Australian Government
Services Australia

medicare

PBS

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

Important information

Initial applications to start PBS-subsidised treatment 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.

Under no circumstances will phone approvals be granted for severe Crohn's disease **initial** authority applications.

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, 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 **initial** 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., 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 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, 18 years or over, is being treated by a:

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

12 This application is for:

- ☐ adalimumab (maximum 16 weeks of treatment)
- ☐ infliximab i.v. (at a dose of 5 mg/kg) (maximum 3 doses at weeks 0, 2 and 6)
- ☐ upadacitinib
- ☐ ustekinumab (maximum 2 doses - 1 IV loading at week 0 and 1 SC dose at week 8)
- ☐ vedolizumab i.v. (maximum 3 doses at weeks 0, 2 and 6)

▶ *Go to 15*

or

- ☐ infliximab s.c. with i.v. loading (at a dose of 5 mg/kg) ▶ *Go to 13*

or

- ☐ vedolizumab s.c. ▶ *Go to 14*

13 Does the patient have a concurrent PBS authority application for the IV form of infliximab that is approved or to be approved?

Yes ☐ ▶ *Go to 15*

No ☐

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14 The patient has:

☐ received at least 2 of the 3 initial IV infusions with vedolizumab for this condition at weeks 0, 2 and 6

▶ ***Go to 22***

or

☐ a concurrent authority application for at least 2 of the 3 initial IV infusions with vedolizumab for this condition at weeks 0, 2 and 6

▶ ***Go to 15***

15 The patient 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.

Date of the most recent clinical assessment (DD MM YYYY)

16 The patient has failed to achieve an adequate response to prior systemic therapy with **a tapered course of steroids**, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period

Name of steroid

Starting dose mg

From (DD MM YYYY)

To (DD MM YYYY)

and prior systemic immunosuppressive therapy with

☐ **azathioprine** at a dose of at least 2 mg/kg daily for 3 or more consecutive months

Dose mg

From (DD MM YYYY)

To (DD MM YYYY)

or

☐ **6-mercaptopurine** at a dose of at least 1 mg/kg daily for 3 or more consecutive months

Dose mg

From (DD MM YYYY)

To (DD MM YYYY)

or

☐ **methotrexate** at a dose of at least 15 mg weekly for 3 or more consecutive months

Dose mg

From (DD MM YYYY)

To (DD MM YYYY)

Only one immunosuppressive therapy is required but multiple can be selected. **Only** enter the trials that meet **eligibility** requirements.

17 Contraindication or intolerance

Provide details below where either:

- treatment with any of the drugs is contraindicated according to the relevant TGA–approved Product Information.
- intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal.

Prednisolone

Azathioprine

6-mercaptopurine

Methotrexate

18 Does the patient have contraindications to all of the 4 prior systemic therapies (**a tapered course of steroids, azathioprine, 6-mercaptopurine**, and **methotrexate**) according to the relevant TGA-approved Product Information?

Yes ☐ ▶ ***Go to 20***

No ☐ ▶ ***Go to 19***

19 Provide end date of prior systemic drug therapy (this includes drugs that could not be tolerated)

If the treatment is ongoing, use today's date (DD MM YYYY)

20 The patient has:

☐ a Crohn Disease Activity Index (CDAI) score ≥ 300 as evidence of failure to achieve an adequate response to prior systemic therapy

Baseline CDAI score

Date of assessment (DD MM YYYY)

▶ ***Go to 22***

or

☐ extensive intestinal inflammation affecting > 50 cm of the small intestine as evidenced by radiological imaging

and

☐ a CDAI score ≥ 220

Baseline CDAI score

Date of assessment (DD MM YYYY)

and

☐ evidence of failure to achieve an adequate response to prior systemic therapy ▶ ***Go to 21***

or

☐ short gut syndrome with diagnostic imaging or surgical evidence, or has had an ilestomy or colostomy

and

☐ evidence of intestinal inflammation and failure to achieve an adequate response to prior systemic therapy. ▶ ***Go to 21***

21 The patient has:

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

or

- ☐ been assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug

or

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

All assessments, pathology tests and diagnostic imaging studies must be completed **within 4 weeks** of the date of application, and should be performed preferably whilst still on conventional treatment, but no longer than 4 weeks following cessation of the most recent prior treatment, unless all prior treatments are contraindicated.

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

Checklist

22 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

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)

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

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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	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