

Psoriatic arthritis – change, recommencement or demonstration of response authority application

When to use this form

Use this form to apply for **changing** or **recommencing** PBS-subsidised biological agents for patients aged 18 years or older with psoriatic arthritis.

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 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.

Call charges may apply.

Under no circumstances will phone approvals be granted for **change** or **recommencement** authority applications.

Where the term 'biological agents' appears, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab.

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.

The patient remains eligible to receive **continuing** treatment providing they continue to sustain a response to treatment.

After a written authority application for the **first continuing** treatment has been approved, **subsequent continuing** treatment with PBS-subsidised biosimilar brands of biological agents are Authority Required (Streamlined) and do not require authority approval from Services Australia for the listed quantity and repeats.

Section 100 arrangements for infliximab 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 authority 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 agent.

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

13 The patient is:

changing from an alternate PBS-subsidised biological agent, and an authority prescription for at least 2 i.v. doses of infliximab at weeks 0 and 2 is attached

or

recommencing PBS-subsidised infliximab after a treatment break and an authority prescription for 1 i.v. dose of infliximab at week 0 is attached.

14 The patient:

is **changing** PBS-subsidised biological treatment for this condition after a break **< 5 years**

and

will be submitting a new baseline

or

will be using the previous baseline

► **Go to 15**

or

is **recommencing** PBS-subsidised biological agent treatment for this condition after a break **< 5 years**:

and

the demonstration of response from the time of cessation is provided with this application

or

the demonstration of response was submitted to Services Australia at the time of treatment cessation

and

will be submitting a new baseline

or

will be using the previous baseline

► **Go to 15**

or

is **recommencing** PBS-subsidised biological treatment for this condition after a break **> 5 years**

and

will be submitting a new baseline

and

previously received PBS-subsidised biological treatment for this condition

► **Go to 19**

15 The patient:

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

and

has not failed or ceased to respond to PBS-subsidised treatment with the biological agent being applied for this condition in this 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 since **1 October 2021**.

16 The patient:

has **failed** to demonstrate or sustain a response to the most recent PBS-subsidised biological agent

or

has experienced a **serious adverse reaction** of a severity necessitating permanent withdrawal of the most recent PBS-subsidised biological agent.

Give details of treatment and adverse reaction

or

has **demonstrated or sustain an adequate response** to the most recent PBS-subsidised biological agent.

If the patient is demonstrating a response

► **Go to 17**

If new baselines are being provided

► **Go to 19**

If the patient is not demonstrating a response and is not providing a new baseline

► **Go to 21**

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

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

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

Erythrocyte sedimentation rate (ESR) level

Date of test (DD MM YYYY)

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and/or

C-reactive protein (CRP) level

Date of test (DD MM YYYY)

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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

where the baseline is at least 20 active joints, a reduction by %

or

where the baseline is at least 4 major joints (elbow, wrist, knee, ankle, shoulder and/or hip), a reduction by %

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"/>		<input type="checkbox"/>
Indicate number of active joints (right hand only)		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"/>		<input type="checkbox"/>
Indicate number of active joints (right foot only)		Indicate number of active joints (left foot only)

Active joint count for demonstration of response

Date of joint 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.

► **Go to 21**

For a patient submitting a new baseline

19 The patient has:

an elevated ESR > 25 mm/hr, no more than 4 weeks old
 ESR level Date of test (DD MM YYYY)

and/or

an elevated CRP > 15 mg/L, no more than 4 weeks old
 CRP level 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.

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

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.....

and

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

or

at least 4 major active (swollen and tender) joints: elbow, wrist, knee, ankle, shoulder and/or hip.

20 Indicate affected joints 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"/>		<input type="checkbox"/>
Indicate number of active joints (right hand only)		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"/>		<input type="checkbox"/>
Indicate number of active joints (right foot only)		Indicate number of active joints (left foot only)

Current active joint count

Date of joint 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.

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 servicessaustralia.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

Date (DD MM YYYY)

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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 servicessaustralia.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