



Tumour Necrosis Factor alpha (TNF α) antagonist treatment for ankylosing spondylitis PBS authority application



Supporting information form

Initial PBS-subsidised treatment for continuing treatment of adult patients who were commenced on TNF α antagonist treatment with infliximab before 1 March 2004 or etanercept before 1 July 2004 or adalimumab before 1 November 2006

Instructions

You must lodge these forms for patients undergoing **initial PBS-subsidised treatment, for continuing treatment, by a rheumatologist, of adults with documented history of active ankylosing spondylitis who have radiographically (plain X-Ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis and who were receiving treatment with infliximab before 1 March 2004 or etanercept before 1 July 2004 or adalimumab before 1 November 2006.**

These forms must be completed by a rheumatologist with expertise in the management of adults with active ankylosing spondylitis.

Section 100 arrangements – infliximab only

This item is only available to a patient who is attending an approved private hospital or public participating hospital or public hospital and is a day admitted patient, a non-admitted patient or a patient on discharge. This is not a PBS benefit for inpatients of the hospital.

The hospital provider number must be included on this form.

Eligibility

Patients are eligible for PBS-subsidised treatment with only one TNF α antagonist at any time.

Patients must commence PBS-subsidised treatment with the TNF α antagonist agent with which they are currently receiving treatment.

Patient acknowledgment form

The patient acknowledgement form must be signed by the patient and the prescriber in the presence of a witness (over 18 years of age) and must be sent with the application.

Authority prescription form

A completed Authority prescription form must be attached to these forms. The medical indication section of the Authority prescription form does not need to be completed when submitted with the supporting information form.

- **Infliximab:** The prescription may only be written for the appropriate number of vials, based on patient weight, to dose the patient with a maximum of 5 mg/kg of infliximab and three repeats.

No applications for increased maximum repeats will be authorised.

- **Etanercept:** (25 mg strength only) The prescription may only be written for a quantity of two sets and five repeats.
- **Adalimumab:** The prescription may only be written for a quantity of two injections and five repeats.

No applications for increased maximum quantities or repeats will be authorised.

In writing

All applications must be in writing and must include sufficient information to determine the patient's eligibility according to the above criteria. **Erythrocyte sedimentation rate (ESR) and/or C-Reactive protein (CRP) and Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) test results must be provided and must have been made at a date no earlier than one month before the application date.**

Phone approvals

Where less than the maximum initial supply has been approved at the time of the initial authority application, subsequent authority approvals may be granted to complete an initial treatment, and may be requested by telephone. Please call **1800 700 270*** option 2.

Under no circumstances will telephone approvals be granted for complete initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 24 weeks.

Applications for continuing treatment

The first application for continuing treatment should be made no earlier than 20 weeks and no later than 24 weeks from commencement of PBS-subsidised treatment.

Only 24 weeks of treatment will be approved under this criterion.

Where a response assessment is not submitted to Medicare Australia within four weeks of the cessation of treatment, patients will be deemed to have failed to respond to treatment with that TNF α antagonist.

Changing to an alternate TNF α antagonist treatment

Patients who wish to change to an alternate TNF α antagonist treatment must first commence PBS-subsidised treatment with the TNF α antagonist for which they are currently receiving treatment and must be assessed after a minimum of 12 weeks of PBS-subsidised treatment.

To avoid confusion, applications for patients who wish to change to an alternate TNF α antagonist treatment should be accompanied by the previously approved authority prescription or the remaining repeats for the TNF α antagonist treatment the patient is ceasing.

Treatment failure – re treatment

Patients who fail to demonstrate an adequate response to treatment with a TNF α antagonist agent are eligible to trial an alternate agent provided they have not previously failed, or ceased to respond to that agent.

Patients who have either failed, or ceased to respond to treatment three times are deemed to have completed a treatment cycle and they must have, at a minimum, a five year break in PBS-subsidised TNF α antagonist treatment.

Recommencement of treatment after a five year break in PBS-subsidised therapy

Patients who wish to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF α antagonist therapy of at least five years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least one NSAID, at an adequate dose, for a minimum of three consecutive months immediately before the time the BASDAI, ESR and/or CRP levels are measured.

* Call charges apply from mobiles and pay phones only



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Adult patient acknowledgement form

Adult patient acknowledgement form where patients commenced treatment with infliximab before 1 March 2004 *or* etanercept before 1 July 2004 *or* adalimumab before 1 November 2006

Print neatly in **BLOCK LETTERS**

This form must be signed by the patient and the prescriber in the presence of a witness (over 18 years of age) and sent to Medicare Australia with the supporting information form.

