

Nelarabine - Newly Diagnosed T-cell Acute Lymphoblastic 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 (m²):

* 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:
- | | |
|---|---|
| <input type="radio"/> 1-Unknown primary (submit pathology report and clinic note) | <input type="radio"/> 2-Clinical document review (identify the patient history that needs to be reviewed against eligibility criteria in Additional Comments below) |
| <input type="radio"/> 3-Regimen modification - schedule (complete questions a and b) | <input type="radio"/> 4-Regimen modification - drug substitutions (complete questions a and c) |
| <input type="radio"/> 5-Withholding a drug in combination therapy from start of treatment (complete questions d, e and f) | <input type="radio"/> 6-Maintenance therapy delay (submit clinic note) |
| <input type="radio"/> 7-Prior systemic therapy clinical trials (complete question g) | <input type="radio"/> 8-Modification due to supply interruption/drug shortage |
| <input type="radio"/> 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:

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2. Eligibility Criteria

Nelarabine is used in addition to front-line multiagent chemotherapy for the treatment of patients aged 1 to 30 years with newly diagnosed intermediate- or high-risk T-cell acute lymphoblastic leukemia (T-ALL). ☐ Yes

3. Funded Dose

Nelarabine 650 mg/m²/day given intravenously (IV) on 5 consecutive days, when administered with a multiagent chemotherapy regimen.

Treatment should continue until disease progression, unacceptable toxicity, or completion of six 5-day courses, whichever comes first.

[ST-QBP regimen code(s): ABFM+NELA(CONS), ABFM+NELA(DELAYEDINT), ABFM+NELA(MNT)]

4. Notes

1. Patients must not have pre-existing peripheral neurotoxicity of grade 2 or greater as per the National Cancer Institute's Common Terminology Criteria for Adverse Events (CTCAE).

Supporting Documents

None required at the time of enrolment.

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

- Clinic note(s) detailing the patient's diagnosis, risk stratification, and protocol.

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

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Day Month Year