Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Azacitidine - Intermediate-2 and High-Risk Myelodysplastic Syndrome (MDS)

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

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 (comple question g)
○ 8-Modification due to supply interruption/drug shortage
○ Other (specify)

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: ☐ Yes

Azacitidine is used for the treatment of adult patients with Intermediate-2 and high-risk myelodysplastic syndrome (MDS) who are not eligible for hematopoietic stem cell transplantation according to the International Prognostic Scoring System (IPSS).

3. Baseline Information

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

b. IPSS score (if cytogenetics and/or bone marrow blasts do not confer an IPSS score of >= 1.5, baseline CBC will be required to confirm eligibility):

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

Number of cytopenias[1]:
○ 0 or 1
○ 2 or 3
○ Not Required

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

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

Specify (other): _____

c. WHO classification/FAB subtype:
○ RA ○ RARS ○ RCMD ○ RCMD-RS
○ RAEB-1 ○ RAEB-2 ○ RCUD ○ MDS NOS
○ CMML1 ○ CMML2 ○ CMML with WBC <13 and =10% marrow blasts

d. Transfusion dependency ○ 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) MDS?

- ○ 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. Please note that the eligibility for azacitidine under this MDS policy is based upon the IPSS result and not the revised IPSS.

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 may be required to submit 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%.

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

7. Supporting Documents

None required at time of enrolment.

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

- Bone marrow aspirate or biopsy within 8 weeks of treatment initiation (whichever report produces the worst percentage)
- Baseline cytogenetics report and/or lab work demonstrating number of cytopenias (if requirements are not met with the bone marrow report alone)

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

....
Day Month Year

Form 989