

# Azacitidine - Acute Myeloid Leukemia (AML) Greater Than 30% Blasts

This form must be completed before the first dose is dispensed.

## 1. Patient Profile

- \* Surname: .....
- \* Given Name: .....
- \* OHIN: ..... \* Chart Number: .....
- \* Postal Code: .....
- \* Height (cm): ..... \* Weight (kg): .....
- \* BSA (m<sup>2</sup>): ..... \* Gender:  Male  Female  Other
- \* Date of Birth: .....  
Day    Month    Year
- \* Site: .....
- \* Attending Physician (MRP- Most Responsible Physician): .....
- Requested Prior Approval  Yes    \* Patient on Clinical Trial  Yes  No
- Specify Trial:  OTHER
- Other (specify): .....
- Specify Arm:  
 Standard of care arm                       Experimental arm

## Prior Approval Request

- \* Select the appropriate prior approval scenario:

- 1-Unknown primary (submit pathology report and clinic note)
- 2-Clinical document review (identify the patient history that needs to be reviewed against eligibility criteria in Additional Comments below)
- 3-Regimen modification - schedule (complete questions a and b)
- 4-Regimen modification - drug substitutions (complete questions a and c)
- 5-Withholding a drug in combination therapy from start of treatment (complete questions d, e and f)
- 6-Maintenance therapy delay (submit clinic note)
- 7-Prior systemic therapy clinical trials (complete question g)
- 8-Modification due to supply interruption/drug shortage
- Other (specify)

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**All relevant supporting documentation must be submitted at the time of prior approval. Documentation may include a pathology report, clinic note, and/or CT scans.**

a. Co-morbidities / toxicity / justification:

.....

b. Intended regimen schedule: .....

c. Intended regimen: .....

d. Drug(s) to be held: .....

e. Rationale for holding drug(s): .....

f. Intention to introduce drug at a later date?  Yes

g. Prior clinical trial identifier (e.g., NCT ID, trial name) and treatment description (e.g., arm, drug/regimen): .....

h. Anticipated date of first treatment: \_\_\_\_\_  
Day    Month    Year

i. Additional comments:

\_\_\_\_\_

## 2. Eligibility Criteria

The patient must meet the following criteria:

- Azacitidine is used for the treatment of older adult patients with newly diagnosed acute myeloid leukemia (AML) with greater than 30% bone marrow blasts without immediate intent for hematopoietic stem cell transplant (HSCT) or who are unfit for induction chemotherapy.  Yes

## 3. Baseline Information

a. ECOG Performance Status at the time of enrolment  0     1     2

## 4. Funded Dose

Azacitidine subcutaneously (SC) according to one of these intended dosing schedules (repeated every 28 days; 1 cycle = every 28 days)<sup>1</sup>

- 75 mg/m<sup>2</sup> sc daily for 7 consecutive days
- 75 mg/m<sup>2</sup> sc daily for 6 consecutive days
- 75 mg/m<sup>2</sup> sc 5-2-2 (5 consecutive days of treatment, followed by 2 consecutive days without treatment, and then 2 consecutive days of treatment every 28 days)

Treatments will be funded as long as the patient continues to benefit or until disease progression or unacceptable toxicity, whichever comes first.

ST-QBP regimen code: AZCT

## 5. Notes

1. The NDFP will only fund the dosing schedules listed on the form, as per Ministry criteria. An exception is the one-off situation that may occur (e.g. statutory holidays). Sites are encouraged to contact their Reimbursement Analyst should there be questions relating to the one-off scenarios.

## 6. FAQs

**i. My patient is currently receiving azacitidine through non-publicly funded means. Can my patient be transitioned over to receive funding through the New Drug Funding Program (NDFP)?**

Provided the funding criteria were met at the time of treatment initiation and the patient's disease has not progressed, your patient may be eligible for continued coverage of azacitidine through NDFP. Please submit as a prior approval request including the most recent clinic note (outlining the response to azacitidine therapy, if able to assess).

**ii. My patient is currently receiving low-dose cytarabine (or other palliative chemotherapy) and I would like to switch them to azacitidine. Is this eligible for funding through NDFP?**

Patients who are currently on low-dose cytarabine or other palliative chemotherapy for newly diagnosed AML and whose disease has not progressed will be eligible to switch to azacitidine under this policy. Please submit as a prior approval request including the most recent clinic note (outlining the response to current therapy, if able to assess).

## 7. Supporting Documents

None required at time of enrolment.

In the event of an audit, the following should be available to document eligibility:

- Clinic note(s) demonstrating the patient's treatment history and response to therapy.
- Bone marrow biopsy report showing greater than 30% blasts.

Signature of Attending Physician (MRP- Most Responsible Physician): .....

.....  
Day    Month    Year