Australian Government
Department of Human Services

medicare

PBS

Crohn disease
Continuing PBS authority application
Supporting information

Purpose of this form

This form is to be completed by a gastroenterologist (code 87), a consultant physician in internal medicine specialising in gastroenterology (code 81) or a consultant physician in general medicine specialising in gastroenterology (code 82).

You must lodge this form for an adult patient (over 18 years of age) who is either:

- **continuing** Pharmaceutical Benefits Scheme (PBS) subsidised treatment

  or
- **changing** to an alternate PBS subsidised treatment for which the patient is eligible

  or
- **demonstrating** a response to the current PBS subsidised treatment for all patients not continuing treatment at this time.

Where the term biological Disease Modifying Drugs (bDMDs) appears it refers to adalimumab, infliximab and vedolizumab. Patients are eligible for PBS subsidised treatment with only 1 bDMD at any time.

Applications for patients who wish to change to an alternate bDMD should be accompanied by the previously approved authority prescription or the remaining repeats for the bDMD the patient is stopping.

Where applicable, any 1 of the baseline criteria supplied with the initial application may be used to determine response to a course of treatment and eligibility for continued therapy, according to the criteria for the continuing treatment restriction.

Patients who are approved for PBS subsidised treatment based on a Crohn Disease Activity Index (CDAI) score must demonstrate a response to treatment with a CDAI score of 150, or less, within 1 month of stopping treatment.

All applications must be in writing and must include sufficient information to determine the patient's eligibility according to the PBS criteria.

A demonstration of response before stopping treatment temporarily may be submitted using this form and faxed to **1300 154 019**.

The information on this form is correct at the time of publishing and is subject to change.

Section 100 arrangements—for infliximab and vedolizumab

These items are only available to a patient who is attending either:

- an approved private hospital
- a public participating hospital

or

- a public hospital

and is either

- a day admitted patient
- a non-admitted patient

or

- a patient on discharge.

These are not PBS benefits for in-patients of the hospital. The hospital provider number must be included on the application form.

Authority prescription form

Continuing treatment

For all continuing applications, a completed authority prescription form must be attached to this form.

Adalimumab: The authority prescription must be written for a quantity of 2 doses and 5 repeats. The form of adalimumab required must be stipulated as either pre filled syringe or pre filled pen.

Infliximab: The authority prescription must be written for a quantity of vials sufficient to dose the patient at 5 mg/kg and 2 repeats.

Vedolizumab: A completed authority prescription form must be written for a quantity of 1 vial and 2 repeats.

Change treatment

For change to adalimumab: 2 completed authority prescriptions must be attached to this form. The first prescription must be written for the induction pack quantity of 6 doses and no repeats. The second prescription must be written for a quantity of 2 doses and 2 repeats. The form of adalimumab required must be stipulated as either pre filled syringe or pre filled pen.

For change to infliximab: 1 completed authority prescription form must be attached to this form and must be written for a quantity of vials sufficient to dose the patient at 5 mg/kg and 2 repeats.

For change to vedolizumab: 1 completed authority prescription form must be written for a quantity of 1 vial and 2 repeats.

The medical indication section of the authority prescription form does not need to be completed when submitted with this form.

Phone approvals

Under no circumstance will phone approvals be granted for **initial** authority applications or for treatment that would otherwise extend the treatment period.

Applications for continuing treatment

The assessment of the patient's response to a change in the course of treatment must be made after a minimum of 12 weeks of initial treatment with adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab so there is adequate time for a response to be demonstrated.

Assessment following a continuous treatment course should be made after 20 weeks of treatment. Patients may qualify to receive up to 24 weeks of continuing treatment with bDMDs provided they have demonstrated an adequate response to treatment.

For more information

For more information, go to our website **humanservices.gov.au/healthprofessionals** or call **1800 700 270** Monday to Friday, between 8.00 am and 5.00 pm, Australian Eastern Standard Time.

Note: Call charges apply from mobile phones.

Filling in this form

- **Please use black or blue pen**
- Print in BLOCK LETTERS
- Mark boxes like this ☐ with a ✓ or ✗
- Where you see a box like this ☐ ▶ ***Go to 5*** skip to the question number shown. You do not need to answer the questions in between.

Returning your form

Check that you have answered all the questions you need to answer and that you have signed and dated this form.

