Australian Government
Services Australia

medicare

PBS

Severe chronic plaque psoriasis paediatric – ustekinumab – initial, change, recommencement or demonstration of response authority application

When to use this form

Use this form to apply for **initial, change, recommencement or demonstration of response** to PBS-subsidised treatment with ustekinumab for patients under 18 years with severe chronic plaque psoriasis.

Important information

Initial, change, recommencement or demonstration of response 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.

A copy of the PASI calculation sheets is provided for your convenience, but is not required to be submitted for all applications.

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 **initial, change, recommencement or demonstration of response** to treatment.

Treatment specifics

The patient cannot receive more than **28 weeks** of treatment under these restrictions.

For more information

Go to **servicesaustralia.gov.au/healthprofessionals**

Australian Government
Services Australia

medicare

PBS

Severe chronic plaque psoriasis paediatric – ustekinumab – initial, change, recommencement or demonstration of response authority application

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 (DD MM YYYY)

4 Patient's weight

kg

Prescriber's details

5 Prescriber number

6 Dr ☐ Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other

Family name

First given name

7 Business phone number (including area code)

Alternative phone number (including area code)

Conditions and criteria

To qualify for PBS authority approval, the following conditions must be met.

8 Is the patient, under 18 years, being treated by a dermatologist?

No ☐

Yes ☐

9 The patient:

☐ has severe chronic plaque psoriasis

and

☐ will receive treatment with this biological medicine as systemic monotherapy or in combination with methotrexate.

10 The patient:

☐ has not received prior PBS-subsidised treatment with biological medicine for this condition and has had lesions for at least 6 months from the time of initial diagnosis

▶ *Go to 11*

or

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

Date of last biological treatment (DD MM YYYY)

▶ *Go to 13*

or

☐ is demonstrating a response to the current PBS-subsidised treatment before temporarily stopping treatment with this biological medicine

Demonstration of response can be submitted when recommencing treatment.

▶ *Go to 14*

or

☐ is changing or recommencing PBS-subsidised biologicial treatment for this condition **after a break of less than 5 years**

and

☐ has not failed or ceased to respond to this biological medicine more than once during the current treatment cycle

and

☐ has not failed or ceased to respond to PBS-subsidised biological medicine(s) 3 times for this condition in this treatment cycle

Date of last biological treatment (DD MM YYYY)

MCA0PB320 2405

and is changing or recommencing therapy due to:

- ☐ failure of response
- ☐ intolerance to the current biological treatment
- ☐ adequate response

If submitting new baseline ▶ ***Go to 13***
If demonstrating response ▶ ***Go to 14***

11 The patient has failed to achieve an adequate response, as indicated by the Psoriasis Area and Severity Index (PASI) assessment, following a **minimum of 6 weeks** treatment to **at least 2** of the following 3 treatments:

☐ **phototherapy** (UVB or PUVA)

From (DD MM YYYY)
To (DD MM YYYY)
Dose (if applicable) mg
PASI score
Date of assessment (DD MM YYYY)

and/or

☐ **methotrexate**

From (DD MM YYYY)
To (DD MM YYYY)
Dose (if applicable) mg
PASI score
Date of assessment (DD MM YYYY)

and/or

☐ **acitretin**

From (DD MM YYYY)
To (DD MM YYYY)
Dose (if applicable) mg
PASI score
Date of assessment (DD MM YYYY)

A PASI assessment must be completed for each prior treatment course preferably whilst still on treatment, but **no later than 4 weeks** following cessation of treatment. The most recent PASI assessment must not be **older than 4 weeks** at the time of application.

12 Provide details of contraindications or intolerances to any of the prior therapies above including the degree of toxicity and dose.

For details of the toxicity criteria, go to **servicesaustralia.gov.au/healthprofessionals**

Intolerance must be of a severity to necessitate permanent treatment withdrawal.

Phototherapy (UVB or PUVA)

Methotrexate

Acitretin

13 **New baseline**

The patient has:

☐ a current whole body PASI score > 15

PASI score
Date of assessment (DD MM YYYY)

or

☐ chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm or 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 or palm of a hand or sole of a foot

PASI score
Date of assessment (DD MM YYYY)

▶ ***Go to 15***

14 Demonstration of response

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)

PASI score

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).

PASI score

Date of assessment (DD MM YYYY)

Provide a PASI assessment conducted preferably whilst still on treatment, but **no later than 4 weeks** following cessation of treatment.

Checklist

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

☐ Details of the proposed prescription(s).

☐ The PASI calculation sheet (face, hand and foot only).

Privacy notice

16 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**

17 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

Australian Government
Services Australia

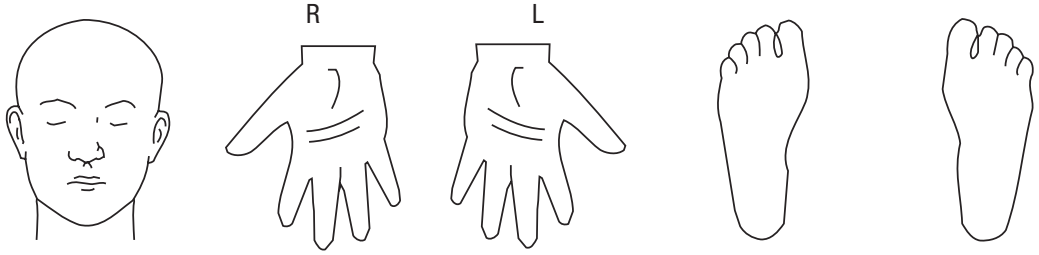
medicare

PBS

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)



Australian Government
Services Australia

medicare

PBS

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 score (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

Reset form