

# Rheumatoid arthritis – change or recommencement authority application

## Online PBS Authorities



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

For more information and how to access the **Online PBS Authorities** system, go to [servicesaustralia.gov.au/hppbsauthorities](https://servicesaustralia.gov.au/hppbsauthorities)

## When to use this form

Use this form to apply for **changing** or **recommencing** PBS-subsidised biological medicines for patients 18 years or over with severe active rheumatoid arthritis.

## Important information

Authority applications can be made 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 **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.

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 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](https://servicesaustralia.gov.au/healthprofessionals)

**medicare**



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## 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 Most recent biological medicine

Dates of the most recent treatment course

From (DD MM YYYY)

To (DD MM YYYY)

### 12 This application is for:

☐ abatacept i.v.

(at a dose specified in the product information)

☐ abatacept s.c.

☐ abatacept s.c. with i.v. loading

(at a dose specified in the product information)

☐ adalimumab

☐ baricitinib

☐ certolizumab pegol

☐ 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

► Go to 14

or

☐ infliximab s.c. with i.v. loading

(at a dose of 3 mg/kg)

► Go to 13



MCA0PB247 2506

13 Does the patient have a concurrent PBS authority application for the IV form of infliximab?

Yes ☐

No ☐

14 The patient:

☐ is **changing** PBS-subsidised biological treatment for this condition after a break **< 24 months** (including **no break**)

► **Go to 15**

or

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

► **Go to 15**

or

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

► **Go to 19**

15 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 (JIA) or systemic juvenile idiopathic arthritis (sJIA) 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

16 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

17 The patient:

☐ has experienced a **serious adverse reaction** necessitating permanent treatment withdrawal to the most recent course of PBS-subsidised biological medicine treatment

Provide details of the treatment and adverse reaction

► **Go to 18**

or

☐ has **failed** to demonstrate an adequate response to the most recent course of PBS-subsidised biological medicine treatment

► **Go to 18**

or

☐ has **demonstrated an adequate response** to the most recent course of PBS-subsidised biological medicine treatment

► **Go to 21**

or

☐ is transitioning from JIA or sJIA

► **Go to 18**

18 Is the patient submitting a new baseline?

Yes ☐ ► **Go to 22**

No ☐ ► **Go to 23**

19 The patient:

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

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

☐ will be submitting a new baseline

20 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

► **Go to 22**

**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.

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

☐ an erythrocyte sedimentation rate (ESR)  $\leq$  25mm/hr

Responding ESR  mm/hr

Date of test (DD MM YYYY)

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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**or**

☐ an ESR reduced by at least 20% from baseline

Baseline ESR  mm/hr

Responding ESR  mm/hr

Date of responding ESR (DD MM YYYY)

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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**and/or**

☐ a C-reactive protein (CRP) level  $\leq$  15mg/L

Responding CRP  mg/L

Date of test (DD MM YYYY)

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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**or**

☐ a CRP reduced by at least 20% from baseline

Baseline CRP  mg/L

Responding CRP  mg/L

Date of responding CRP (DD MM YYYY)

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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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  $\leq$  10

Responding active joint count

Date of assessment (DD MM YYYY)

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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**or**

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

Baseline total active joint count

Responding total active joint count

Date of assessment (DD MM YYYY)

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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**or**

☐ a major joint count of  $\leq$  2

Responding major joint count

Date of assessment (DD MM YYYY)

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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**or**

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

Baseline major joint count

Responding major joint count

Date of assessment (DD MM YYYY)

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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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.

**► Go to 23**

## For a patient submitting a baseline

22 The patient has:

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

and/or

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

or

☐ the requirement to demonstrate an elevated ESR or CRP could not be met due to  
  
☐ treatment with prednisolone dosed at 7.5mg or higher daily (or equivalent)

or

☐ treatment with a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent)

or

☐ provide an acceptable reason the patient could not demonstrate an elevated ESR or CRP level

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 active major 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

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

☐ Details of the proposed prescription(s).

## Privacy notice

24 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](https://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](https://servicesaustralia.gov.au/hpos)

25 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)



## 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](https://servicesaustralia.gov.au/hpos)
- or
- by post (signature required) to  
Services Australia  
Complex Drugs Programs  
Reply Paid 9826  
HOBART TAS 7001