



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 | | |
|------------------------|--|--|--|
| When to use this form | Use this form to apply for dose escalation therapy continuing treatment with PBS-subsidised azacitiding 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 | | |



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| 0 | Online PBS Authorities | | Conditions and criteria | | |
|----------------------|--|----|---|--|--|
| | You do not need to complete this form if you use the Online PBS Authorities system. | | qualify for PBS authority approval, the following conditions ust be met. | | |
| Pa | Go to servicesaustralia.gov.au/hppbsauthorities | 7 | Has the patient previously received PBS-subsidised treatment with oral azacitidine for this condition? | | |
| 1 | Medicare card number | | Yes | | |
| 2 | or Department of Veterans' Affairs card number Or Dr Mr Mrs Miss Ms Other | 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 | | |
| - | Family name | 9 | Provide details of the pathology report demonstrating the blast | | |
| | | Ŭ | percentage: | | |
| | First given name | | Date of test (DD MM YYYY) | | |
| | | | | | |
| 3 | Date of birth (DD MM YYYY) | | Unique identifying number/code or provider number | | |
| - | | | | | |
| | | 10 | Is the patient receiving concomitant PBS-subsidised treatment | | |
| Prescriber's details | | | with midostaurin? | | |
| 4 | Prescriber number | | Yes | | |
| - | | | | | |
| | | Ch | ecklist | | |
| 5 | Dr 🗌 Mr 🗌 Mrs 🗌 Miss 🗌 Ms 🗌 Other 📖 | 11 | The relevant attachments need to be provided with | | |
| | Family name | | this form. | | |
| | | | Details of the proposed prescription(s). | | |
| | First given name | | | | |
| | | | | | |
| 6 | Business phone number (including area code) | | | | |
| | | | | | |
| | Alternative phone number (including area code) | | | | |
| | | | | | |
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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**

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**

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)

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**

or

• by post (signature required) to

Services Australia Complex Drugs Programs Reply Paid 9826 HOBART TAS 7001