treatment, with at least two non-steroidal anti-inflammatory drugs (NSAIDs).

Provide details of prior NSAID treatment.

NSAID

Dose mg

from / / to / /

NSAID

Dose mg

from / / to / /

NSAID

Dose mg

from / / to / /

Provide details of contraindications or intolerance to NSAID prior therapy including the degree of toxicity.

For details of the toxicity criteria go to **www.medicareaustralia.gov.au > For health professionals > PBS > Specialised drugs (PBS) A-I > Ankylosing spondylitis**

Intolerance must be of a severity to necessitate permanent treatment withdrawal.

Contraindication or toxicity and grade.

and

☐ has completed an appropriate concomitant exercise program

Current assessment of patient

12 The patient can demonstrate failure to achieve an adequate response to NSAID treatment and concomitant exercise program by:

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

and

☐ an elevated ESR greater than 25 mm/hr

ESR level | Date of test / /

and/or

☐ an elevated CRP greater than 10 mg/L

CRP level | Date of test / /

☐ I have elected to provide only one marker at baseline and will assess all applications for the continuing treatment based on this same marker.

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

Attachments

Attach plain X-Ray documentation, the completed exercise self certification form, the completed BASDAI assessment and a completed authority prescription form.

Prescriber's declaration

13 I declare that:

- the information on this form is correct

Prescriber's signature

Date / /

Privacy note

The information provided on this form will be used to assess eligibility of a nominated person to receive PBS subsidised treatment. The collection of this information is authorised by the *National Health Act 1953*. This information may be disclosed to the Department of Health and Ageing, Department of Veterans' Affairs or as authorised or required by law.

Australian Government
Medicare Australia

PBS

Ankylosing spondylitis
Exercise program self certification

Patient's declaration

I

Print full name in **BLOCK LETTERS**

declare that:

- *I have undertaken a minimum exercise program, as detailed below, in conjunction with appropriate NSAID therapy, over the entire three month period immediately before this application*
- *I have performed stretch and range of motion exercises for a minimum of five times per week*

and either

- *an aerobic exercise of at least 20 minutes duration on at least three different occasions per week, or*
- *a group exercise class at least once per week.*

Indicate by ticking the relevant exercise undertaken in the following table ☑

Week commencing		Stretch and motion exercise (5 x per week)						Aerobic activity (3 x per week)				Group exercise (1x per week)
/ /	Wk 1						and either				or	
/ /	Wk 2											
/ /	Wk 3											
/ /	Wk 4											
/ /	Wk 5											
/ /	Wk 6											
/ /	Wk 7											
/ /	Wk 8											
/ /	Wk 9											
/ /	Wk 10											
/ /	Wk 11											
/ /	Wk 12											

Patient's signature

Date / /

Prescriber's declaration

I

Print full name in **BLOCK LETTERS**

I declare that:

- I have instructed the patient in an adequate exercise program.

Prescriber's signature

Date / /

Australian Government
Medicare Australia

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

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

None ⊢——————————————————————⊣ Very severe

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

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

None ⊢——————————————————————⊣ Very severe

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

None ⊢——————————————————————⊣ Very severe

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

Patient's declaration

7 I _____

Print full name in **BLOCK LETTERS**

declare that:

- *I have completed the above six questions.*
- *I did not have access to any prior BASDAI assessments completed by myself.*

Patient's signature

Date

/ /

Prescriber's declaration

8 I _____

Print full name in **BLOCK LETTERS**

declare that:

- *as the prescriber of a TNFαantagonist for the above patient I witnessed the patient complete the above questions.*
- *they had no access to any prior BASDAI.*

Prescriber's signature

Date

/ /