

# Acute myeloid leukaemia – oral azacitidine – dose escalation therapy continuing authority application

## Online PBS Authorities



Requesting PBS Authorities online provides an immediate assessment in real time.

For more information and how to access the **Online PBS Authorities** system, go to [servicesaustralia.gov.au/hppbsauthorities](https://servicesaustralia.gov.au/hppbsauthorities)

## When to use this form

Use this form to apply for **dose escalation therapy continuing** treatment with PBS-subsidised azacitidine tablets for patients with acute myeloid leukaemia (AML).

## Important information

**Dose escalation therapy continuing** treatment applications can be made in real time 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 AML **dose escalation therapy continuing** 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 **dose escalation therapy continuing** treatment.

## Treatment specifics

Oral azacitidine should not be used interchangeably with injectable azacitidine due to differences in the exposure, dose and schedule of treatment.

This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 6 months following cessation of therapy.

## For more information

Go to [servicesaustralia.gov.au/healthprofessionals](https://servicesaustralia.gov.au/healthprofessionals)

# Acute myeloid leukaemia – oral azacitidine – dose escalation therapy continuing authority application

## Online PBS Authorities



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

Go to [servicesaustralia.gov.au/hppbsauthorities](https://servicesaustralia.gov.au/hppbsauthorities)

## 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)

## Conditions and criteria

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

### 7 Has the patient previously received PBS-subsidised treatment with oral azacitidine for this condition?

No ☐

Yes ☐

### 8 In conjunction with clinical assessment and in order to extend the dose schedule as per the TGA-approved Product Information, the patient has between 5% to 15% blasts in either the:

☐ bone marrow

or

☐ peripheral blood

### 9 Provide details of the pathology report demonstrating the blast percentage:

Date of test (DD MM YYYY)

Unique identifying number/code or provider number

### 10 Is the patient receiving concomitant PBS-subsidised treatment with midostaurin?

No ☐

Yes ☐

## Checklist

### 11 The relevant attachments need to be provided with this form.

☐ Details of the proposed prescription(s).



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## Privacy notice

- 12** 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](https://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](https://servicesaustralia.gov.au/hpos)

### 13 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)

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Prescriber's signature (**only** required if returning by post)


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## 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](https://servicesaustralia.gov.au/hpos)
- **or**
- by post (signature required) to  
Services Australia  
Complex Drugs Programs  
Reply Paid 9826  
HOBART TAS 7001