

13 Has the patient previously received this biological medicine (in any form) as their most recent course of PBS-subsidised treatment for this condition?

No ☐

Yes ☐ Dates of the most recent treatment course

From (DD MM YYYY)

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To (DD MM YYYY)

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14 The patient has demonstrated or sustained an adequate response to treatment with this drug, defined as:

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

CDAI score

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

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or

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

- ☐ blood: normalisation of the platelet count
- ☐ blood: erythrocyte sedimentation rate (ESR) ≤ 25 mm/hour
- ☐ blood: 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

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

or

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

Checklist

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

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

Privacy notice

16 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

17 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.
- ☐ I have read, understood and agree to the above.

Date (DD MM YYYY) (you **must** date this declaration)

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Prescriber's signature (**only** required if returning by post)


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Returning this form

Return this form, the authority prescription form(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

Adult Crohn's Disease Activity Index

Week ending (DD MM YYYY)

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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 0	sum = 0 x 2	0
Abdominal pain † (cumulative total over the last 7 days)	Daily assessment † 0 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 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 > 37.8°C	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) Females (42 – Hct)	score = score =	x 6 x 6
Weight (Maximum deduction of -10 for overweight patients)	Standard kg Current kg	kg kg	100 x $\left(1 - \frac{\text{current}}{\text{standard}}\right)$
TOTAL CDAI SCORE			

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