Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Gemtuzumab Ozogamicin (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

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)

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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:

- 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

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

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

4. Funded Dose

Induction: Gemtuzumab ozogamicin 3 mg/m^2 (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^2 (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 inpatient setting.

6. FAQs

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

Sites using DSP or HL7 to submit inpatient claims must enter them on this inpatient policy manually until further notice, and be sure to **select "inpatient"** as the treatment setting on each claim. Sites not using DSP or HL7 can submit using their established process for claims reimbursement.

Only inpatient treatment claims should be submitted on this policy. Claims for outpatient use must be submitted under the policy titled 'Gemtuzumab Ozogamicin (Outpatient) – 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 the outpatient policy** until the initial inpatient treatment claims have been submitted.

Supporting Documents

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

Form 907