Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Liposomal Daunorubicin and Liposomal Cytarabine (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:

Liposomal daunorubicin and liposomal cytarabine will be used in adult patients with newly diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC) who are deemed fit for intensive chemotherapy. ☐ Yes

3. Baseline Information

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

a. Type of AML diagnosis at the time of enrolment ○ t-AML ○ AML-MRC

b. ECOG Performance Status at the time of enrolment ○ 0 ○ 1 ○ 2 ○ 3 (If performance status is related to AML and is expected to improve with treatment)

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

d. If yes to 3c, how many induction doses of liposomal daunorubicin and liposomal cytarabine did the patient receive?
○ 1 ○ 2 ○ 3 ○ 4 ○ 5

e. If yes to 3c, how many consolidation doses of liposomal daunorubicin and liposomal cytarabine did the patient receive?
○ 0 ○ 1 ○ 2 ○ 3

4. Funded Dose

First Induction:
Liposomal daunorubicin 44 mg/m^2 and liposomal cytarabine 100 mg/m^2 intravenously (IV) on days 1, 3, and 5

Second Induction (if required):
Liposomal daunorubicin 44 mg/m^2 and liposomal cytarabine 100 mg/m^2 IV on days 1 and 3

Consolidation:
Liposomal daunorubicin 29 mg/m^2 and liposomal cytarabine 65 mg/m^2 IV on days 1 and 3

Liposomal daunorubicin and liposomal cytarabine is funded for up to 2 cycles of induction therapy. Patients who achieve complete remission (CR) or CR with incomplete neutrophil or platelet recovery (CRi) during induction cycles are eligible for up to an additional 2 cycles of consolidation therapy using liposomal daunorubicin and liposomal cytarabine.

5. Notes

1. Vyxeos® is a product containing two drugs (liposomal daunorubicin and liposomal cytarabine) in one IV dosage form.

2. t-AML is defined as a pathological diagnosis of AML as per the World Health Organization (WHO) criteria and documented history of prior cytotoxic or radiation therapy for an unrelated disease.

3. AML-MRC is defined as a pathological diagnosis of AML as per the WHO criteria and one of the documented antecedent hematologic disorders:
    - bone marrow documentation of myelodysplastic syndrome (MDS) before diagnosis of AML with or without prior use of a hypomethylating agent OR
    - bone marrow documentation of chronic myelomonocytic leukemia (CMMoL) before diagnosis of AML OR
    - de novo AML with fluorescence in situ hybridization or cytogenetic changes linked to MDS as per WHO criteria

4. Liposomal daunorubicin and liposomal cytarabine is not funded if used in combination with other anti-cancer therapies.

5. All doses (induction and consolidation) are to be submitted through eClaims using the corresponding enrolment forms for inpatient and outpatient use. This policy is only for doses administered in the outpatient setting.

6. FAQs

i. **The calculated dose of Vyxeos® will have two components (e.g., liposomal daunorubicin and liposomal cytarabine). For the purposes of reimbursement, which component of Vxyeos® do I submit to eClaims (i.e. the liposomal daunorubicin dose, the liposomal cytarabine dose, or both doses)?**

In order to receive the correct reimbursement for the dose administered, please submit the administered dose using the **liposomal daunorubicin component only**. Sites should not submit the liposomal cytarabine component. Similarly, sites should not submit the sum of the liposomal daunorubicin component plus the liposomal cytarabine component to eClaims.

ii. **Vyxeos® is a combination of two chemotherapies in one IV formulation. Will the reimbursement price reflect the liposomal daunorubicin or the liposomal cytarabine component or both?**

The Provincial Drug Reimbursement Program's reimbursement price (in cost per milligram) will be based on the **liposomal daunorubicin component** to cover both components.

iii. **My patient is currently receiving liposomal daunorubicin and liposomal cytarabine for previously untreated t-AML or AML-MRC. The liposomal daunorubicin and liposomal cytarabine is paid for by alternative funding sources (e.g. patient support program, private insurance, hospital budget). Can my patient be transitioned to receive public funding under the New Drug Funding Program (NDFP)?**

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 under the NDFP. Please submit a prior approval request including a clinic note from initiation of therapy and the most recent clinic note (if applicable).

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

Only outpatient treatment claims should be submitted under this policy. Doses administered in the outpatient setting are submitted as per the site's usual procedure. Inpatient administered doses must be submitted under the policy "Liposomal Daunorubicin and Liposomal Cytarabine (Inpatient) – Previously Untreated Acute Myeloid Leukemia (AML)". Sites using DSP or HL7 must submit inpatient claims manually until March 13, 2023 (as per communication on Aug 10, 2022). Please ensure to select "inpatient" as the treatment setting for each claim.

Supporting Documents

None required at time of enrolment.

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

- Pathology report confirming t-AML or AML-MRC
- Clinic note(s) discussing prior cytotoxic and/or radiation therapy for an unrelated disease which preceded the diagnosis of t-AML
- Pathology report confirming CR or CRi post induction

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

....
Day Month Year

Form 974