Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Azacitidine - Acute Myeloid Leukemia (AML)

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^2): * 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

Request prior approval for enrolment

* Justification for Funding

2. Eligibility Criteria

The patient must meet the following criteria: ☐ Yes

- Azacitidine is used for the treatment of adult patients with Acute Myeloid Leukemia (AML) who are not eligible for hematopoietic stem cell transplantation and who have 20-30% blasts and multilineage dysplasia, according to World Health Organization (WHO) classification.

NOTE: The patient has 20-30% blasts prior to any treatment for the current AML diagnosis.

3. Baseline Information

a. Date of diagnosis: _____ Day _____ Month _____ Year

b. IPSS score:

Bone marrow blasts (%): ○ < 5 ○ 5-10 ○ 11-20 ○ 21-30

Number of cytopenias[1]: ○ 0 ○ 1 ○ 2 ○ 3

Karyotype[2]:
○ Good ○ Intermediate ○ Poor ○ Inconclusive
○ Not done ○ Pending

Total score: ○ 1.5 ○ 2 ○ >= 2.5

Reason cytogenetics testing not done:
○ Specimen failed to produce dividing cells
○ Report was not received at beginning of treatment
○ Other

Specify (other):

c. AML with 20-30% blasts according to the WHO classification. ☐ Yes

d. Transfusion dependency (defined as at least 1 unit every 4 weeks for the preceeding 8 weeks). ○ Yes ○ No

Average # RBC units/month for the preceding 2 months: _____

e. ECOG Performance status: ○ 0 ○ 1 ○ 2 ○ 3

4. Treatment Information

a. Has the patient received azacitidine prior to the NDFP? ○ Yes ○ No

The total # of doses received: .....

b. Does the patient have therapy-related (secondary) AML?

- ○ Yes
- ○ No

5. Funded Dose

Intended dosing schedule *(repeated every 28 days; 1 cycle = every 28 days)*[4]

- ○ *75 mg/m^2 sc daily for 7 consecutive days*
- ○ *75 mg/m^2 sc daily for 6 consecutive days*
- ○ *75 mg/m^2 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)*

6. Notes

1. Cytopenias defined as Hb < 100 g/L, Platelets < 100 x 10^9/L, Absolute Neutrophils < 1.5 x10^9/L.

2. Definition of karyotype:
a. Good: normal, -Y, del (20q), del (5q)
b. Intermediate: other karyotypic abnormalities
c. Poor: complex (= 3 abnormalities or chromosome 7 abnormality)

3. Definitions of ECOG:

   0 = Fully active, able to carry on all pre-disease activities without restriction.

   1 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature.

   2 = Ambulatory and capable of all self-care but unable to carry out any work activities. Out of bed > 50%.

   3 = Capable of only limited self-care, confined to bed or chair > 50% waking hours.

   4 = Completely disabled, cannot carry on any self-care, totally confined to bed or chair.

4. The NDFP will only fund the regimens 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 the NDFP should there be questions relating to the one-off scenarios.

5. Evidence of eligibility must be demonstrated either with a bone marrow aspirate or biopsy, whichever report produces the worst percentage.

6. As part of reimbursement, sites are required to submit to the NDFP copies of the baseline bone marrow and cytogenetics report. If cytogenetics is inconclusive or not done, the patient may still meet criteria based on the IPSS score being intermediate-2 or higher by virtue of the percent blast count and the number of cytopenias. In certain situations, the provision of prior cytogenetics is sufficient if the MDS is confirmed by morphology and

   a. If IPSS score meets criteria without the need for cytogenetics, or
   b. If blast count is 20-30%.

7. Treatments will be funded as long as the patient continues to benefit or until disease progression.

7. Supporting Documents

To ensure reimbursement of your claim, both the completed enrolment form and a copy of the required documentation (where applicable) must be submitted through CCO e-Claims.

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

....
Day Month Year