

Juvenile idiopathic arthritis – change of treatment after resolution of critical shortage of tocilizumab application

When to use this form	Use this authority application form to apply for change of treatment from Pharmaceutical Benefits Scheme (PBS) subsidised adalimumab or etanercept to tocilizumab after resolution of critical shortage of tocilizumab for patients with severe active juvenile idiopathic arthritis.
Important information	Change after resolution of critical shortage of tocilizumab applications must be in writing and must include sufficient supporting information to determine the patient's eligibility according to the PBS criteria. 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 change after resolution of critical shortage of tocilizumab treatment. Applications for continuing treatment must be made in writing to Services Australia and must include a continuing treatment authority application form that provides sufficient supporting information to determine the patient's eligibility according to the PBS criteria.
Section 100 arrangements for tocilizumab i.v. only	<p>These items are available to a patient who is attending:</p> <ul style="list-style-type: none">• an approved private hospital• a public participating hospital, or• a public hospital <p>and is:</p> <ul style="list-style-type: none">• a day admitted patient• a non-admitted patient, or• a patient on discharge. <p>These items are not available as a PBS benefit for in-patients of the hospital.</p> <p>The hospital name and provider number must be included in this form.</p> <p>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.</p>
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 Business phone number
 ()

Alternative phone number

Hospital details (for tocilizumab i.v. only)

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 has severe active juvenile idiopathic arthritis (JIA) and:

is under 18 years of age

and

is being treated by a paediatric rheumatologist

or

is under the supervision of a paediatric rheumatology treatment centre

or

is an adult with onset prior to the age of 18 years

and is being treated by:

a rheumatologist

or

a clinical immunologist with expertise in the management of rheumatoid arthritis.

11 Was the patient receiving PBS subsidised treatment with tocilizumab for JIA prior to 1 November 2021?

No

Yes

12 Has the patient been receiving PBS subsidised treatment with a biological medicine for JIA in place of tocilizumab due to critical supply shortage of tocilizumab?

No

Yes

13 Is the patient switching back to tocilizumab as the shortage has been resolved?

No

Yes

14 The patient:

- has received ≥ 12 weeks of therapy under the critical shortage of tocilizumab restriction as their most recent treatment and the demonstration of response assessment was conducted within the timeframe specified in the restriction

Dates of the most recent treatment course

From / / to / /

▶ **Go to 15**

or

- has received < 12 weeks of therapy under the critical shortage of tocilizumab restriction as their most recent treatment and evidence of response is not required due insufficient treatment length

Dates of the most recent treatment course

From / / to / /

▶ **Go to 19**

or

- is changing back to tocilizumab after the shortage has been resolved and has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of the previous PBS subsidised biological agent under the tocilizumab critical shortage listing.

Give details of treatment and adverse reaction

▶ **Go to 19**

Demonstrating a response

15 The patient is:

- < 18 years of age

▶ **Go to 16**

or

- ≥ 18 years of age and commenced treatment prior to turning 18

▶ **Go to 16**

or

- ≥ 18 years of age and commenced treatment after turning 18.

▶ **Go to 17**

16 Has the patient demonstrated an adequate response confirmed by a reduction in the major or active joints count by at least 50% from baseline?

No

Yes ▶ **Go to 18**

17 The patient has:

- demonstrated or sustained an adequate response to treatment with this drug (irrespective of form), confirmed by:

erythrocyte sedimentation rate (ESR) result

Date of test

 / /

and/or

C-reactive protein (CRP) result

Date of test

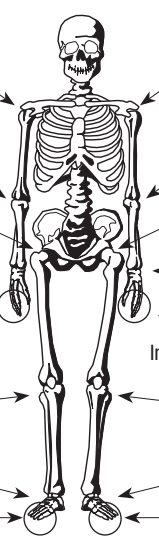
 / /

Where only 1 marker (ESR or CRP) has been provided at baseline, the same marker must be used for assessment for all continuing applications.

and

- has a reduction in the major or active joints count by at least 50% from baseline.

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

Right side		Left side
<input type="checkbox"/> shoulder		<input type="checkbox"/> shoulder
<input type="checkbox"/> elbow		<input type="checkbox"/> elbow
<input type="checkbox"/> hip		<input type="checkbox"/> hip
<input type="checkbox"/> wrist		<input type="checkbox"/> wrist
<input type="checkbox"/> Indicate number of active joints (right hand only)		<input type="checkbox"/> Indicate number of active joints (left hand only)
<input type="checkbox"/> knee		<input type="checkbox"/> knee
<input type="checkbox"/> ankle		<input type="checkbox"/> ankle
<input type="checkbox"/> Indicate number of active joints (right foot only)		<input type="checkbox"/> Indicate number of active joints (left foot only)


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.

Checklist

- 19**  The relevant attachments need to be provided with this form.
- The completed authority prescription form(s).

Privacy notice

- 20** 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

21 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



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