

# Gemtuzumab Ozogamicin (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<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
- 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:

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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:

- Gemtuzumab ozogamicin is used in combination with daunorubicin and cytarabine for the treatment of adult patients with previously untreated, *de novo* CD33-positive acute myeloid leukemia (AML), except acute promyelocytic leukemia (APL).  Yes
- Treatment should be for patients with good performance status, and who have favourable, intermediate, or unknown cytogenetics (using the European LeukemiaNet (ELN) 2017 risk classification).

## 3. Baseline Information

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

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

b. ELN risk stratification  Favourable  Intermediate  
 Unknown  
 Test result not yet available

Please provide the patient's updated ELN risk stratification (in prior cases of unknown or test results not available at time of inpatient enrolment)  Favourable  Intermediate  
 Unknown  
 N/A - results provided on inpatient enrolment form and there has been no change

## 4. Funded Dose

**Induction:** Gemtuzumab ozogamicin 3 mg/m<sup>2</sup> (up to a maximum single dose of 4.5 mg) intravenously (IV) on days 1, 4, and 7 in combination with cytarabine and daunorubicin.

Treatment with gemtuzumab ozogamicin, in combination with daunorubicin and cytarabine, is funded for one induction cycle only.

**Consolidation:** Gemtuzumab ozogamicin 3 mg/m<sup>2</sup> (up to a maximum single dose of 4.5 mg) IV on day 1 in combination with cytarabine, or cytarabine and daunorubicin.

For those achieving complete remission following induction, gemtuzumab ozogamicin is funded for up to two cycles, in combination with standard cytarabine consolidation or cytarabine and daunorubicin consolidation [ST-QBP regimen codes for outpatient use only: CYTA(HD)+GEMT or CYTADAUN+GEMT].

## 5. Notes

1. In the event where the cytogenetic status is unknown (that is, because the test was unsuccessful) or when the cytogenetic test result is not yet available, gemtuzumab ozogamicin could be initiated during induction therapy.
2. Once a patient's cytogenetic status is confirmed as being adverse risk, gemtuzumab ozogamicin is no longer eligible for funding.
3. Gemtuzumab ozogamicin is not funded for use in patients with adverse cytogenetics, therapy-related AML or in combination with midostaurin for FMS-like tyrosine kinase 3 (FLT3)-mutated acute myeloid leukemia (AML).
4. Gemtuzumab ozogamicin may be funded if idarubicin is used as an alternative anthracycline to daunorubicin, in combination with cytarabine.
5. Gemtuzumab ozogamicin is not funded if used in combination with other treatments (e.g., FLAG-IDA or azacitidine). Gemtuzumab ozogamicin may be used with an anthracycline and high-dose cytarabine (or high-dose cytarabine alone) as consolidative therapy based on institutional best practice.
6. Gemtuzumab ozogamicin is not funded for relapsed or refractory AML or when used as a single-agent.
7. Patients with *de novo* CD33-positive, FLT3-positive AML with favourable, intermediate, or unknown cytogenetics may use one of either gemtuzumab ozogamicin or midostaurin (assuming other eligibility criteria are met).
8. All doses (induction and consolidation) are to be submitted through eClaims using separate enrolment forms for inpatient and outpatient use. This policy is only for doses administered in the outpatient setting.

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## 6. FAQs

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- i. **My patient is currently receiving gemtuzumab ozogamicin for previously untreated, *de novo* CD33-positive AML through non-publicly funded means. Can my patient be transitioned over to receive funding under an Ontario Health funding program?**

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 gemtuzumab ozogamicin under the respective inpatient or outpatient policies. Please submit as a prior approval request including the most recent clinic note (outlining the response to treatment).

- ii. **My patient is currently receiving induction or consolidation therapy for previously untreated *de novo* CD33-positive AML. Could gemtuzumab ozogamicin be added to their chemotherapy backbone?**

Yes, provided that the patient still has chemotherapy to be administered and are otherwise eligible for this therapy, gemtuzumab ozogamicin may be added. Please submit as a prior approval request including the most recent clinic note (outlining the response to treatment).

- iii. **My patient who has initiated induction therapy with gemtuzumab ozogamicin, in combination with daunorubicin and cytarabine, was subsequently found to be FLT3-mutated. What treatment options may be considered?**

Provided the funding criteria are met, patients may continue with gemtuzumab ozogamicin or switch to midostaurin. For a switch to midostaurin for outpatient use, please submit a request to the Ministry's Exceptional Access Program.

- iv. **How will treatment claims be managed in eClaims?**

Treatment claims should be submitted in eClaims using the established process for claims reimbursement.

Only outpatient treatment claims should be submitted on this policy. Claims for inpatient use must be submitted under the policy titled 'Gemtuzumab Ozogamicin (Inpatient) – Previously Untreated Acute Myeloid Leukemia'.

**Sites submitting claims via OPIS / HL7 / DSP:** to ensure auto-submitted treatments are routed to the correct policy version, **do not enrol a patient in this outpatient policy** until the initial inpatient treatment claims have been submitted.

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## Supporting Documents

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None required at the time of enrolment.

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

- Clinic notes indicating treatment history, cytogenetic results, and the pathology report confirming CD33 positivity.

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

.....  
Day    Month    Year