Australian Government
Services Australia

medicare

PBS

Chronic pouchitis – vedolizumab – initial grandfather authority application

When to use this form

Use this form to apply for **initial grandfather** PBS-subsidised vedolizumab for patients with moderate to severe chronic pouchitis who have received non-PBS-subsidised treatment with vedolizumab for the same condition prior to **1 December 2024**.

Important information

Initial grandfather applications to start PBS-subsidised treatment must be in writing and must include sufficient information to determine the patient's eligibility according to the PBS criteria.

Under no circumstances will phone approvals be granted for moderate to severe chronic pouchitis **initial grandfather** 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 grandfather** treatment.

Patients may qualify for PBS-subsidised treatment under this restriction once only. For **continuing** PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

After a written authority application for **initial grandfather** 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

The prescriber must have excluded 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.

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 Family name

First given name

3 Date of birth (DD MM YYYY)

Prescriber's details

4 Prescriber number

5 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 Has the patient previously received non-PBS-subsidised treatment with this drug for this condition prior to **1 December 2024**?

- Yes ☐
- No ☐

11 Provide the date this non-PBS-subsidised treatment was commenced (DD MM YYYY)

12 Is the patient currently receiving treatment with this drug for this condition?

- Yes ☐
- No ☐

13 Has the patient received non-PBS-subsidised treatment for the first three doses of induction?

- Yes ☐ ***Go to 14***
- No ☐ ***Go to 15***

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14 Has the patient demonstrated a partial or complete response to treatment with this drug for this condition as determined by the treating clinician?

Yes ☐
No ☐

15 Was the treatment initiated in combination with standard of care antibiotic?

Yes ☐
No ☐

16 Had the patient undergone ileal pouch anal anastomosis (IPAA) due to ulcerative colitis (UC) at least one year prior to initiating non-PBS-subsidised treatment with this drug for this condition?

Yes ☐
No ☐

17 Was the condition 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 ☐

18 When initiating non-PBS-subsidised treatment with this drug for this condition, the patient had:

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

Baseline mPDAI score

Date of assessment (no more than 4 weeks prior to commencing non-PBS-subsidised treatment)
(DD MM YYYY)

and

☐ a minimum endoscopic mPDAI sub-score ≥ 2

Baseline endoscopic mPDAI sub-score

Date of assessment (no more than 4 weeks prior to commencing non-PBS-subsidised treatment)
(DD MM YYYY)

19 Prior to commencing non-PBS-subsidised treatment with this drug for this condition, the patient 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

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

Checklist

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

☐ Details of the proposed prescription(s).

Privacy notice

21 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**

22 **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