Australian Government
Department of Human Services

medicare

PBS

Ulcerative colitis (moderate to severe) PBS subsidised authority application

Supporting information

Purpose of this form

You must lodge this form for a patient starting Pharmaceutical Benefits Scheme (PBS) subsidised treatment with either infliximab or vedolizumab (adult patients only) for moderate to severe ulcerative colitis. Adult patients (18 years of age and over) are eligible for PBS subsidised treatment with either infliximab or vedolizumab at any one time. Paediatric patients are only eligible for infliximab.

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

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

Important information

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

The current Mayo clinic or partial Mayo clinic or PUCAI assessment must be **no more than 1 month old** at the time of application.

Patients who commenced non PBS subsidised treatment with either infliximab before 1 December 2014 or vedolizumab before 1 August 2015 must supply a baseline assessment immediately before commencing treatment with either infliximab or vedolizumab. A current partial Mayo clinic score or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet, including the date of assessment of the patient's condition, is also required to be submitted with this application. Where a baseline assessment is not available, call the Australian Government Department of Human Services on **1800 700 270** to discuss, Monday to Friday, between 8.00 am and 5.00 pm, Australian Eastern Standard Time.

Note: Call charges apply from mobile phones.

Acknowledgments

The patient's or parent's or authorised guardian's for patients aged 6 to 17 years and the prescriber's acknowledgements must be completed and signed before submitting the form.

Section 100 arrangements

These items are available to a patient who is attending:

- 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 items are not available as PBS benefits for in-patients of a hospital. The hospital provider number must be included in the application form.

Authority prescription form

A completed authority prescription form must be attached to this form.

Infliximab: A 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: A 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.

Applications for continuing treatment

Phone authorities will be granted for continuing treatment **only**.

Applications to **change** treatment (adult patients only) or to **recommence** treatment must be competed on this application form.

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 authority application form, completed authority prescription form and all relevant attachments to:

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

Australian Government
Department of Human Services

medicare

PBS

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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

[/ /]

4 Patient's weight

[ ] kg

Patient's acknowledgement (or patient's/guardian's if patient 6 to 17 years of age)

5 **I acknowledge that:**

- the prescriber has explained the nature of the ongoing monitoring and testing required to demonstrate an adequate response to therapy, **and**
- the PBS subsidised treatment will cease if the predetermined response criterion for ongoing PBS subsidised treatment, as outlined in the restriction for continuing treatment and as explained by my prescriber, is unable to be demonstrated or sustained, **and**
- my prescriber has explained the circumstances surrounding PBS subsidised treatment with infliximab or vedolizumab for the treatment of ulcerative colitis.

Patient's name (or patient's/guardian's if patient 6 to 17 years of age)

[ ]

Patient's signature (or patient's/guardian's if patient 6 to 17 years of age)

[✍]

Date

[/ /]

Prescriber's details

6 Prescriber number

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

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

Family name

[ ]

First given name

[ ]

8 Business phone number

[( )]

Alternative phone number

[ ]

Fax number

[( )]

9 Specialist type

Tick the option applicable

☐ a gastroenterologist (code 87)

or

☐ a consultant physician [internal medicine specialising in gastroenterology (code 81)]

or

☐ a consultant physician [general medicine specialising in gastroenterology (code 82)]

or

☐ a paediatrician

or

☐ a specialist paediatric gastroenterologist

Prescriber's acknowledgement

10 **I acknowledge that I have explained to the patient or parent/guardian:**

- the circumstances surrounding PBS subsidised treatment with infliximab or vedolizumab for the treatment of ulcerative colitis.

Prescriber's signature

[✍]

Date

[/ /]

Hospital details

11 Hospital name

12 Hospital provider number

Biological agent details

13 Has the patient received non PBS subsidised treatment with either infliximab before 1 December 2014, or vedolizumab for this condition before 1 August 2015?

No ☐ ***Go to 14***

Yes ☐ ***Go to 18***

14 This application is for treatment of a patient with moderate to severe ulcerative colitis:

a) Initial treatment with:

☐ infliximab ***Go to 15***

or

☐ vedolizumab (adult patients only)

and

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

Go to 15

or

b) Change in treatment to (adult patients only):

☐ infliximab

Go to Attachments

or

☐ vedolizumab (adult patients only)

and

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

Go to Attachments

or

c) Recommencement of treatment with:

☐ infliximab (all patients)

and

☐ provide results demonstrating the patient's response to the most recent treatment course with this drug from within 1 month of treatment cessation

Go to Attachments

or

☐ vedolizumab (adult patients only)

and

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

and

☐ provide results demonstrating the patient's response to the most recent treatment course with this drug from within 1 month of treatment cessation

Go to Attachments

Conditions and criteria

15 The patient has failed to achieve an adequate response to:

☐ a 5-aminosalicylate (5-ASA) oral preparation in a standard dose for induction of remission for 3 or more months

Name of drug used

Dose

mg

Dates of treatment

From / / to / /

and

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

Give details below

Dose

mg

Dates of treatment

From / / to / /

or

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

Give details below

Dose

mg

Dates of treatment

From / / to / /

or

☐ a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period

Give details below

Name of drug used

Starting dose

mg

Dates of treatment

From / / to / /

Contraindication or toxicity and grade to prior therapy

16 Give details below where:

- treatment with any of the drugs is contraindicated according to the relevant Therapeutic Goods Administration, approved Product Information, **or**
- intolerance to treatment with any of the drugs develops which is of a severity necessitating permanent treatment withdrawal.

Include the degree of toxicity. Details of the accepted toxicities, including severity, can be found on our website at **humanservices.gov.au/healthprofessionals**

Give details below of intolerance including the degree of toxicity to any of the following:

5-ASA	Grade

Azathioprine	Grade

6-Mercaptopurine	Grade

Steroids	Grade

17 The patient:

Tick the option applicable

☐ is an adult and has a Mayo clinic score ≥ 6

or

☐ is an adult and has a partial Mayo clinic score ≥ 6 and their rectal bleeding and stool frequency subscores are both ≥ 2 (endoscopy subscore is not required for a partial Mayo clinic score)

or

☐ is aged 6 to 17 years and has a Paediatric Ulcerative Colitis Activity Index (PUCAI) score ≥ 30

Go to Attachments

Grandfather patient's condition and criteria

18 Give dates of prior treatment for this condition

From / / to / /

with either

☐ infliximab

or

☐ vedolizumab

and

before commencing non PBS subsidised treatment, the patient:

a) ☐ was an adult and had either a:

(i) ☐ Mayo clinic score ≥ 6

or

(ii) ☐ partial Mayo clinic score ≥ 6, provided the rectal bleeding and stool frequency subscores were both ≥ 2 (endoscopy score is not required for a partial Mayo score)

or

b) ☐ was a child aged 6 to 17 years and had a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of ≥ 30

or

c) ☐ had a documented history of moderate to severe refractory ulcerative colitis, where a Mayo, partial Mayo or PUCAI baseline assessment is not available

and

☐ the patient has demonstrated or sustained an adequate response to treatment.

Attachments

Attach all relevant Mayo or PUCAI assessments. Grandfather patients should supply a baseline assessment and must supply a current assessment.

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.
- patients may qualify for PBS subsidised treatment under this restriction once only.

Prescriber's signature

Date / /

Reset form Print form