Australian Government
Services Australia

medicare

PBS

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

When to use this form

Use this form to apply for **changing or recommencing** 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

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 **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 approvals be granted for juvenile idiopathic arthritis for adult patients with onset prior to age 18 **change** or **recommencement** 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 **changing** or **recommencing** treatment.

The patient remains eligible to receive **continuing** treatment providing they continue to sustain a response to 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 Dr ☐ Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other

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 Dr ☐ Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other

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 older, 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:

☐ adalimumab

☐ etanercept

☐ tocilizumab i.v.

☐ tocilizumab s.c.

MCA0PB282 250205

13 The patient:

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

and

☐ will be submitting a new baseline

or

☐ will be using the previous baseline

▶ ***Go to 14***

or

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

and

☐ will be submitting a new baseline

or

☐ will be using the previous baseline

▶ ***Go to 14***

or

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

and

☐ has had a break in treatment of **24 months or more** from the most recently approved PBS-subsidised biological medicine for this condition

or

☐ has not received PBS-subsidised biological medicine for **at least 5 years**

and

☐ failed or ceased to respond to PBS-subsidised biological medicine treatment **3** times in their **last treatment cycle**

and

☐ will be submitting a new baseline

▶ ***Go to 17***

14 The patient:

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

and

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

and

☐ has not already failed, or ceased to respond to, PBS-subsidised treatment with this drug (the biological medicine this application is for) for this condition during the current treatment cycle

and

☐ has not already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle

15 The patient has:

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

or

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

or

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

Provide details of treatment and adverse reaction

If the patient is demonstrating a response	▶ ***Go to 16***
If the patient is providing a new baseline	▶ ***Go to 17***
If the patient is not demonstrating a response and is not providing a new baseline	▶ ***Go to 18***

For a patient demonstrating a response (to current or previous biological medicine)

The response assessment should be conducted while still on treatment, but **no later than 4 weeks** following cessation of treatment.

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

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

ESR

mm/hr

Date of test (DD MM YYYY)

or

☐ an ESR reduced by at least 20% from ESR provided at baseline

Baseline ESR

mm/hr

Current ESR

mm/hr

Date of test (DD MM YYYY)

and/or

☐ a C-reactive protein (CRP) level ≤ 15mg/L

CRP

mg/L

Date of test (DD MM YYYY)

or

☐ a CRP reduced by at least 20% from CRP provided at baseline

Baseline CRP

mg/L

Current CRP

mg/L

Date of test (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.

and

☐ an active joint count of < 10 active (swollen and tender) joints

Current active joint count

Date of assessment (DD MM YYYY)

or

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

Baseline total active joint count

Current active joint count

Date of assessment (DD MM YYYY)

or

☐ a major active joint count of ≤ 2

Current major joint count

Date of assessment (DD MM YYYY)

or

☐ at least a 50% reduction in the number of the following major active joints, down from at least 4: elbow, wrist, knee and/or ankle, and/or shoulder, cervical spine and/or hip

Baseline major active joint count

Current major joint count

Date of assessment (DD MM YYYY)

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

17 The patient has:

☐ an elevated ESR > 25 mm/hr

Baseline ESR level

mm/hr

Date of test (DD MM YYYY)

and/or

☐ an elevated CRP > 15 mg/L

Baseline CRP level

mg/L

Date of test (DD MM YYYY)

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

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 major active joints from elbow, wrist, knee, and/or ankle; and/or shoulder, cervical spine and/or hip

Baseline major active 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 measurements of **new baseline** joint count, ESR and/or CRP must be **no more than 4 weeks old** at the time of application.

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 **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**

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)

If returning by post, print and sign by hand.

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

Reset form