Australian Government
Services Australia

medicare

PBS

Rheumatoid arthritis – initial 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 **initial** PBS-subsidised biological medicines (**originator** brands) for patients 18 years or over with severe active rheumatoid arthritis.

Important information

Initial applications to start PBS-subsidised treatment with **originator** brands 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 **initial** 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 **initial** 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 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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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, 18 years or over, is being treated by a:

- ☐ rheumatologist
- ☐ clinical immunologist with expertise in the management of rheumatoid arthritis

11 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.
- ☐ infliximab s.c. with i.v. loading (and an authority prescription for at least 2 i.v. doses at weeks 0 and 2 is attached)
- ☐ tocilizumab i.v.
- ☐ tocilizumab s.c.
- ☐ tofacitinib
- ☐ upadacitinib

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12 The patient:

☐ has not previously received PBS-subsidised treatment with a biological medicine for this condition

and

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

mg per week

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

13 In the past 24 months, has the patient failed to achieve an adequate response to a trial of at least 6 months intensive disease-modifying anti-rheumatic drugs (DMARD) treatment with at least 2 DMARDs at required minimum doses for a minimum of 3 months each?

No ☐ ***Go to 14***

Yes ☐ Provide details of DMARD treatment

DMARD	**From** (DD MM YYYY)	**To** (DD MM YYYY	**Dose**	**Minimum dose**
a) methotrexate				20 mg/week
b) hydroxychloroquine				200 mg/day
c) leflunomide				10 mg/day
d) sulfasalazine				2 g/day

- All patients must trial **a)**, **and either b)**, **and/or c)**, **and/or d)**, or
- If treatment with a) is contraindicated or the patient is intolerant of the required minimum dose for the required minimum 3 months of treatment, then the intensive treatment trial must be **any 2 of b)**, **c)**, **or d)**, or
- If treatment with 2 of b), c) or d) is contraindicated or the patient is intolerant of the required minimum dose for the required minimum 3 months of treatment, then the remaining tolerated DMARD must be trialled for at least 3 months of continuous treatment.

Refer to the PBS restrictions for DMARD requirement(s).

14 If applicable, provide details of contraindications or severe intolerances to DMARD treatment, including the drug name, the degree of toxicity and dose.

For details of the toxicity criteria, go to **servicesaustralia.gov.au/healthprofessionals**

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

Name of prior DMARD therapy	**Details of contraindications or intolerances including the degree of toxicity and dose**

15 The patient has failed to achieve an adequate response to prior DMARDs treatment demonstrated by:

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

Baseline ESR level mm/hr | Date of test (DD MM YYYY)

and/or

☐ an elevated C-reactive protein (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.

The joint count and ESR and/or CRP must be determined at the completion of the DMARD trial, but prior to ceasing DMARD therapy. All measures must be **no more than 4 weeks old** at the time of initial application.

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.

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