Australian Government
Services Australia

medicare

PBS

Acute lymphoblastic leukaemia inotuzumab ozogamicin initial (induction) authority application

When to use this form

Use this authority application form (this form) to apply for **initial (induction)** Pharmaceutical Benefits Scheme (PBS) subsidised inotuzumab ozogamicin for acute lymphoblastic leukaemia.

Important information

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

Under no circumstances will phone approvals be granted for **initial (induction)** authority applications to extend the treatment period.

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

Consolidation treatment

This form is ONLY for **initial (induction)** treatment.

For **continuing** PBS subsidised treatment, an initial patient must qualify under the consolidation treatment restriction.

After a written authority application for **initial (induction)** treatment has been approved, applications for **consolidation** treatment can be made by phone.

Call **1800 700 270** Monday to Friday, 8 am to 5 pm, local time.

Call charges may apply.

Section 100 arrangements

This item is available to a patient who is attending:

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

and is:

- a day admitted patient
- a non-admitted patient, **or**
- a 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 form.

Treatment specifics

The patient cannot receive more than 3 treatment cycles under the **initial (induction)** treatment phase.

Treatment with this drug for this condition must not exceed 6 treatment cycles in a lifetime.

Two completed authority prescriptions forms should be submitted for induction treatment cycles: the first prescription for the loading dose at a dose no higher than 0.8mg/m^2 and the second prescription for two doses at a dose no higher than 0.5mg/m^2.

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

[/ /]

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

[( )]

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 Is the patient's condition relapsed or refractory B-precursor cell acute lymphoblastic leukaemia with an Eastern Cooperative Oncology Group (ECOG) performance status of 2 or less?

No ☐

Yes ☐

10 Is the condition CD22-positive?

No ☐

Yes ☐

11 The condition is:

☐ Philadelphia chromosome negative

☐ Philadelphia chromosome positive and the patient has previously received tyrosine kinase inhibitor

12 Has the patient received more than 1 line of salvage therapy?

No ☐

Yes ☐

13 Does the condition have more than 5% blasts in bone marrow?

No ☐

Yes ☐ Provide the percentage of blasts in bone marrow

[%]

14 The patient has received intensive combination chemotherapy for:

☐ initial treatment of acute lymphoblastic leukaemia

Date of most recent chemotherapy

[/ /]

or

☐ subsequent salvage therapy.

Provide the line of salvage therapy

[ ]

and

date of most recent chemotherapy

[/ /]

15 Is this treatment exceeding more than 3 cycles under this restriction?

No ☐

Yes ☐

16 Is this treatment exceeding more than 6 cycles in a lifetime?

No ☐

Yes ☐

Checklist

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

- ☐ The completed authority prescription form(s).
- ☐ Evidence that the condition is CD22-positive.
- ☐ The bone marrow biopsy report no more than 1 month old.

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/privacy**

Prescriber's declaration

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 the completed authority prescription form(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.

Prescriber's signature

On completion, print and sign by hand.

Date

/ /

Reset form Print form

Returning this form

Return this form and any supporting documents:

- **online**, upload this form, the authority prescription form(s) and any relevant attachments through Health Professional Online Services (HPOS) at **servicesaustralia.gov.au/hpos**

  or

- by post, send this form, the authority prescription form(s) and any relevant attachments to:

  Services Australia
  Complex Drugs Programs
  Reply Paid 9826
  HOBART TAS 7001