

Crohn's disease adult – initial authority application

When to use this form

Use this form to apply for **initial** PBS-subsidised biological agents for patients aged 18 years or older with severe Crohn's disease.

Important information

Initial applications to start PBS-subsidised treatment must be 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.

Call charges may apply.

Where the term 'biological agent' appears, it refers to adalimumab, infliximab, 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 a written authority application for the **first continuing** treatment has been approved, **subsequent continuing** treatment with PBS-subsidised biosimilar brands of biological agents 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 (loading doses) only

These items are available to a patient who is attending:

- an approved private hospital
- a public participating hospital, **or**
- a public hospital

and is:

- a day admitted patient
- a non-admitted patient, **or**
- a patient on discharge.

These items are not available as a PBS benefit for in-patients of a 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 agent.

A patient who has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered to have failed treatment with that particular PBS-subsidised biological agent.

For more information

Go to servicesaustralia.gov.au/healthprofessionals

13 The patient:

has not received any prior PBS-subsidised biological agent treatment for this condition, and an authority prescription for at least 2 i.v. doses of vedolizumab at weeks 0 and 2 is attached.

▶ **Go to 14**

or

has received PBS subsidy for at least 2 i.v. doses of vedolizumab for this condition at weeks 0 and 2, and has received no other prior PBS-subsidised biological agent for this condition.

▶ **Go to 19**

14 The patient:

has confirmed severe Crohn's 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)

15 The patient:

has a Crohn's Disease Activity Index (CDAI) Score ≥ 300 (no more than 4 weeks old) as evidence of failure to achieve an adequate response to prior systemic therapy

CDAI Score

Date of assessment (DD MM YYYY)

▶ **Go to 17**

or

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

and

has evidence of failure to achieve an adequate response to prior systemic therapy

and

has a CDAI score ≥ 220 , no more than 4 weeks old

CDAI Score

Date of assessment (DD MM YYYY)

▶ **Go to 16**

or

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

and

has evidence of intestinal inflammation and failure to achieve an adequate response to prior systemic therapy.

▶ **Go to 16**

16 The patient has failed to achieve an adequate response to prior therapy as demonstrated by:

clinical assessment of the patient being in a high faecal output state

or

clinical assessment that the patient is 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

or

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

blood: higher than normal platelet count

blood: an elevated erythrocyte sedimentation rate (ESR) > 25 mm/hour

blood: a C-reactive protein (CRP) level > 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.

17 The patient has failed to achieve an adequate response to prior systemic immunosuppressive 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 drug

Starting dose mg

From (DD MM YYYY)

To (DD MM YYYY)

and

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)

18 Contraindication or intolerance necessitating permanent treatment withdrawal

Give details below where either:

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

Include the degree of toxicity. For details of the accepted toxicities, including severity, go to servicesaustralia.gov.au/healthprofessionals

Contraindication or toxicity and grade


Prednisolone	Grade
<input type="text"/>	<input type="text"/>

Azathioprine	Grade
<input type="text"/>	<input type="text"/>

6-mercaptopurine	Grade
<input type="text"/>	<input type="text"/>

Methotrexate	Grade
<input type="text"/>	<input type="text"/>

Checklist

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

- The completed authority prescription form(s).
- If applicable, the relevant pathology reports, diagnostic imaging test(s) and/or the completed current CDAI calculation sheet.

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/privacy

Prescriber's declaration

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 the completed authority prescription form(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.

Prescriber's signature



Date (DD MM YYYY)

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Returning this form

Return this form and any supporting documents:

- **online**, upload this form, the authority prescription form(s) and any relevant attachments through Health Professional Online Services (HPOS) at servicesaustralia.gov.au/hpos **or**
- by post, send this form, the authority prescription form(s) and any relevant attachments to:

Services Australia
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

medicare



1 Week ending (DD MM YYYY)

Patient's full name

Gender Male Female

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	
	<input type="text"/>			
Abdominal pain † (cumulative total over the last 7 days)	Daily assessment †	sum =	x 5	
	<input type="text"/>			
General well being ‡ (cumulative total over the last 7 days)	Daily assessment ‡	sum =	x 7	
	<input type="text"/>			
Extra-intestinal				
Arthritis/arthralgia	None = 0	score =	x 20	
	Yes = 1			
Iritis/uveitis	None = 0	score =	x 20	
	Yes = 1			
Skin/mouth lesions	None = 0	score =	x 20	
	Yes = 1			
Peri-anal disease	None = 0	score =	x 20	
	Yes = 1			
Other fistula	None = 0	score =	x 20	
	Yes = 1			
Fever > 37.8°C	None = 0	score =	x 20	
	Yes = 1			
Anti-diarrhoeals	None = 0	score =	x 30	
	Yes = 1			
Abdominal mass	None = 0	score =	x 10	
	Questionable = 2			
	Definite = 5			
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 x $\left(1 - \frac{\text{current}}{\text{standard}}\right)$	
	Current kg	kg		
TOTAL CDAI SCORE				<input type="text"/>

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

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Prescriber's declaration

- 3 I declare that the information I have provided in this form is complete and correct.
I understand that giving false or misleading information is a serious offence.

Prescriber's full name (Print in BLOCK LETTERS)

Prescriber's signature



Date (DD MM YYYY)