Australian Government
Services Australia

medicare

PBS

Juvenile idiopathic arthritis for adult patients with onset prior to age 18 change or recommencement or demonstration of response authority application

When to use this form

Use this authority application form (this form) for a patient **changing or recommencing** 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.

This form can also be used for **demonstrating a response** to the current PBS subsidised treatment before temporarily stopping treatment.

Important information

Authority 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 **change or recommencement** 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 **changing or recommencing** treatment or **demonstrating** a response to treatment before temporarily stopping 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.

A demonstration of response must be conducted while the patient is on or within 4 weeks of cessation to the most recent course of PBS subsidised treatment.

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 – for tocilizumab i.v. 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.

11 Dates of the most recent treatment course

From [/ /] to [/ /]

Conditions and criteria

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

12 The patient aged 18 years or older is:

☐ **demonstrating** a response to the current PBS subsidised treatment before temporarily stopping treatment with this biological agent

Demonstration of response can be submitted when recommencing treatment

▶ ***Go to 15***

or

☐ **changing or recommencing** PBS subsidised biological agent treatment after a break **< 24 months** from the most recent PBS subsidised biological agent for this condition

and

☐ will be submitting a new baseline

or

☐ will be using the previous baseline

▶ ***Go to 13***

or

☐ **recommencing** PBS subsidised biological agent treatment after a break **> 24 months** from the most recent PBS subsidised biological agent for this condition

or

☐ has not received PBS subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS subsidised biological agent treatment 3 times in their last treatment cycle

and

☐ will be submitting a new baseline

▶ ***Go to 18***

13 The patient:

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

and

☐ has previously received PBS subsidised treatment with a biological agent for this condition in this treatment cycle

and

☐ has not already failed, or ceased to respond to, PBS subsidised treatment with this drug for this condition within this treatment cycle

14 The patient:

☐ has **failed** to demonstrate or sustain a response with the previous biological agent

or

☐ has experienced a **serious adverse reaction** of a severity resulting in the necessity for permanent withdrawal of the previous PBS subsidised biological agent.

Give details of treatment and adverse reaction

or

☐ has **demonstrated a response** to the previous PBS subsidised biological agent treatment

If patient is demonstrating a response ▶ ***Go to 15***

If new baselines are being provided ▶ ***Go to 17***

For a patient demonstrating a response

15 The patient has demonstrated an adequate response to treatment as confirmed by:

☐ an Erythrocyte Sedimentation Rate (ESR) no greater than 25mm/h

or

☐ a C-Reactive Protein (CRP) no greater than 15mg/L

or

☐ either marker reduced by at least 20% from baseline

Provide relevant details of:

ESR _____ mm/h

Date of test ___/___/___

CRP _____ mg/L

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.

16 The patient has demonstrated an adequate response to treatment as confirmed by:

☐ a reduction in at least 20 active joints count to fewer than 10 active joints

or

☐ a reduction in at least 20 active joints count by _____ %

or

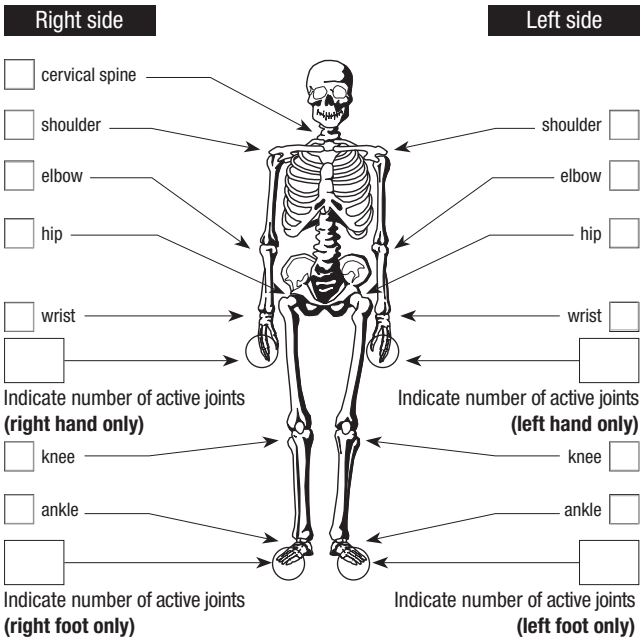
☐ a reduction in the major active joints count (from at least 4) by _____ % for

☐ 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).

17 Indicate affected joints demonstrating a response on the diagram and complete the boxes below:



Active joint count for demonstration of response

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.

For a patient submitting a new baseline

18 The patient has:

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

ESR result

Date of test / /

and/or

☐ an elevated C-reactive protein (CRP) > 10 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 requirement to demonstrate an elevated ESR or CRP cannot be met, state the reason why.

19 The patient has:

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

or

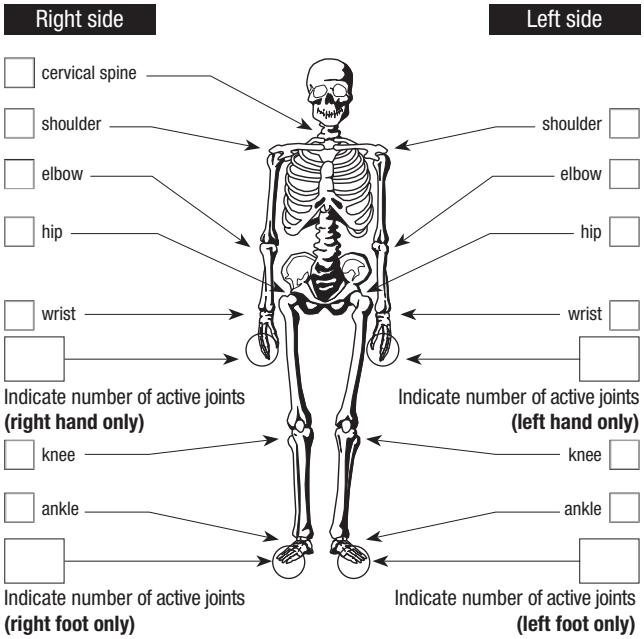
☐ at least 4 major active joints:

☐ 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).

20 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

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

☐ The completed authority prescription form(s).

Privacy notice

22 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

23 **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

/ /

Reset form Print form

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