

Acute lymphoblastic leukaemia – inotuzumab ozogamicin – initial (induction) authority application

Online PBS Authorities



You do not need to complete this form if you use the **Online PBS Authorities** system.

For more information and how to access the **Online PBS Authorities** system, go to servicesaustralia.gov.au/hppbsauthorities

When to use this form

Use this form to apply for **initial (induction)** PBS-subsidised inotuzumab ozogamicin for acute lymphoblastic leukaemia.

Important information

Initial (Induction) applications can be made using the **Online PBS Authorities** system or 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 acute lymphoblastic leukaemia **initial (induction)** authority applications.

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 an authority application for **initial (induction)** treatment has been approved, applications for **consolidation** 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

This item is available to a patient who is attending:

- an approved private hospital, **or**
- a public participating 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 in a lifetime.

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/m² and the second prescription for two doses at a dose no higher than 0.5mg/m².

For more information

Go to servicesaustralia.gov.au/healthprofessionals

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

- Yes
No

15 Provide the following details:

Percentage of blasts in bone marrow (no more than 1 month old)

 %

Date of bone marrow biopsy report (DD MM YYYY)

16 Is the condition Philadelphia chromosome positive?

- Yes **Go to 17**
No **Go to 18**

17 Has the patient previously received a tyrosine kinase inhibitor (TKI)?

- Yes
No

18 Will this approval exceed the maximum of 3 treatment cycles under this restriction in a lifetime?

- Yes
No

19 Will treatment with this drug for this condition (including PBS-subsidised and non-PBS-subsidised induction and consolidation) exceed 6 treatment cycles in a lifetime?

- Yes
No

20 Is this request for an in-patient in a public hospital setting?

- Yes
No

Checklist

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

- Details of the proposed prescription(s).
 Evidence that the condition is CD22-positive.
 The bone marrow biopsy report no more than 1 month old.

Privacy notice

22 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

23 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)

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
- by post (signature required) to
Services Australia
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001