

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

When to use this form

Use this form to apply for **initial** PBS-subsidised biological medicines for patients at least 18 years of age with severe active rheumatoid arthritis.

Important information

Initial applications to start PBS-subsidised treatment 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 **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 an authority application for the **first continuing** treatment with an **originator** brand has been approved, **subsequent continuing** treatments with PBS-subsidised biological medicines are **Authority Required (STREAMLINED)** and do not require authority approval from Services Australia for the listed quantity and repeats.

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.

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



medicare



Rheumatoid arthritis – initial authority application

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, at least 18 years of age, is being treated by a:

rheumatologist

clinical immunologist with expertise in the management of rheumatoid arthritis

11 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)

infliximab s.c. with i.v. loading (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



MCA0PB109 2606

12 Has the patient received PBS-subsidised treatment with a biological medicine 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 In the past 24 months, the patient has failed to achieve an adequate response to a trial of:

at least 6 months of intensive treatment with at least 2 disease modifying anti-rheumatic drugs (DMARDs) for a minimum of 3 months each, one being methotrexate at a dose of at least 20 mg weekly

or

at least 6 months of intensive treatment with at least 2 DMARDs for a minimum of 3 months each, where methotrexate is contraindicated/cannot be tolerated at a 20 mg weekly dose

or

at least 3 months of continuous treatment with 1 remaining tolerated DMARD at a required minimum dose where all other DMARDs are contraindicated/not tolerated

or

none of the above due to contraindications/severe intolerances to all of the DMARDs specified in the restrictions

15 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).

16 If applicable, provide details of contraindications or intolerance to prior DMARD treatment.

Provide details of **contraindications** according to the relevant TGA-approved Product Information

methotrexate	
hydroxychloroquine	
leflunomide	
sulfasalazine	

Provide details of **intolerances** of severity to necessitate permanent treatment withdrawal

DMARD	Details of intolerances including severity and dose
methotrexate	
hydroxychloroquine	
leflunomide	
sulfasalazine	

17 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 Date of test (DD MM YYYY)
 mm/hr

and/or

an elevated C-reactive protein (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

other - 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)

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

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.

Checklist

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

Details of the proposed prescription(s).

Privacy notice

19 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 servicessaustralia.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 servicessaustralia.gov.au/hpos

20 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 servicessaustralia.gov.au/hpos
- by post (signature required) to
Services Australia
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001