Australian Government
Services Australia

medicare

PBS

Psoriatic arthritis – 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 patients 18 years or over with severe psoriatic arthritis.

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 severe psoriatic arthritis **change** or **recommencement** authority applications.

Where the term 'biological medicine' appears, it refers to adalimumab, bimekizumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, risankizumab, 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.

After an authority application for the **first continuing** treatment has been approved, **subsequent continuing** treatments with PBS-subsidised biosimilar brands of biological medicines 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.

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 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 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 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 Family name

First given name

3 Date of birth (DD MM YYYY)

4 Patient's weight

kg

Prescriber's details

5 Prescriber number

6 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 is being treated by a:

- ☐ rheumatologist
- ☐ clinical immunologist with expertise in the management of psoriatic arthritis.

11 This application is for:

- ☐ adalimumab
- ☐ bimekizumab
- ☐ certolizumab pegol
- ☐ etanercept
- ☐ golimumab
- ☐ guselkumab
- ☐ infliximab i.v. (at a dose of 5 mg/kg)
- ☐ ixekizumab
- ☐ risankizumab
- ☐ secukinumab
- ☐ tofacitinib
- ☐ upadacitinib
- ☐ ustekinumab

▶ *Go to 13*

or

- ☐ infliximab s.c. with i.v. loading (at a dose of 5 mg/kg)

▶ *Go to 12*

12 Does the patient have a concurrent PBS authority application for the IV form of infliximab that is approved or to be approved?

- Yes ☐
- No ☐

MCA0PB260 2507

13 The patient:

☐ is **changing** PBS-subsidised biological treatment for this condition after a break **< 5 years** (including **no break**)

▶ ***Go to 14***

or

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

▶ ***Go to 14***

or

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

and

☐ has previously received PBS-subsidised treatment with a biological medicine for this condition

and

☐ has had a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition

and

☐ will be submitting a new baseline

▶ ***Go to 19***

14 The patient:

☐ has received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle (since **1 October 2021**)

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 (since **1 October 2021**)

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**.

15 The patient:

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

Provide details of the treatment and adverse reaction

▶ ***Go to 16***

or

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

▶ ***Go to 16***

or

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

▶ ***Go to 17***

16 Is the patient submitting a new baseline?

Yes ☐ ▶ ***Go to 19***

No ☐ ▶ ***Go to 20***

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

17 Has the assessment of response been conducted following a **minimum of 12 weeks** of therapy and **no later than 4 weeks** from cessation of the most recent course of treatment?

Yes ☐
No ☐

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

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

Responding ESR ____ mm/hr

Date of test (DD MM YYYY)

__ __ __ __ __

or

☐ an ESR reduced by at least 20% from baseline

Baseline ESR ____ mm/hr

Responding ESR ____ mm/hr

Date of responding ESR (DD MM YYYY)

__ __ __ __ __

and/or

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

Responding CRP ____ mg/L

Date of test (DD MM YYYY)

__ __ __ __ __

or

☐ a CRP reduced by at least 20% from baseline

Baseline CRP ____ mg/L

Responding CRP ____ mg/L

Date of responding CRP (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

☐ a total active joint count of ≤ 10

Responding total active joint count ____

Date of assessment (DD MM YYYY)

__ __ __ __ __

or

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

Baseline total active joint count ____

Responding total active joint count ____

Date of assessment (DD MM YYYY)

__ __ __ __ __

or

☐ a major joint count of ≤ 2

Responding major joint count ____

Date of assessment (DD MM YYYY)

__ __ __ __ __

or

☐ a major joint count reduced by at least 50% from baseline

Baseline major joint count ____

Responding major joint count ____

Date of assessment (DD MM YYY)

__ __ __ __ __

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 20*

For a patient submitting a new baseline

19 The patient has:

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

Baseline ESR level _____ mm/hr Date of test (DD MM YYYY) __ __ / __ __ / __ __ __ __

and/or

☐ an elevated C-reactive protein (CRP) > 15 mg/L

Baseline CRP level _____ mg/L Date of test (DD MM YYYY) __ __ / __ __ / __ __ __ __

or

☐ the requirement to demonstrate an elevated ESR or CRP could not be met due to

- ☐ treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent)

or

- ☐ treatment with a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent)

or

- ☐ provide an acceptable reason the patient could not demonstrate an elevated ESR or CRP level

_____

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

Baseline major 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

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

☐ Details of the proposed prescription(s).

Privacy notice

21 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**

22 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