Australian Government
Department of Human Services

medicare

PBS

Crohn disease
Initial 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) starting **initial** PBS subsidised treatment with biological Disease Modifying Drugs (bDMDs).

Where the term bDMDs appears it refers to the Tumour Necrosis Factor (TNF) alfa-antagonists (adalimumab and infliximab) and the alpha-4 beta-7 integrin inhibitor (vedolizumab). Patients are eligible for Pharmaceutical Benefits Scheme (PBS) subsidised treatment with only 1 bDMD at any time.

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

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month after stopping the most recent prior treatment.

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.

The lodgement of this application must be made within 1 month of the date of all assessments, pathology tests and diagnostic imaging studies.

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.

Acknowledgements

The patient's and the prescriber's acknowledgements must be completed and signed before submitting the form.

Authority prescription form

Adalimumab: 2 completed authority prescriptions must be attached to this form. The first authority prescription must be written for the induction pack quantity of 6 doses and no repeats. The second authority 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.

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.

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 an initial course of treatment must be made following a minimum of 12 weeks of therapy for 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.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Australian Government Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within this time frame, the patient will be deemed to have failed to respond to treatment.

For continuing treatment for Crohn disease, complete the ***Crohn disease Continuing PBS authority application Supporting information*** form (**PB088**).

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.

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
Department of Human Services

medicare

PBS

Crohn disease
Initial PBS authority application

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.

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

/ /

Patient's acknowledgement

4 **I acknowledge that** PBS subsidised treatment with bDMDs for Crohn disease will stop if:

- subsequent testing demonstrates that I have failed to achieve or sustain a response to treatment as detailed in the criteria.
- I have failed 3 bDMD treatment courses for which I was eligible.

My prescriber has explained the nature of the ongoing monitoring and testing required in order to demonstrate an adequate response to therapy.

Patient's signature

✍

Date

/ /

Prescriber's details

5 Prescriber number

6 Dr ☐ Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other ☐

Family name

First given name

7 Business phone number

( )

Alternative phone number

Fax number

( )

Prescriber's acknowledgement

8 **I have explained:**

- the circumstances governing PBS subsidised treatment with bDMDs for Crohn disease.
- the nature of the ongoing monitoring and testing required to demonstrate an adequate and sustained response to therapy.

I believe these to be understood and accepted by the patient.

Prescriber's signature

✍

Date

/ /

bDMD details

9 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. If the patient commenced non PBS subsidised vedolizumab **prior to 1 August 2015**, provide dates of treatment with vedolizumab

From / /

To / /

Patient's and hospital's details

10 Patient's weight

kg

11 Patient's height

cm

For infliximab and vedolizumab only

12 Hospital's name

13 Hospital's provider number

Conditions and prior treatment

14 To qualify for PBS authority approval, under this criterion, the following conditions must be met.

The patient has:

☐ confirmed Crohn disease defined by standard clinical, endoscopic and/or imaging features, including histological evidence with the diagnosis confirmed by a gastroenterologist

and

☐ signed the patient's acknowledgement

and

☐ failed to achieve an adequate response to prior systemic therapy including:

☐ 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 / /

To / /

and either

☐ azathioprine at a dose of at least 2 mg/kg per day for 3 or more months

Dose mg

From / /

To / /

or

☐ 6-mercaptopurine at a dose of at least 1 mg/kg per day for 3 or more months

Dose mg

From / /

To / /

or

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

Dose mg

From / /

To / /

Give details of contraindications or intolerance including the degree of toxicity.

Details of the toxicity criteria are available at **humanservices.gov.au/healthprofessionals** Intolerance must be of a severity to necessitate permanent treatment withdrawal.

Contraindication or toxicity and grade

Prednisolone
Azathioprine
6–mercaptopurine
Methotrexate

Criteria

15 The following initiation criteria indicate failure to achieve an adequate response to prior treatment. All assessments, pathology tests and diagnostic imaging studies must be made preferably whilst still on treatment, but no longer than 1 month after stopping the most recent prior treatment.

Choose ONE of the following criteria.

The patient has either:

☐ a Crohn's Disease Activity Index (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***

or

☐ commenced non PBS subsidised vedolizumab prior to 1 August 2015

▶ ***Go to 18***

The patient has:

16 ☐ 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

☐ a higher than normal lactoferrin level

and/or

☐ 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

/ /

▶ ***Go to Attachments***

18 The patient had:

☐ a CDAI score of greater than or equal to 300 prior to commencing treatment with vedolizumab

or

☐ a documented history of intestinal inflammation and has diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy

or

☐ a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestine disease affecting more than 50cm of the small intestine

To demonstrate an adequate response to prior non PBS subsidised treatment, you must also complete the ***Crohn disease Continuing PBS authority application Supporting information*** form (**PB088**).

Attachments

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

Privacy notice

19 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

20 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