Australian Government
Services Australia

medicare

PBS

Crohn's disease adult – continuing 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 **continuing** PBS-subsidised biological medicines for patients 18 years or over with severe Crohn's disease.

Important information

Continuing 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 Crohn's disease **continuing** authority applications.

Where the term 'biological medicine' appears, it refers to adalimumab, infliximab, upadacitinib, ustekinumab or vedolizumab.

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.

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. and vedolizumab i.v.

These items are 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.

These items are 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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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

5 Patient's height

cm

Prescriber's details

6 Prescriber number

7 Family name

First given name

8 Business phone number (including area code)

Alternative phone number (including area code)

Hospital details

9 Hospital name

This hospital is a:

- ☐ public hospital
- ☐ private hospital

10 Hospital provider number

Conditions and criteria

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

11 The patient is being treated by a:

- ☐ gastroenterologist
- ☐ consultant physician specialising in gastroenterology (either internal medicine or general medicine).

12 This application is for the:

☐ **first continuing** treatment with:

- ☐ adalimumab
- ☐ ustekinumab
- ☐ infliximab i.v. (at a dose of 5mg/kg)

Go to 13

or

☐ **subsequent continuing** treatment with:

- ☐ adalimumab
- ☐ ustekinumab
- ☐ infliximab i.v. (at a dose of 5mg/kg)

Go to 14

or

☐ **continuing** treatment with:

- ☐ upadacitinib 15mg
- ☐ upadacitinib 30mg
- ☐ vedolizumab i.v.
- ☐ vedolizumab s.c.

Go to 13

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

Yes ☐ ***Go to 15***

No ☐

MCA0PB088 2512

14 Has the patient previously received PBS-subsidised treatment with this drug (regardless of formulation) for this condition under the **first continuing** or **continuing** treatment restriction?

Yes ☐
No ☐

15 Has the assessment of response been conducted within the time frame specified in the PBS restriction?

Yes ☐
No ☐

16 Provide date of clinical assessment (DD MM YYYY)

☐☐ ☐☐ ☐☐☐☐

17 The patient has demonstrated an adequate response to treatment with this drug evidenced by:

Only applicable to patients assessed by CDAI or with extensive small intestine disease at baseline

☐ a reduction in Crohn Disease Activity Index (CDAI) score to a level ≤ 150

CDAI score ☐☐☐☐

Date of assessment (no more than 1 month old) (DD MM YYYY)

☐☐ ☐☐ ☐☐☐☐

Only applicable to patients with short gut syndrome, extensive small intestine disease or an ostomy

☐ an improvement of intestinal inflammation as demonstrated by:

- ☐ blood: normalisation of the platelet count
- ☐ blood: erythrocyte sedimentation rate (ESR) ≤ 25 mm/hr
- ☐ blood: C-reactive protein (CRP) level ≤ 15 mg/L
- ☐ faeces: normalisation of lactoferrin or calprotectin level
- ☐ evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment

Provide the following details for **upadacitinib** applications only (For all other biological medicines, attach the required reports)

Unique serial/identifying number of pathology or diagnostic imaging test(s)

Date(s) of pathology or diagnostic imaging test(s)

or

☐ reversal of high faecal output state

☐ avoidance of the need for surgery or total parenteral nutrition (TPN)

For upadacitinib 30mg only

☐ the condition has not met the improvements specified above due to the prescribed dose of 15mg being too low - this authority application seeks higher dosing of 30mg.

The **same criterion** used to establish baseline **must** be used to assess whether an adequate response to treatment has occurred.

Response assessment must be conducted following a **minimum of** or **up to 12 weeks** of treatment depending on the biological medicine requested. This assessment must be submitted **no later than 4 weeks** from the cessation of treatment.

Checklist

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

☐ Details of the proposed prescription(s).

☐ The relevant pathology reports, diagnostic imaging test(s) and/or the completed Adult Crohn's Disease Activity Index calculation sheet.

Privacy notice

19 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**

20 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

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Adult Crohn's Disease Activity Index

Week ending (DD MM YYYY)

Each parameter in this table must be assigned a value.

			Factor	Subtotal
Liquid stools (cumulative total over the last 7 days)	Number of liquid or soft stools over the last 7 days	sum =	x 2	
Abdominal pain † (cumulative total over the last 7 days)	Daily assessment †	sum =	x 5	
General well being ‡ (cumulative total over the last 7 days)	Daily assessment ‡	sum =	x 7	
Extra-intestinal				
Arthritis/arthralgia	None = 0 Yes = 1	score =	x 20	
Iritis/uveitis	None = 0 Yes = 1	score =	x 20	
Skin/mouth lesions	None = 0 Yes = 1	score =	x 20	
Peri-anal disease	None = 0 Yes = 1	score =	x 20	
Other fistula	None = 0 Yes = 1	score =	x 20	
Fever > 37.8ºC	None = 0 Yes = 1	score =	x 20	
Anti-diarrhoeals	None = 0 Yes = 1	score =	x 30	
Abdominal mass	None = 0 Questionable = 2 Definite = 5	score =	x 10	
Haematocrit (Hct)	Males (47 – Hct)	score =	x 6	
	Females (42 – Hct)	score =	x 6	
Weight (Maximum deduction of -10 for overweight patients)	Standard kg Current kg	kg kg	$100 \times \left(1 - \frac{\text{current}}{\text{standard}}\right)$	
			TOTAL CDAI SCORE	

† **Abdominal pain**	None = 0
	Intermediate = 1 or 2
	Severe = 3
‡ **General well being**	Well = 0
	Intermediate = 1, 2 or 3
	Terrible = 4

Reset form