Australian Government
Services Australia

medicare

PBS

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

When to use this form

Use this authority application form (this form) to apply for **initial** Pharmaceutical Benefits Scheme (PBS) subsidised biological agents 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 must be in writing and must include sufficient supporting information to determine the patient's eligibility according to the PBS criteria.

Applications for balance of supply may 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.

Call charges may apply.

Under no circumstances will phone approvals be granted for **initial** authority applications.

The patient must be treated by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis.

Where the term 'biological agent' 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.

The assessment of the patient's response to the initial course of treatment must be made following a **minimum of 12 weeks** of therapy.

This assessment will be used to determine eligibility for continuing treatment and must be conducted **no later than 4 weeks** from the date of completion of this initial course of treatment. Where a response assessment is not conducted and submitted to Services Australia, the patient will be deemed to have failed to respond to treatment.

Section 100 arrangements for tocilizumab i.v. only

This item is available to a patient who is attending:

- an approved private hospital
- a public participating hospital, **or**
- a public hospital

and is:

- a day admitted patient
- a non-admitted patient, **or**
- a patient on discharge.

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

The hospital name and provider number must be included in this form.

Treatment specifics

A patient who has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered to have failed treatment with that PBS subsidised biological agent.

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

[/ /]

4 Patient's current weight

[ ] kg

Prescriber's details

5 Prescriber number

[ ]

6 Dr ☐ Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other [ ]

Family name

[ ]

First given name

[ ]

7 Work phone number

[( )]

Alternative phone number

[ ]

Fax number

[( )]

Hospital details – tocilizumab only

8 Hospital name

[ ]

This hospital is a:

☐ public hospital

☐ private hospital

9 Hospital provider number

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

Biological agent details

10 Which biological agent is this application for?

☐ Adalimumab

☐ Etanercept

☐ Tocilizumab i.v.

☐ Tocilizumab s.c.

Conditions and criteria

To qualify for PBS authority approval, the following conditions must be met.

11 The patient:

☐ is aged 18 years or older

and

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

12 Has the patient failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease-modifying anti-rheumatic drugs (DMARDs), which includes at least 3 months continuous treatment with a minimum of at least 2 DMARDs?

No ☐

Yes ☐ Give details of 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
e)	azathioprine	/ /	/ /		1 mg/kg/day
f)	cyclosporin	/ /	/ /		2 mg/kg/day
g)	sodium aurothiomalate	/ /	/ /		50 mg weekly

All patients must trial: **a)**, **and either b)**, **and/or c)**, **and/or d).**

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)** (If intolerant provide details to the maximum tolerated dose of methotrexate).

If treatment with 3 or more of a), 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 intensive treatment trial must be completed with: **1 or more of e)**, **f)**, **or g)**.

Refer to PBS.gov.au for further information regarding DMARD requirements.

13 If applicable, provide details of contraindications or intolerances to any of the prior therapies including the drug name and the degree of toxicity.

For details of the toxicity criteria, go to **servicesaustralia/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

Current assessment of patient

14 The patient can demonstrate failure to achieve an adequate response to 6 months of intensive prior DMARD treatment 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 1 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.

15 The patient has:

☐ an active joint count of at least 20 active (swollen and tender) joints

or

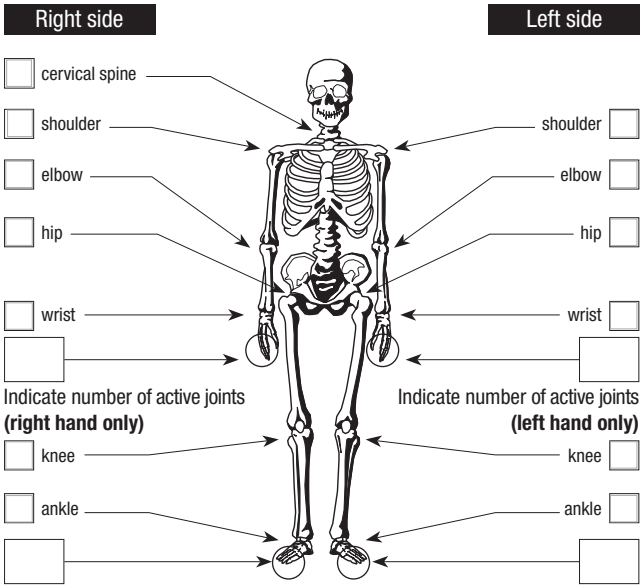
☐ at least 4 major active joints:

☐ elbow, wrist, knee and/or ankle (assessed as swollen or tender)

and/or

☐ shoulder, cervical spine and/or hip (assessed as pain in passive movement and restricted passive movement due to active disease and not irreversible damage).

16 Indicate affected joints on the diagram and complete the boxes below



Current active joint count

Date of joint assessment / /

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.

☐ The completed authority prescription form(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/privacy**

Prescriber's declaration

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 the completed authority prescription form(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.

Prescriber's signature

On completion, print and sign by hand.

Date / /

Returning this form

Return this form and any supporting documents:

- **online**, upload this form, the authority prescription form(s) and any relevant attachments through Health Professional Online Services (HPOS) at **servicesaustralia.gov.au/hpos**

  or

- by post, send this form, the authority prescription form(s) and any relevant attachments to:

  Services Australia
  Complex Drugs Programs
  Reply Paid 9826
  HOBART TAS 7001

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