Australian Government
Services Australia

medicare

PBS

Rheumatoid arthritis – 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 severe active rheumatoid arthritis.

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 **change** or **recommencement** authority applications.

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

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 the **first continuing** treatment has been approved, **subsequent continuing** treatment 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 abatacept i.v., infliximab i.v. and tocilizumab i.v. only

These items are available to a patient who is attending:

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

and is:

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

These items are 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 an assessment is not conducted within this 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 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 for abatacept i.v., infliximab i.v. and tocilizumab i.v. only

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

☐ a clinical immunologist with expertise in the management of rheumatoid arthritis

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:

☐ abatacept i.v.

☐ abatacept s.c.

☐ abatacept s.c. with i.v. loading

☐ adalimumab

☐ baricitinib

☐ certolizumab pegol

☐ etanercept

☐ golimumab

☐ infliximab i.v.

☐ tocilizumab i.v.

☐ tocilizumab s.c.

☐ tofacitinib

☐ upadacitinib

▶ *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*

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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.

14 The patient:

☐ is **changing** PBS-subsidised biological treatment for this condition after a break **< 24 months**

and

☐ will be submitting a new baseline

or

☐ will be using the previous baseline

or

☐ is **recommencing** PBS-subsidised biological treatment for this condition after a break **< 24 months**

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 **> 24 months**

and

☐ will be submitting a new baseline

and

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

▶ *Go to 19*

15 The patient:

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

and

☐ has not failed or ceased to respond to previous PBS-subsidised treatment with the biological agent being applied for this condition

and

☐ has not already failed, or ceased to respond to, PBS-subsidised biological agent treatment for this condition 5 times

and

☐ if applicable, is currently receiving methotrexate, at a dose of

_____ mg per week

(minimum methotrexate requirement is 7.5 mg per week for PBS-subsidised abatacept, golimumab and infliximab).

16 The patient:

☐ has **failed** to demonstrate or sustain a response with 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 21*

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:

☐ Erythrocyte sedimentation rate (ESR) level

Date of test (DD MM YYYY)

and/or

☐ C-reactive protein (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.

and

☐ where the baseline is at least 20 active (swollen and tender) joints, a reduction

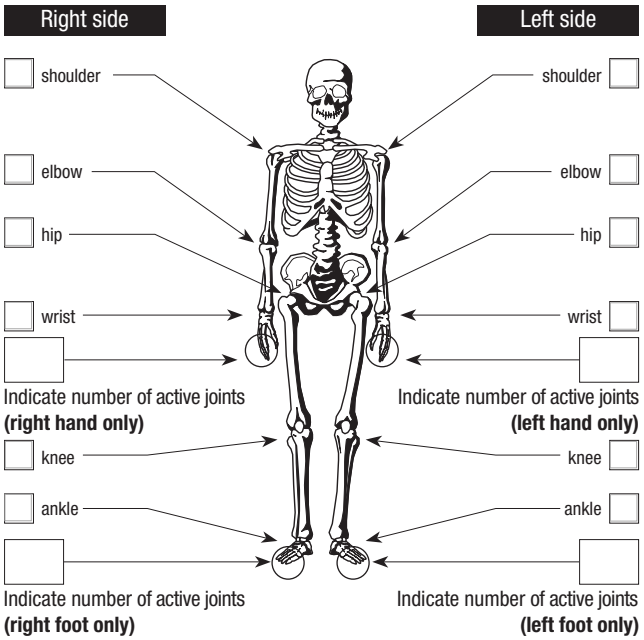
by %

or

☐ where the baseline is at least 4 major joints (elbow, wrist, knee, ankle, shoulder and/or hip), a reduction

by %

18 Indicate affected joints demonstrating a response on the diagram and complete the boxes below:



Active joint count for demonstration of response

Date of joint assessment (DD MM YYYY)

Where a patient has at least 4 active major joints and less than 20 total active joints at baseline, assessment of the major joints only will be used for all continuing applications.

For a patient submitting a new baseline

19 The patient has:

☐ an ESR > 25 mm/hr, no more than 4 weeks old

ESR level

Date of test (DD MM YYYY)

and/or

☐ an elevated CRP > 15 mg/L, no more than 4 weeks old

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.

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

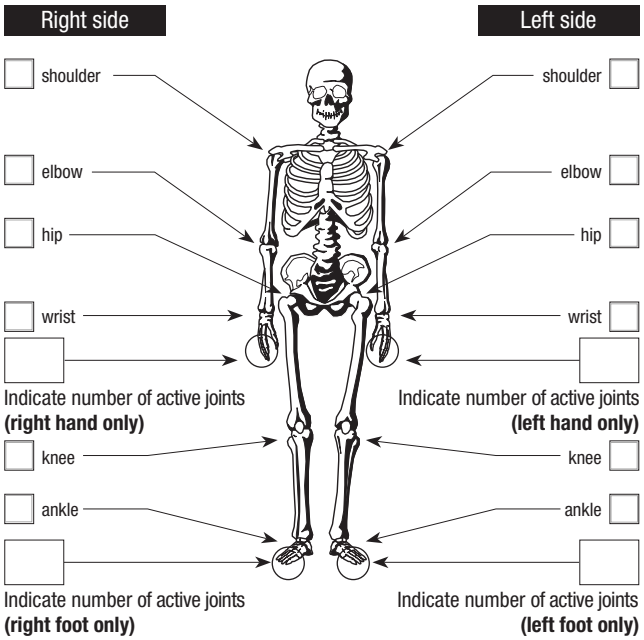
and

☐ an active joint count of at least 20 active (swollen and tender) joints

or

☐ at least 4 major active joints: elbow, wrist, knee, ankle, shoulder and/or hip.

20 Indicate affected joints on the diagram and complete the boxes below:



Current active joint count

Date of joint assessment (DD MM YYYY)

Where a patient has at least 4 active major joints and less than 20 total active joints at baseline, assessment of the major joints only will be used for all continuing applications.

Checklist

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

☐ The completed authority prescription form(s).

Privacy notice

22 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/privacy**

Prescriber's declaration

23 **I declare that**:

- I am aware 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 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