

Juvenile idiopathic arthritis - for adult patients with onset prior to age 18 - initial 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

When to use this form

Use this form to apply for **initial** PBS-subsidised biological medicines for an adult patient with a documented history of juvenile idiopathic arthritis with onset prior to the age of 18 years.

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 **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 be granted for juvenile idiopathic arthritis for adult patients with onset prior to age 18 **initial** authority applications.

Where the term 'biological medicine' appears, it refers to adalimumab, etanercept and tocilizumab.

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 has been approved, **subsequent continuing** treatments with PBS-subsidised biosimilar brands of adalimumab are **Authority Required (STREAMLINED)** and do not require authority approval from Services Australia for the listed quantity and repeats.

Section 100 arrangements for tocilizumab i.v.

This item is 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.

This item is not available as a PBS benefit for in-patients of a public hospital.

The hospital name and provider number must be included in this 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 Family name

First given name

3 Date of birth (DD MM YYYY)

4 Patient's current 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, 18 years or over, is being treated by a:

☐ rheumatologist

☐ clinical immunologist with expertise in the management of
rheumatoid arthritis

and

☐ has a documented history of severe active juvenile
idiopathic arthritis with onset prior to the age of 18 years.

11 This application is for:

☐ adalimumab

☐ etanercept

☐ tocilizumab i.v.

☐ tocilizumab s.c.

12 In the past 24 months, has the patient failed to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) including at least 3 months continuous treatment with each of at least 2 DMARDs, or failed a trial of 3 months continuous treatment with 1 DMARD if the patient has contraindications/intolerances to all other DMARDs

Yes ☐ **Go to 13**

No, the patient has contraindications/intolerances to all
DMARDs specified in the restrictions ☐ **Go to 14**



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13 Provide details of prior DMARD treatment

DMARD	From	To	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 intolerances to the DMARDs listed above including the drug name and the degree of toxicity.

For details of the toxicity criteria, go to [servicesaustralia/healthprofessionals](https://www.servicesaustralia.gov.au/healthprofessionals)

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

Name of prior drug therapy	Details of contraindications or intolerances including the degree of toxicity	If an intolerance, provide the maximum tolerated dose of the drug

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

ESR result

Date of test

and/or

☐ an elevated C-reactive protein (CRP) > 15 mg/L

CRP result

Date of test

Where only one marker (ESR or CRP) has been provided at baseline, the same marker must be used for assessment for all continuing applications.

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

16 The patient has:

☐ 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 and/or ankle; and/or shoulder, cervical spine 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. 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

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

☐ Details of the proposed prescription(s).

Privacy notice

18 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

19 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
- or
- by post (signature required) to
Services Australia,
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001