Australian Government
Services Australia

medicare

PBS

Crohn's disease adult – 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 Crohn's disease.

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.

Under no circumstances will phone approvals be granted for severe Crohn's disease **change** or **recommencement** 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 **changing** or **recommencing** treatment or **demonstrating a response** to treatment before temporarily stopping treatment.

After a written authority application for **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., vedolizumab i.v. and ustekinumab 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 an assessment 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**

Australian Government
Services Australia

medicare

PBS

Crohn's disease adult – 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 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 Most recent biological medicine

Dates of the most recent treatment course

From (DD MM YYYY)

To (DD MM YYYY)

MCA0PB235 2506

13 This application is for:

- ☐ adalimumab
- ☐ infliximab i.v.
- ☐ upadacitinib
- ☐ ustekinumab i.v.
- ☐ vedolizumab i.v.
- ☐ vedolizumab s.c. with i.v. loading
  (and an authority prescription for at least 2 i.v. doses at weeks 0 and 2 is attached)

▶ *Go to 15*

or

- ☐ infliximab s.c. with i.v. loading

▶ *Go to 14*

or

- ☐ **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 18*

14 The patient is:

- ☐ **changing** from an alternate PBS-subsidised biological medicine, and an authority prescription for at least 2 i.v. doses of infliximab at weeks 0 and 2 is attached

or

- ☐ **recommencing** PBS-subsidised infliximab after a treatment break, and an authority prescription for 1 i.v. dose of infliximab at week 0 is attached.

15 The patient:

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

  and

  - ☐ will be submitting a new baseline

  or

  - ☐ will be using the previous baseline

▶ *Go to 16*

or

- ☐ is **recommencing** PBS-subsidised biological medicine 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 16*

or

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

  and

  - ☐ has confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician.

  and

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

  and

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

  and

  - ☐ will be submitting a new baseline

▶ *Go to 19*

16 The patient:

☐ has received prior 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 this drug (the biological medicine this application is for) for this condition during the current 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

or

☐ has failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle (if prescribing a newly listed biological medicine).

17 The patient:

☐ has **failed** to demonstrate or sustain a 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.

or

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

If the patient is demonstrating a response	▶ ***Go to 18***
If the patient is providing a new baseline	▶ ***Go to 19***
If the patient is not demonstrating a response and is not providing a new baseline	▶ ***Go to 21***

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

The response assessment should be conducted while still on treatment, but **no later than 4 weeks** following cessation of treatment.

18 The patient has demonstrated an adequate response to treatment evidenced by:

☐ a reduction in the Crohn's Disease Activity Index (CDAI) score ≤ 150 if assessed by CDAI or if affected by extensive small intestine disease

CDAI score

Date of assessment (DD MM YYYY)

or

☐ an improvement of intestinal inflammation as demonstrated by at least **one** of the following:

- ☐ blood: normalisation of platelet count
- ☐ erythrocyte sedimentation rate (ESR) ≤ 25 mm/hr
- ☐ C-reactive protein (CRP) ≤ 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

or

☐ reversal of high faecal output state

Date of assessment (DD MM YYYY)

or

☐ avoidance of the need for surgery or total parenteral nutrition (TPN) if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Date of assessment (DD MM YYYY)

▶ ***Go to 21***

For a patient submitting a new baseline

19 The patient:

☐ has a Crohn's Disease Activity Index (CDAI) score > 300

CDAI score

Date of assessment (no more than 4 weeks old)
(DD MM YYYY)

▶ *Go to 21*

or

☐ has extensive intestinal inflammation affecting > 50 cm of the small intestine as evidenced by documented history and radiological evidence

and

☐ has a CDAI score ≥ 220

CDAI score

Date of assessment (no more than 4 weeks old)
(DD MM YYYY)

and

☐ a copy of the completed CDAI calculation sheet is attached

▶ *Go to 20*

or

☐ has diagnostic imaging or surgical evidence of short gut syndrome or has had an ileostomy or colostomy

and

☐ has documented history of intestinal inflammation.

▶ *Go to 20*

20 The patient has:

☐ been clinically assessed as being in a high faecal output state

Provide the date of the most recent clinical assessment
(DD MM YYYY)

or

☐ been clinically assessed as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option in absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient

Provide the date of the most recent clinical assessment
(DD MM YYYY)

or

☐ evidence of intestinal inflammation demonstrated by at least **one** of the following:

- ☐ higher than normal platelet count
- ☐ an elevated erythrocyte sedimentation rate (ESR) > 25 mm/hr
- ☐ a C-reactive protein (CRP) > 15 mg/L
- ☐ a higher than normal lactoferrin or calprotectin level in faeces
- ☐ diagnostic imaging of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Provide pathology reports or diagnostic imaging.

Checklist

21 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

22 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**

23 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 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

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	kg	$100 \times \left(1 - \frac{\text{current}}{\text{standard}}\right)$	
	Current kg	kg		
			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