Send the completed form(s) to:

Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

Australian Government
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Patient's details

1 Medicare card number

[ ][ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ] Ref no. [ ]

or

Department of Veterans' Affairs card number

[ ]

2 Dr ☐ Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other [ ]

Family name

[ ]

First given name

[ ]

3 Date of birth

[/ /]

Prescriber's details

4 Prescriber number

[ ][ ][ ][ ][ ][ ][ ]

5 Dr ☐ Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other [ ]

Family name

[ ]

First given name

[ ]

6 Business phone number

[( )]

Alternative phone number

[ ]

Fax number

[( )]

bDMD details

7 This application is for:

☐ **continuing** treatment with the current PBS subsidised bDMD

or

☐ **changing** treatment to an alternate PBS subsidised bDMD for which the patient is eligible

or

☐ **demonstrating** a response to the current PBS subsidised bDMD before temporarily stopping treatment.

8 Which bDMD is this application for?

☐ adalimumab

☐ infliximab

☐ vedolizumab

☐ the patient will be assessed for the risk of developing progressive multifocal leukoencephalopathy while undergoing vedolizumab treatment.

Patient's and hospital's details

9 Patient's weight

[kg]

10 Patient's height

[cm]

For infliximab and vedolizumab only

11 Hospital's name

[ ]

12 Hospital's provider number

[ ][ ][ ][ ][ ][ ][ ]

Current assessment of patient

13 The patient has:

☐ demonstrated a response to current treatment

▶ ***Go to 14***

or

☐ failed to demonstrate a response to current treatment

and

☐ I wish to use a previous baseline set

▶ ***Go to Attachments***

or

☐ this assessment is to be considered as the new baseline.

▶ ***Go to 15***

14 The patient has demonstrated a response to treatment by 1 of the following options (which must have been provided at baseline):

either

☐ a current CDAI score which is 150 or less

▶ ***Go to Attachments***

or

☐ a) the patient has improvement of intestinal inflammation as documented by:

i) Blood

☐ normalisation of platelet count

and/or

☐ an Erythrocyte Sedimentation Rate (ESR) no greater than 25 mm per hour

and/or

☐ a C-Reactive Protein (CRP) no greater than 15 mg per L

and/or

ii) Faeces

☐ a normalisation of lactoferrin level

and/or

☐ a normalisation of calprotectin level

and/or

iii) Diagnostic imaging

☐ evidence of mucosal healing as demonstrated by diagnostic imaging findings

and/or

☐ b) reversal of high faecal output state

Date of assessment

/ /

and/or

☐ c) has been assessed clinically as no longer requiring surgery or Total Parenteral Nutrition (TPN).

Date of assessment

/ /

Go to Attachments

15 The patient has failed to respond to treatment and the following assessment is to be considered the new baseline.

The patient has:

☐ a CDAI assessment which is 300 or more

Go to Attachments

or

☐ extensive small intestine disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine

Go to 16

or

☐ diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy and has evidence of intestinal inflammation.

Go to 17

16 The patient has:

☐ a CDAI assessment which is 220 or more

and

17 ☐ a) evidence of active intestinal inflammation including:

i) Blood

☐ higher than normal platelet count

and/or

☐ an elevated Erythrocyte Sedimentation Rate (ESR) greater than 25 mm per hour

and/or

☐ a C-Reactive Protein (CRP) greater than 15 mg per L

and/or

ii) Faeces

☐ (i) a higher than normal lactoferrin level

and/or

☐ (ii) a higher than normal calprotectin level

and/or

iii) Diagnostic imaging

☐ demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery

and/or

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

Date of assessment

/ /

and/or

☐ c) been assessed clinically as requiring surgery or Total Parenteral Nutrition (TPN) as the next therapeutic option, in the absence of bDMDs treatment.

Date of assessment

/ /

Attachments

Attach all relevant CDAI, pathology and diagnostic imaging reports and a completed authority prescription form(s).

Privacy notice

18 Your personal information is protected by law, including the *Privacy Act 1988*, and is collected by the Australian Government Department of Human Services for the assessment and administration of payments and services. This information is required to process your application or claim.

Your information may be used by the department or given to other parties for the purposes of research, investigation or where you have agreed or it is required or authorised by law.

You can get more information about the way in which the Department of Human Services will manage your personal information, including our privacy policy, at **humanservices.gov.au/privacy** or by requesting a copy from the department.

Prescriber's declaration

19 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 signature

Date

/ /

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Adult Crohn disease Activity Index

1 Week ending / / Patient's full name

Sex ☐ 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	
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

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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 full name in BLOCK LETTERS

Prescriber's signature

Date / /

Reset form Print form