Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Azacitidine in combination with Venetoclax (Outpatient) - Previously Untreated Acute Myeloid Leukemia

(This form should 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

Other (specify): _____

Specify Arm:
○ Standard of care arm ○ Experimental arm
○ Blinded / Unknown

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)

.....

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:

Venetoclax in combination with azacitidine is used in adult patients for the treatment of newly diagnosed acute myeloid leukemia (AML) who are 75 years of age or older, or who are 18 to 74 years of age and have comorbidities that preclude the use of intensive induction chemotherapy. ☐ Yes

3. Baseline Information

Does this patient have an enrolment in the inpatient version of this policy? ○ Yes ○ No

a. Is the patient 75 years of age or older and have an ECOG Performance Status of 0 to 2 at the time of enrolment? ○ Yes ○ No

b. Please specify ECOG Performance Status at the time of enrolment: ○ 0 ○ 1 ○ 2

c. If the patient is 18 to 74 years of age, please select all comorbidities at the time of enrolment which preclude the use of intensive induction chemotherapy

- ☐ Not applicable (patient is 75 years of age or older)
- ☐ ECOG of 2
- ☐ ECOG of 3
- ☐ History of congestive heart failure requiring treatment, ejection fraction less than or equal to 50%, or chronic stable angina
- ☐ History of a diffusing capacity for carbon monoxide (DLCO) less than or equal to 65% or forced expiratory volume in one second (FEV_1) less than or equal to 65%
- ☐ Creatinine clearance of 30 to less than 45 mL/minute
- ☐ Moderate hepatic impairment with total bilirubin greater than 1.5 to less than or equal to 3 times upper limit of normal

d. Is the patient transitioning from a private pay or compassionate program? ○ Yes ○ No

4. Funded Dose

Cycle 1:
Azacitidine 75 mg/m^2 subcutaneously once daily for 6 or 7 doses (starting on day 1) in combination with venetoclax 100 mg once daily on day 1, 200 mg once daily on day 2, then 400 mg once daily on days 3 to 28.

Cycle 2 and onwards:
Azacitidine 75 mg/m^2 subcutaneously once daily for 6 or 7 doses (starting on day 1) in combination with venetoclax 400 mg once daily on days 1 to 28.

[repeated every 28 days; 1 cycle = every 28 days]

Treatment should be continued until disease progression or unacceptable toxicity, whichever comes first.

[ST-QBP regimen code: AZCTVENE]

Please select the intended azacitidine schedule:

- ○ 5-2-2 (5 consecutive days of treatment, followed by 2 consecutive days without treatment, and then 2 consecutive days of treatment)
- ○ Once daily for 6 consecutive days
- ○ Once daily for 7 consecutive days

5. Notes

1. Enrolment in this policy is for funding of azacitidine in the outpatient setting only. Funding for outpatient use of venetoclax must be obtained through the Ministry's Exceptional Access Program. Please check that your patient will be eligible for benefits under the Ontario Drug Benefit Program. Some patients may require registration in the Trillium Drug Program.

   Please ensure all doses are submitted through eClaims using the respective enrolment forms for outpatient and inpatient administered doses.

2. For funding of doses administered in the inpatient setting, a separate enrolment form must be submitted. See the policy *'Azacitidine in combination with Venetoclax (Inpatient) - Previously Untreated Acute Myeloid Leukemia'*. Inpatient administration of both azacitidine and venetoclax are funded though the High Cost Therapy Funding Program (HCTFP).

3. The New Drug Funding Program (NDFP) will only fund the azacitidine dosing schedules listed on this form, as per Ministry criteria. Sites are encouraged to contact their Reimbursement Analyst if they have questions on eligible dosing schedules.

4. Patients previously treated with a hypomethylating agent, venetoclax, or chemotherapy for myelodysplastic syndrome (MDS) are not eligible for funding of azacitidine in combination with venetoclax.

5. Patients with high risk MDS who are not fit for intensive induction chemotherapy are not eligible for funding of azacitidine in combination with venetoclax.

6. Azacitidine in combination with venetoclax will be funded in patients with newly diagnosed AML, regardless of cytogenetic risk, providing the patient meets the eligibility criteria.

7. In the event azacitidine is discontinued due to toxicities or intolerance, venetoclax should also be discontinued.

8. For patients without unacceptable toxicity, it is recommended that patients be treated for a minimum of 6 cycles.

9. Patients 75 years of age or older with an ECOG performance status greater than 2 may be eligible for funding under this policy if their performance status is judged to be related to their AML, provided all other criteria are met. Please submit as a prior approval request including the most recent clinic note.

6. FAQs

i. **My patient is currently receiving azacitidine and venetoclax through non-publicly funded means. Can my patient be transitioned to receive public funding for both medications?**

This NDFP policy is intended for public funding of azacitidine in the outpatient setting only. Provided the eligibility criteria were met at the time of treatment initiation and the patient's disease has not progressed, your patient may be eligible for public funding. Please submit a prior approval request in eClaims, including a clinic note from the initiation of therapy and a recent clinic note discussing treatment response.

In order to obtain public funding for outpatient venetoclax, a separate application must be submitted to the Ministry's Exceptional Access Program.

ii. **My patient is currently receiving first-line treatment for AML (e.g. single agent azacitidine, low dose cytarabine, or low dose cytarabine with venetoclax). Can my patient be transitioned to combination azacitidine and venetoclax?**

Provided the eligibility criteria were met at the time of treatment initiation and the patient's disease has not progressed, your patient may be eligible for funding of outpatient azacitidine under this policy. Please submit a prior approval request including a clinic note from the initiation of therapy and a recent clinic note discussing treatment response.

Note that this policy is for NDFP funding of the azacitidine component only. Outpatient funding of venetoclax must be obtained from the Ministry's Exceptional Access Program.

iii. **How will inpatient and outpatient treatment claims be managed in eClaims?**

Only outpatient treatment claims for azacitidine should be submitted under this policy. Azacitidine doses administered in the outpatient setting are submitted as per the site's usual procedure. Claims for doses administered in the inpatient setting must be submitted under the policy *'Azacitidine in combination with Venetoclax (Inpatient) - Previously Untreated Acute Myeloid Leukemia'*. Sites using DSP or HL7 must submit inpatient claims under the respective policy manually until March 13, 2023 (as per communication on Aug 10, 2022). When submitting inpatient treatment claims, please ensure to select "inpatient" as the treatment setting.

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, response to therapy, comorbidities precluding the use of intensive induction chemotherapy (if applicable), and confirmation that treatment is being administered in an outpatient setting.
- Bone marrow biopsy or aspirate confirming a diagnosis of AML.

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

Day Month Year