

Severe chronic plaque psoriasis – 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 medicines for patients 18 years or over with severe chronic plaque psoriasis.

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.

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 **changing** or **recommencing** treatment or **demonstrating a response** to treatment before temporarily stopping treatment.

After a written 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. only

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 an assessment is not conducted within this 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

14 The patient, 18 years or over:

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 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

has previously received PBS-subsidised biological treatment for this condition

and

will receive treatment with a biological medicine as systemic monotherapy (other than methotrexate).

► **Go to 18**

15 The patient:

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

and

has not failed or ceased to respond to PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle (since **1 February 2019**)

and

has not failed or ceased to respond to PBS-subsidised treatment with the biological medicine being applied for this condition in this treatment cycle

and

will receive treatment with a biological medicine as systemic monotherapy (other than methotrexate).

16 The patient:

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

or

has **demonstrated** or **sustained an adequate response** to the most recent PBS-subsidised biological medicine

or

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

Provide details of treatment and adverse reaction

| |
|--|
| |
| |
| |
| |

If the patient is demonstrating a response ► **Go to 17**

If the patient is providing a new baseline ► **Go to 18**

If the patient is not demonstrating a response and is not providing a new baseline ► **Go to 19**

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

The PASI 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:

PASI score reduced by 75% or more, or sustained at this level, compared to the baseline values (for whole body chronic plaque psoriasis only)

PASI score

Date of assessment (DD MM YYYY)

| | | | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|
| | | | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|

or

PASI symptom subscores for all 3 of erythema, thickness and scaling have been reduced to slight or better, or sustained at this level, compared to the baseline values (applies to face, hand and foot chronic plaque psoriasis only)

Date of assessment (DD MM YYYY)

| | | | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|
| | | | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|

or

a reduction by 75% or more in the skin area affected, or sustained at this level, compared to the baseline values (applies to face, hand and foot chronic plaque psoriasis only).

Date of assessment (DD MM YYYY)

| | | | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|
| | | | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|

► **Go to 19**

For a patient submitting a new baseline

18 The patient:

- has a current whole body PASI score > 15

PASI score

Date of assessment (DD MM YYYY)

or

- has chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:
- at least 2** of the **3** PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe


or

- the skin affected **is** **≥ 30%** of the face, palm of a hand or sole of a foot.

Date of assessment (DD MM YYYY)

The PASI assessment must not be **older than 4 weeks** at the time of application.

Checklist

- 19  The relevant attachments need to be provided with this form.

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

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 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
or
- by post (signature required) to
Services Australia
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

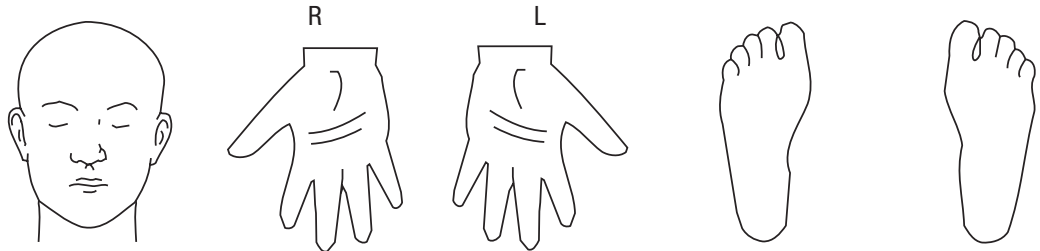
PASI calculation and body diagram – face, hand and foot

medicare



| 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 | 0 = none | 0 = none | 0 = none | 0 = none |
| | 1 = slight | 1 = slight | 1 = slight | 1 = slight | 1 = slight |
| | 2 = moderate | 2 = moderate | 2 = moderate | 2 = moderate | 2 = moderate |
| | 3 = severe | 3 = severe | 3 = severe | 3 = severe | 3 = severe |
| | 4 = very severe | 4 = very severe | 4 = very severe | 4 = very severe | 4 = very severe |
| Thickness | 0 = none | 0 = none | 0 = none | 0 = none | 0 = none |
| | 1 = slight | 1 = slight | 1 = slight | 1 = slight | 1 = slight |
| | 2 = moderate | 2 = moderate | 2 = moderate | 2 = moderate | 2 = moderate |
| | 3 = severe | 3 = severe | 3 = severe | 3 = severe | 3 = severe |
| | 4 = very severe | 4 = very severe | 4 = very severe | 4 = very severe | 4 = very severe |
| Scaling | 0 = none | 0 = none | 0 = none | 0 = none | 0 = none |
| | 1 = slight | 1 = slight | 1 = slight | 1 = slight | 1 = slight |
| | 2 = moderate | 2 = moderate | 2 = moderate | 2 = moderate | 2 = moderate |
| | 3 = severe | 3 = severe | 3 = severe | 3 = severe | 3 = severe |
| | 4 = very severe | 4 = very severe | 4 = very severe | 4 = very severe | 4 = very severe |

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



PASI calculation and body diagram – whole body

medicare



| 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

