Ontario Santé
Health Ontario

eClaims
Demandes de remboursement en ligne

Eligibility Form

# Azacitidine in combination with Ivosidenib (Inpatient) - 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

Specify Trial:
○ Clinical Trial 1 ○ Clinical Trial 2
○ Clinical Trial 3 ○ Other

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

Azacitidine, in combination with ivosidenib, will be used for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) with an isocitrate dehydrogenase 1 (IDH1) R132 mutation who are not eligible for intensive induction chemotherapy. ☐ Yes

## 3. Baseline Information

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

b. Is the patient transitioning from a compassionate access program for ivosidenib? ○ Yes ○ No

c. Does the patient have an enrolment in the outpatient version of this policy? ○ Yes ○ No

d. Is the patient 75 years of age or older at the time of enrolment?

○ Yes ○ No

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

○ ECOG 2 or greater
○ Severe cardiac disorder
○ Severe pulmonary disorder
○ Creatinine clearance less than 45 mL/minute
○ Bilirubin level greater than 1.5 times the upper limit of normal

## 4. Funded Dose

Azacitidine 75 mg/$m^2$ subcutaneously once daily for 6 or 7 doses (starting on day 1), in combination with ivosidenib 500 mg orally once daily on days 1 to 28.

[1 cycle = 28 days]

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

* 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 of this policy is for funding of azacitidine and ivosidenib doses administered in the inpatient setting only.

   Please ensure all claims are submitted through eClaims under the appropriate policies for inpatient and outpatient administered doses.

2. For funding of doses administered in the outpatient setting, a separate enrolment form must be submitted. See the policy ‘Azacitidine in combination with ivosidenib (Outpatient) – Previously Untreated Acute Myeloid Leukemia’. Outpatient azacitidine is funded through the New Drug Funding Program (NDFP) whereas outpatient ivosidenib funding is obtained through the Ministry’s Exceptional Access Program. At the initiation of therapy, please check that your patient is eligible for benefits under the Ontario Drug Benefit Program. Some patients may require registration in the Trillium Drug Program.

3. Patients who were previously treated for AML, with the exception of treatments to stabilize disease (such as hydroxyurea and leukapheresis), are not eligible for funding of azacitidine in combination with ivosidenib.

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

## 6. FAQs

1. **My patient is currently receiving azacitidine and ivosidenib through non-publicly funded means (e.g. patient support program). Can my patient be transitioned to receive funding through the High Cost Therapy Funding Program (HCTFP)?**

   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 continued coverage through the HCTFP.

2. **What is the process for transitioning my patient from a non-publicly funded program to HCTFP funding?**

   If your patient meets all of the eligibility criteria outlined in this policy, please submit as a regular eClaims enrolment.

   Prior approval requests are reserved for instances where there is clinical uncertainty on eligibility. In these circumstances, please specify your reason(s) for uncertainty and upload the following:
   - A clinic note from treatment initiation, and
   - The most recent clinic note (if applicable).

   **Please note:** Patients who meet the HCTFP eligibility criteria and are enrolled in the manufacturer's patient support program (PSP) for ivosidenib are eligible to receive continued drug supply through the PSP until November 29, 2025, inclusive.

   After this date, patients who met the HCTFP eligibility criteria at the point of treatment initiation are eligible to transition to HCTFP funding for the remainder of their treatment course. Although sites may enroll their patient onto this policy at any time beforehand, any treatment claims submitted to eClaims for ivosidenib that were given on or before the PSP transition date will be denied.

3. **My patient is awaiting IDH1 R132 inhibitor test results. Can we start therapy with azacitidine with ivosidenib in the interim?**

   No, the IDH1 R132 mutation must be confirmed prior to initiation of azacitidine with ivosidenib.

4. **My patient is currently receiving azacitidine monotherapy. Can ivosidenib be added?**

   On a time-limited basis and provided the patient has not progressed on treatment, and meets all the eligibility criteria, the addition of ivosidenib may be funded under this policy. Please submit as a prior approval request in eClaims including the most recent clinic note outlining the treatment history and response to treatment, if able to assess.

## 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:
- Clinic note(s) outlining 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 inpatient setting
- Bone marrow biopsy or aspirate confirming a diagnosis of AML.
- IDH1 R132 mutation result using next generation sequencing (NGS) or polymerase chain reaction (PCR) testing.

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

..... ..... .....
Day Month Year