Australian Government
Services Australia

medicare

PBS

Rheumatoid arthritis – continuing authority application

Online PBS Authorities

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 either the **first continuing** PBS-subsidised biological medicines or **continuing** PBS-subsidised infliximab s.c. for patients 18 years or over with severe active rheumatoid arthritis.

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.

Important information

Authority applications can be made in real time using the **Online PBS Authorities** system or 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.

Under no circumstances will phone approvals be granted for rheumatoid arthritis **first continuing** authority applications for **originator** brands and **continuing** authority applications for infliximab s.c.

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 the **first continuing** treatment with an **originator** brand and **continuing** treatment with infliximab s.c.

After an 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.

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 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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Online PBS Authorities

You do not need to complete this form if you use the **Online PBS Authorities** system.

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

Patient's details

1 Medicare card number

Ref no.

or

Department of Veterans' Affairs card number

2 Family name

First given name

3 Date of birth (DD MM YYYY)

4 Patient's weight

kg

Prescriber's details

5 Prescriber number

6 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 This application is for:

- ☐ the **first continuing** treatment with:
  - ☐ abatacept i.v. (at a dose specified in the product information)
  - ☐ abatacept s.c.
  - ☐ adalimumab
  - ☐ baricitinib
  - ☐ certolizumab
  - ☐ etanercept
  - ☐ golimumab
  - ☐ infliximab i.v. (at a dose of 3 mg/kg)
  - ☐ tocilizumab i.v. (at a dose of 8 mg/kg to a maximum of 800 mg)
  - ☐ tocilizumab s.c.
  - ☐ tofacitinib
  - ☐ upadacitinib

or

- ☐ **continuing** treatment with:
  - ☐ infliximab s.c.

MCA0PB111 2506

12 Has the patient previously received this biological medicine (regardless of formulation) as their most recent course of PBS-subsidised treatment for this condition?

Yes ☐
No ☐

13 Will the treatment be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly (applicable only to **abatacept, golimumab** and **infliximab**)?

Yes ☐ dose [mg] per week
No ☐
Not applicable ☐ the application is **not** for abatacept, golimumab or infliximab

14 Has the assessment of response been conducted following a minimum of 12 weeks of therapy and **no later than 4 weeks** from cessation of the most recent course of treatment?

Yes ☐
No ☐

15 The patient has demonstrated an adequate response to the most recent course of PBS-subsidised biological medicine evidenced by:

☐ an erythrocyte sedimentation rate (ESR) ≤ 25mm/hr

ESR [mm/hr]

Date of test (DD MM YYYY)

[ ][ ] [ ][ ] [ ][ ][ ][ ]

or

☐ an ESR reduced by at least 20% from baseline

Baseline ESR [mm/hr]

Current ESR [mm/hr]

Date of current ESR (DD MM YYYY)

[ ][ ] [ ][ ] [ ][ ][ ][ ]

and/or

☐ a C-reactive protein (CRP) level ≤ 15mg/L

CRP [mg/L]

Date of test (DD MM YYYY)

[ ][ ] [ ][ ] [ ][ ][ ][ ]

or

☐ a CRP reduced by at least 20% from baseline

Baseline CRP [mg/L]

Current CRP [mg/L]

Date of current CRP (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

☐ a total active joint count of ≤ 10

Current active joint count [ ]

Date of assessment (DD MM YYYY)

[ ][ ] [ ][ ] [ ][ ][ ][ ]

or

☐ a total active joint count reduced by at least 50% from baseline

Baseline total active joint count

[ ]

Current total active joint count [ ]

Date of assessment (DD MM YYYY)

[ ][ ] [ ][ ] [ ][ ][ ][ ]

or

☐ a major joint count of ≤ 2

Current major joint count [ ]

Date of assessment (DD MM YYYY)

[ ][ ] [ ][ ] [ ][ ][ ][ ]

or

☐ a major joint count reduced by at least 50% from baseline

Baseline major joint count

[ ]

Current 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.

Checklist

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

☐ Details of the proposed prescription(s).

Privacy notice

17 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**

18 **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.

Reset form

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