



Azacitidine

Initial PBS authority application

Supporting information

Important information

You must lodge this form for a patient starting **initial** PBS subsidised treatment with azacitidine for the treatment of:

- Myelodysplastic syndrome classified as intermediate-2 or high risk according to the International Prognostic Scoring System (IPSS), or
- Chronic myelomonocytic leukaemia (10 per cent to 29 per cent marrow blasts without myeloproliferative disorder), or
- Acute myeloid leukaemia with 20 per cent to 30 per cent marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification.

The following pathology reports are required with each application:

- bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome, chronic myelomonocytic leukaemia or acute myeloid leukaemia
- full blood examination report
- and for myelodysplastic syndrome, a copy of the pathology report detailing the cytogenetics demonstrating intermediate-2 or high risk disease according to the IPSS.

All applications must be in writing and must include sufficient information to determine the patient's eligibility according to the PBS criteria.

Section 100 arrangements

This item is only available to a patient:

who is attending either

- an approved private hospital
- a public participating hospital

or

- a public hospital

and is either

- a day admitted patient
- a non-admitted patient

or

- a patient on discharge

This is not a PBS benefit for in-patients of the hospital. The hospital provider number must be included on the application form.

Acknowledgements

The patient's and the prescriber's acknowledgements must be signed in the presence of a witness (over 18 years of age).

Authority prescription form

A completed authority prescription form must be attached to this form.

The medical indication section of the authority prescription form does not need to be completed when submitted with this form.

Phone approvals

Under no circumstance will phone approvals be granted for complete authority applications, or for treatment that would otherwise extend the treatment period.

Applications for continuing treatment

Continuing PBS subsidised treatment for patients who do not have progressive disease may be obtained by phone, call **1800 700 270** (call charges may apply) and select option 3, between 8.00 am to 5.00 pm EST, Monday to Friday.

Assistance

If you need assistance completing this form or need more information call **1800 700 270** (call charges may apply) and select option 3, between 8.00 am and 5.00 pm EST, Monday to Friday or go to **www.medicareaustralia.gov.au > For health professionals > PBS > Specialised drugs (PBS) A-I > Azacitidine**

Lodgement

Send the completed authority application form, a completed authority prescription form and all relevant pathology reports to:

Medicare Australia

Prior written approval of specialised drugs

Reply Paid 9826

Hobart TAS 7001

Print in **BLOCK LETTERS**

Tick where applicable



Azacitidine

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Patient's details

1 Medicare card number

- - Ref no.

2 Mr Mrs Miss Ms Other

Family name

First given name

3 Date of birth

/ /

4 Body surface area

m²

Patient's acknowledgement

5 I acknowledge that PBS subsidised treatment with azacitidine for the treatment of:

- myelodysplastic syndrome, or
- chronic myelomonocytic leukaemia, or
- acute myeloid leukaemia

will stop if:

- subsequent testing demonstrates the disease has progressed.

My prescriber has explained to me the nature of the ongoing monitoring and testing required to demonstrate an adequate response to treatment.

Patient's signature

Date

/ /

Prescriber's details

6 Prescriber number

7 Family name

First given name

8 Work phone number

Alternative phone number

Fax number

Hospital details

9 Hospital name

10 Hospital provider number

Prescriber's declaration and acknowledgement

11 I declare that I have explained to the patient:

- the circumstances governing PBS subsidised treatment with azacitidine
- the nature of the ongoing monitoring and testing required to demonstrate the disease has not progressed.

I acknowledge that:

- if disease progression occurs I will stop treatment with azacitidine.

I believe these to be understood and accepted by the patient.

Prescriber's signature

Date

/ /

Witness's acknowledgement

12 I have witnessed the signatures of **BOTH** the patient and the prescriber.

Witness's full name (over 18 years of age)

Witness's signature

Date

/ /

Conditions and criteria

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

13 The patient:

has signed the patient acknowledgement

and

has had a full blood examination

and

has been diagnosed with either:

myelodysplastic syndrome classified as intermediate-2 or high risk according to the International Prognostic Scoring System (IPSS),

go to 14

or

chronic myelomonocytic leukaemia (10 per cent to 29 per cent marrow blasts without myeloproliferative disorder)

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or

acute myeloid leukaemia with 20 per cent to 30 per cent marrow blasts and multi-lineage dysplasia

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Myelodysplastic syndrome classification			
	Parameter	value	score
Marrow blasts	< 5%	0	
	5% - 10%	0.5	
	11% - 20%	1.5	
	21% - 30%	2	
Cytogenetic abnormalities	normal	0	
	(-Y) alone	0	
	del (5q) alone	0	
	del (20q) alone	0	
	other abnormalities	0.5	
	3 or more abnormalities	1	
	chromosome 7 abnormalities	1	
Cytopenia	Hb < 100 g/L neutrophils < 1.8 x 10 ⁹ /L platelets < 100 x 10 ⁹ /L	0 or 1 cytopenia	0
		2 or 3 cytopenia	0.5
TOTAL SCORE (must be ≥ 1.5)			

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15 Attachments



Attach bone marrow pathology report, full blood examination report, cytogenetic report and completed authority prescription form.

Prescriber's declaration

16 I declare that:

- the information provided on this form is correct.

Prescriber's signature

Date

/ /

Privacy note

The information provided on this form will be used to assess eligibility of a nominated person to receive PBS subsidised treatment. The collection of this information is authorised by the *National Health Act 1953*. This information may be disclosed to the Department of Health and Ageing, Department of Veterans' Affairs or as authorised or required by law.