

Severe chronic plaque psoriasis – continuing authority application

Online PBS Authorities



Requesting PBS Authorities online provides an immediate assessment in real time.

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 **continuing** PBS-subsidised biological medicines for patients 18 years or over with severe chronic plaque psoriasis.

Important information

Continuing authority applications can be made in real time 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 chronic plaque psoriasis **continuing** authority applications.

Where the term 'biological medicine' appears, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab.

A copy of the PASI calculation sheets is provided for your convenience.

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 **continuing** 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 biological medicines are **Authority Required (STREAMLINED)** and do not require authority approval from Services Australia for the listed quantity and repeats.

Continuing treatment with PBS-subsidised **infliximab s.c.** is **Authority Required (STREAMLINED)** and does 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 particular PBS-subsidised biological medicine.

For more information

Go to servicesaustralia.gov.au/healthprofessionals

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You do not need to complete this form if you use the
Online PBS Authorities system.

Go to servicesaustralia.gov.au/hppbsauthorities

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 Is the patient being treated by a dermatologist?

Yes ☐

No ☐

11 Has the patient received this drug (regardless of formulation) as their most recent course of PBS-subsidised biological medicine treatment for this condition?

Yes ☐

No ☐

12 Is this treatment systemic monotherapy (other than methotrexate)?

Yes ☐

No ☐



MCA0PB113 2608

13 This application is for the

- ☐ **first continuing** treatment with:
- ☐ adalimumab
 - ☐ etanercept
 - ☐ infliximab i.v. (at a dose of 5 mg/kg)
 - ☐ ustekinumab

► **Go to 15**

or

- ☐ **subsequent continuing** treatment with:
- ☐ adalimumab
 - ☐ etanercept
 - ☐ infliximab i.v. (at a dose of 5 mg/kg)
 - ☐ ustekinumab

► **Go to 15**

or

- ☐ **continuing** treatment with:
- ☐ bimekizumab
 - ☐ guselkumab
 - ☐ ixekizumab
 - ☐ risankizumab
 - ☐ secukinumab
 - ☐ tildrakizumab (100 mg dosage regimen)
 - ☐ tildrakizumab (200 mg dosage regimen)

► **Go to 15**

► **Go to 14**

14 The patient has demonstrated an adequate response to the most recent course of treatment with this drug at the:

- ☐ 100 mg dosage regimen

and

- ☐ the treating physician has determined that a more satisfactory response can be achieved at the 200 mg dosage regimen

or

- ☐ 200 mg dosage regimen

15 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 ☐

16 The condition is affecting the:

- ☐ whole body

► **Go to 17**

or

- ☐ face/hand/foot

► **Go to 18**

17 The patient has demonstrated an adequate response to treatment with this drug evidenced by a Psoriasis Area and Severity Index (PASI) score reduced:

- ☐ to **3.75** or less

Responding PASI score

Date of response assessment (DD MM YYYY)

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or

- ☐ by at least **75%**, or sustained at this level, compared to the baseline value for this treatment cycle

Baseline PASI score

Responding PASI score

Date of response assessment (DD MM YYYY)

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► **Go to 22**

18 The patient has demonstrated an adequate response to treatment with this drug evidenced by a reduction:

- ☐ in the PASI symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values

► **Go to 19**

or

- ☐ to **7.5%** or less in the skin area affected

► **Go to 20**

or

- ☐ by at least **75%** in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle

► **Go to 21**

19 Response assessments have been performed on the same affected area assessed at baseline, with the area being:

(Select **one responding area only** with all 3 subscores reduced to **0 or 1**)

- ☐ face ☐ right palm ☐ left palm
☐ right sole ☐ left sole

Provide responding PASI symptom subscores for that area

Erythema subscore

Thickness subscore

Scaling subscore

Date of response assessment (DD MM YYYY)

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► **Go to 22**

20 Response assessments have been performed on the same affected area assessed at baseline, with the area being:

(Select **one responding area only** with skin area affected reduced to **7.5% or less**)

☐ face ☐ right palm ☐ left palm

☐ right sole ☐ left sole

Responding numerical % for that area

%

Date of response assessment (DD MM YYYY)

► **Go to 22**

21 Response assessments have been performed on the same affected area assessed at baseline, with the area being:

(Select **one responding area only** reduced by at least 75% from baseline)

☐ face ☐ right palm ☐ left palm

☐ right sole ☐ left sole

Qualifying baseline numerical % for that area

%

Responding numerical % for that same area

%

Date of response assessment (DD MM YYYY)

Checklist

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

- ☐ Details of the proposed prescription(s).
☐ The completed PASI calculation sheet(s).

