Australian Government
Services Australia

medicare

PBS

Chronic pouchitis – vedolizumab – initial or recommencement authority application

When to use this form

Use this form to apply for **initial** or **recommencing** PBS-subsidised vedolizumab for patients with moderate to severe chronic pouchitis.

Important information

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

Applications for **balance of supply** can be made in real time using the **Online PBS Authorities** system or by phone. Call 1800 700 270 Monday to Friday, 8 am to 5 pm, local time.

Under no circumstances will phone approvals be granted for moderate to severe chronic pouchitis **initial** or **recommencement** authority applications.

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

Continuing treatment

This form is ONLY for **initial** or **recommencing** treatment.

After a written authority application for **initial** or **recommencing** treatment has been approved, applications for continuing treatment can be made in real time using the **Online PBS Authorities** system or by phone. Call 1800 700 270 Monday to Friday, 8 am to 5 pm, local time.

Section 100 arrangements for vedolizumab i.v.

This item is available to a patient who is attending:

- an approved private hospital, **or**
- a public hospital

and is a:

- day admitted patient
- non-admitted patient, **or**
- patient on discharge.

This item is not available as a PBS benefit for in-patients of a public hospital.

The hospital name and provider number must be included in this authority form.

Treatment specifics

Applications for initial PBS-subsidised treatment of this condition must be received within 4 weeks of the endoscopy to confirm diagnosis. The prescriber must exclude secondary causes of pouchitis, for example:

- Ischaemia
- Crohn's disease (CD) or CD of the pouch
- Irritable pouch syndrome
- Predominant cuffitis
- Pouch stricture or pouch fistula
- Active infection
- NSAIDs
- Coeliac disease

Patients must not receive more than 14 weeks of treatment under this restriction.

For more information

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

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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 (DD MM YYYY)

Prescriber's details

4 Prescriber number

5 Dr ☐ Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other

Family name

First given name

6 Business phone number (including area code)

Alternative phone number (including area code)

Hospital details

7 Hospital name

This hospital is a:

☐ public hospital

☐ private hospital

8 Hospital provider number

Conditions and criteria

To qualify for PBS authority approval, the following conditions must be met.

9 The patient is being treated by a:

☐ gastroenterologist

☐ consultant physician specialising in gastroenterology (either general medicine or internal medicine)

10 Will the treatment be initiated in combination with standard of care antibiotic?

Yes ☐

No ☐

11 Has the patient previously received PBS-subsidised treatment with this drug for this condition?

Yes ☐ ***Go to 12***

No ☐ ***Go to 13***

12 The patient:

☐ is recommencing PBS-subsidised treatment with this drug for this condition after a break

Dates of the most recent treatment course

From (DD MM YYYY)

To (DD MM YYYY)

and

☐ has not already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition

Go to 17

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13 Has the patient undergone ileal pouch anal anastomosis (IPAA) due to ulcerative colitis (UC) at least one year previously?

Yes ☐
No ☐

14 Does the patient have moderate to severe chronic pouchitis confirmed based on the patient's symptoms, treatment history and baseline endoscopic examination of the pouch (pouchoscopy), and with secondary causes of pouchitis excluded?

Yes ☐
No ☐

15 The patient has:

☐ a Modified Pouchitis Disease Activity Index (mPDAI) score ≥ 5

Baseline mPDAI score

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

and

☐ a minimum endoscopic mPDAI sub-score ≥ 2

Baseline endoscopic mPDAI sub-score

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

16 The patient has had:

☐ at least 3 recurrent episodes of pouchitis within the previous year each of which was treated with at least 2 weeks of antibiotic or other prescription therapy

Therapy for episode 1
Dosage mg/day
From (DD MM YYYY)
To (DD MM YYYY)

Therapy for episode 2
Dosage mg/day
From (DD MM YYYY)
To (DD MM YYYY)

Therapy for episode 3
Dosage mg/day
From (DD MM YYYY)
To (DD MM YYYY)

or

☐ maintenance antibiotic therapy taken continuously for at least 4 weeks before commencing treatment with this drug

Required maintenance antibiotic therapy
Dosage mg/day
From (DD MM YYYY)
To (DD MM YYYY)

Checklist

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

☐ Details of the proposed prescription(s).

Privacy notice

18 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**

19 **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)

If returning by post, print and sign by hand.

Reset form

Returning this form

Return this form, details of the proposed prescription(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