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.

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

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)

0 3 9 2 3 1 3 5 9 2

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 ☐

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)

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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 0 0 0 0 0 0 0	sum = 0	x 2	0
Abdominal pain † (cumulative total over the last 7 days)	Daily assessment † 0 0 0 0 0 0 0	sum = 0	x 5	0
General well being ‡ (cumulative total over the last 7 days)	Daily assessment ‡ 0 0 0 0 0 0 0	sum = 0	x 7	0
Extra-intestinal				
Arthritis/arthralgia	None = 0 / Yes = 1	score = 0	x 20	0
Iritis/uveitis	None = 0 / Yes = 1	score = 0	x 20	0
Skin/mouth lesions	None = 0 / Yes = 1	score = 0	x 20	0
Peri-anal disease	None = 0 / Yes = 1	score = 0	x 20	0
Other fistula	None = 0 / Yes = 1	score = 0	x 20	0
Fever > 37.8ºC	None = 0 / Yes = 1	score = 0	x 20	0
Anti-diarrhoeals	None = 0 / Yes = 1	score = 0	x 30	0
Abdominal mass	None = 0 / Questionable = 2 / Definite = 5	score = 0	x 10	0
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 Current kg ___ kg	$100 \times \left(1 - \dfrac{current}{standard} \right)$		

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