Privacy note: The information collected on this form will be used to assess applications and eligibility for the nominated patient under the PBS-subsidised treatment with TNF α antagonists for ankylosing spondylitis. The collection of this information is authorised under provisions of the *National Health Act 1953* and may be disclosed to the Department of Human Services, Department of Health and Ageing, or as authorised or required by law.

Patient's acknowledgement

Medicare/DVA number

Family name

First given name

Date of birth / /

I understand and acknowledge that Pharmaceutical Benefits Scheme (PBS) subsidised treatment with TNF α antagonist agents for active ankylosing spondylitis will cease if subsequent testing demonstrates that I have failed to achieve or sustain a response to treatment as detailed in the criteria. I also understand that I cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF α more than once.

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

Signature of patient

Prescriber's acknowledgement

I have explained the circumstances governing the continuation of PBS-subsidised treatment with TNF α antagonists for ankylosing spondylitis and the nature of the ongoing monitoring and testing required in order to demonstrate an adequate and sustained response to therapy. I have also explained the conditions of an interchangeability cycle. To the best of my knowledge I believe these to be understood and accepted by the patient.

Signature of prescriber

Prescriber's name

Witness

I have witnessed the signatures of **both** the patient and the prescriber.

Signature of witness (over 18 years of age)

Witness's name

Date / /



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Please complete all parts of this application.
Print neatly in **BLOCK LETTERS**

Part 1 – patient’s details

Medicare/DVA number

Family name

First given name

Date of birth

Which TNF α antagonist is this application for? (*tick one only*)

Infliximab Patient’s current weight kg
 or etanercept
 or adalimumab

Please provide details of the most recent prior TNF α antagonist treatment

Date range from: (1st dose) / /
 to (last dose) / /

Part 2 – conditions and criteria

To qualify for PBS authority approval under this criterion your patient must meet the following conditions.

Please indicate by ticking

the patient named above is an adult patient with a documented history of active ankylosing spondylitis

and

has signed and supplied a *Patient acknowledgement* form

and

has documented radiographically (plain X-Ray) confirmed Grade II bilateral sacroiliitis

Date of X-Ray / / **Please attach report**

or

has documented radiographically (plain X-Ray) confirmed Grade III unilateral sacroiliitis

Date of X-Ray / / **Please attach report**

and

The patient has demonstrated a response to treatment by achieving **BOTH (a) and (b)**

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of either:

- (i) less than or equal to 5 on a 0 – 10 scale, **or**
- (ii) improved by at least 2 from baseline.

Please attach assessment form(s)

Date of current test / /

Test result

Date of baseline test / /

Test result

The BASDAI must be no more than one month old at the time of initial application.

and

- (b)** (i) an erythrocyte sedimentation rate (ESR) no greater than 25 mm/hour, **or**
- (ii) a C-Reactive protein (CRP) no greater than 10 mg/L, **or**
- (iii) ESR/CRP measurement reduced by at least 20% from pre-treatment baseline (which must have been within one month of commencement of prior treatment).

Please note: Where only one marker (ESR or CRP) has been provided at baseline, the same marker must be provided for all continuing applications.

ESR Current result
Date of test / /

Baseline result
Date of test / /

CRP Current result
Date of test / /

Baseline result
Date of test / /

Part 3 – prescriber's details

Note: Prescriber must be a rheumatologist with expertise in the management of adults with active ankylosing spondylitis.

Prescriber number

Prescriber's name

Prescriber's phone number ()

Prescriber's fax number ()

For infliximab only:

Hospital name

Hospital provider number

Signature of prescriber

Date

Lodgement details

Please send the completed supporting information form, completed patient acknowledgement form and completed Authority prescription and all relevant attachments to:

Medicare Australia
Prior written approval of specialised drugs
Reply Paid 9826
GPO Box 9826
Hobart TAS 7001

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Please 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?
0 |-----| 1/2 |-----| 1 |-----| 1 1/2 |-----| 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 certification

I (full name)

certify that I completed the above six questions on / /

and I did not have access to any prior BASDAI assessments completed by myself.

Patient's signature

Prescriber's certification

I (full name)

as the prescriber of a TNF α antagonist for the above patient, certify that I witnessed the patient complete the above questions and they had no access to any prior BASDAI.

Prescriber's signature