Privacy notice

23 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

24 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)



Returning this form

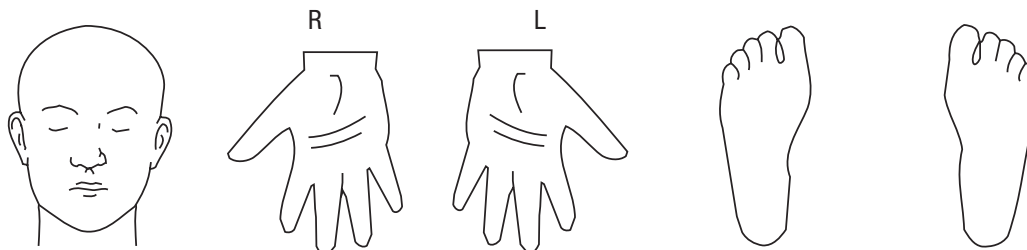
Return this form, details of the proposed prescription(s) and any relevant attachments:

- **online** (no signature required), upload through HPOS at servicesaustralia.gov.au/hpos
- by post (signature required) to
Services Australia
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

PASI calculation and body diagram – face, hand and foot

Body region					
Indicate the degree of involvement of the body region surface as a percentage	FACE	RIGHT PALM	LEFT PALM	RIGHT SOLE	LEFT SOLE
	%	%	%	%	%
OR					
Clearly indicate the plaque characteristics for each body region by circling the number which best corresponds to the patient's skin condition (circle one number in each box)					
Erythema	0 = none 1 = slight 2 = moderate 3 = severe 4 = very severe	0 = none 1 = slight 2 = moderate 3 = severe 4 = very severe	0 = none 1 = slight 2 = moderate 3 = severe 4 = very severe	0 = none 1 = slight 2 = moderate 3 = severe 4 = very severe	0 = none 1 = slight 2 = moderate 3 = severe 4 = very severe
Thickness	0 = none 1 = slight 2 = moderate 3 = severe 4 = very severe	0 = none 1 = slight 2 = moderate 3 = severe 4 = very severe	0 = none 1 = slight 2 = moderate 3 = severe 4 = very severe	0 = none 1 = slight 2 = moderate 3 = severe 4 = very severe	0 = none 1 = slight 2 = moderate 3 = severe 4 = very severe
Scaling	0 = none 1 = slight 2 = moderate 3 = severe 4 = very severe	0 = none 1 = slight 2 = moderate 3 = severe 4 = very severe	0 = none 1 = slight 2 = moderate 3 = severe 4 = very severe	0 = none 1 = slight 2 = moderate 3 = severe 4 = very severe	0 = none 1 = slight 2 = moderate 3 = severe 4 = very severe

Mark clearly on the diagrams the extent of the affected area(s)



PASI calculation and body diagram – whole body

Plaque characteristic	Rating score	Body region (and weighting factor)			
		Head	Upper Limbs	Trunk	Lower Limbs
Erythema	0 = None 1 = Slight 2 = Moderate 3 = Severe 4 = Very severe				
Thickness					
Scaling					
Add together each of the 3 scores for each of the body regions to give 4 separate sub totals.					
Sub Totals		A1=	A2=	A3=	A4=
Multiply each sub total by the amount of body surface area represented by that region i.e. A1 x 0.1 for head, A2 x 0.2 for upper limbs, A3 x 0.3 for trunk, A4 x 0.4 for lower limbs to give a value B1, B2, B3 and B4 for each body region respectively					
		A1 x 0.1 = B1	A2 x 0.2 = B2	A3 x 0.3 = B3	A4 x 0.4 = B4
		B1=	B2=	B3=	B4=
Degree of involvement as % for each body region affected (score each region with score between 0–6)	0 = None 1 = 1–9% 2 = 10–29% 3 = 30–49% 4 = 50–69% 5 = 70–89% 6 = 90–100%				
For each body region multiply sub total B1, B2, B3 and B4 by the <u>score</u> (0–6) of the % of body region involved to give 4 subtotals C1, C2, C3 and C4					
		B1 x score = C1	B2 x score = C2	B3 x score = C3	B4 x score = C4
		C1=	C2=	C3=	C4=
The patient's PASI score is the sum of C1+C2+C3+C4				PASI=	

Shade in the affected areas

