Australian Government
Services Australia

medicare

PBS

Rheumatoid arthritis – 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 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 **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 rheumatoid arthritis **change** or **recommencement** authority applications for **originator** brands.

Where the term 'biological medicine' 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 with an **originator** brand has been approved, **subsequent continuing** treatments with PBS-subsidised biological medicines (excluding infliximab s.c.) 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, **or**
- a public hospital

and is a:

- day admitted patient
- non-admitted patient, **or**
- 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 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 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 rheumatoid arthritis

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 the **originator** brand of:

☐ 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 medicine

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

MCA0PB247 2405

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:

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

or

☐ has received prior PBS-subsidised treatment with a biological medicine under the paediatric severe active juvenile idiopathic arthritis or systemic juvenile idiopathic arthritis indication

and

☐ has not failed to respond to previous PBS-subsidised treatment with this drug (the biological medicine this application is for) for this condition

and

☐ has not already failed, or ceased to respond to, PBS-subsidised biological medicine 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).

15 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 16*

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 treatment with a biological medicine for this condition

▶ *Go to 18*

16 The patient:

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

Give details of 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 new baseline	▶ *Go to 18*
If the patient is not demonstrating a response and is not providing a new baseline	▶ *Go to 20*
If the patient is changing from JIA/sJIA and:	
• providing a baseline	▶ *Go to 19*
• not providing a baseline	▶ *Go to 20*
If the patient is changing from a biosimilar brand and:	
• demonstrating a response	▶ *Go to 17*
• not demonstrating a response	▶ *Go to 18*

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

Assessments 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 the treatment evidenced by:

☐ Erythrocyte sedimentation rate (ESR) level _____ mm/hr
Date of test (DD MM YYYY) ___ ___ _____

and/or

☐ C-reactive protein (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.

and

☐ where baseline is at least 20 total active (swollen and tender) joints, a reduction by at least 50% from baseline
Total active joint count _____ Date of assessment (DD MM YYYY) ___ ___ _____

or

☐ where a baseline is at least 4 major joints (elbow, wrist, knee, ankle, shoulder and/or hip), a reduction by at least 50% from baseline
Major joint count _____ Date of 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.

If the patient is changing from a biosimilar brand ▶ ***Go to 18***

All other applications ▶ ***Go to 20***

For a patient submitting a baseline

18 The patient is:

☐ submitting a new baseline

or

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

19 The patient has:

☐ an elevated ESR > 25 mm/hr
Baseline ESR level _____ mm/hr Date of test (DD MM YYYY) ___ ___ _____

and/or

☐ an elevated CRP > 15 mg/L
Baseline CRP level _____ mg/L Date of test (DD MM YYYY) ___ ___ _____

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

and

☐ a total active joint count of at least 20 active (swollen and tender) joints
Baseline total active joint count _____ Date of assessment (DD MM YYYY) ___ ___ _____

or

☐ at least 4 major active joints from elbow, wrist, knee, ankle, shoulder and/or hip
Baseline major joint count _____ Date of 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.

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.

All measures of **new baseline** joint count, ESR and/or CRP must be **no more than 4 weeks old** at the time of application.

Checklist

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

☐ Details of the proposed prescription(s).

Privacy notice

21 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**

22 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

Reset form