

Regimen Monograph

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A - Regimen Name

ABFM+NELA(DELAYEDINT) Regimen

Augmented Berlin-Frankfurt-Münster regimen (Delayed Intensification) - Nelarabine

Disease Site Hematologic
Leukemia - Acute Lymphoblastic (ALL)

Intent Curative

Regimen Category **evidence-informed :**

Regimen is considered appropriate as part of the standard care of patients; meaningfully improves outcomes (survival, quality of life), tolerability or costs compared to alternatives (recommended by the Disease Site Team and national consensus body e.g. pan-Canadian Oncology Drug Review, pCODR). Recommendation is based on an appropriately conducted phase III clinical trial relevant to the Canadian context OR (where phase III trials are not feasible) an appropriately sized phase II trial. Regimens where one or more drugs are not approved by Health Canada for any indication will be identified under Rationale and Use.

This **Regimen Abstract** is an **abbreviated** version of a Regimen Monograph and contains only top level information on usage, dosing, schedule, cycle length and special notes (if available). Information in regimen abstracts is accurate to the extent of the ST-QBP regimen master listings, and has not undergone the full review process of a regimen monograph. Full regimen monographs will be published for each ST-QBP regimen as they are developed.

The information provided in this document is intended for use only in the management of adults with leukemia, and for cancer centres with expertise in treating acute leukemia.

Rationale and Uses Treatment of adult patients (up to 30 years) with newly diagnosed intermediate- or high-risk T-cell acute lymphoblastic leukemia (T-ALL)

**Supplementary
Public Funding**

[thioguanine](#)

ODB - General Benefit (thioguanine) ([ODB Formulary](#))

[pegaspargase](#)

New Drug Funding Program (Pegaspargase (Outpatient) - Adult Acute Lymphoblastic Leukemia (ALL) Lymphoblastic Lymphoma Mixed or Biphenotypic Leukemia) ([NDFP Website](#))

[calaspargase pegol](#)

New Drug Funding Program (Calaspargase Pegol (Outpatient) - Newly Diagnosed Acute Lymphoblastic Leukemia, Lymphoblastic Lymphoma or Mixed_Biphenotypic Leukemia) ([NDFP Website](#))

[nelarabine](#)

New Drug Funding Program (Nelarabine - Newly Diagnosed T-cell Acute Lymphoblastic Leukemia) ([NDFP Website](#))

dexamethasone

ODB - General Benefit (dexamethasone) ([ODB Formulary](#))

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B - Drug Regimen**Based on the AALL0434 protocol:**

dexamethasone	5 mg /m ²	IV / PO	BID on Days 1-7, 15-21
vinCRISTine	1.5 mg /m ²	IV	Days 1, 8, 15, 50
(maximum 2 mg per dose)			
DOXOrubicin	25 mg /m ²	IV	Day 1, 8, 15
methotrexate	15 mg	IT	Days 1, 36, 43
pegaspargase [†]	2500 units /m ²	IV / IM	Day 4 or 5 or 6 AND Day 50
nelarabine	650 mg /m ²	IV	Days 29-33
cyclophosphamide	1000 mg /m ²	IV	Day 36
cytarabine	75 mg /m ²	IV / Subcut	Days 36-39, 43-46
thioguanine	60 mg /m ²	PO	Days 36-49*

*Omit thioguanine doses in patients receiving cranial radiotherapy during delayed intensification.

[†]May consider calaspargase pegol instead of pegaspargase. Switches may be considered based on product availability; however, patients should not be switched from pegaspargase to calaspargase pegol (or vice versa) for toxicity or silent inactivation.

Different asparaginase products are **not interchangeable** and dosing schedules are different. For example, giving calaspargase pegol at the same dose and frequency as pegaspargase may result in higher asparaginase activity exposures, which may increase toxicities. Refer to local protocols for dosing information.

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C - Cycle Frequency

One 9-week cycle, followed by ABFM+NELA(MNT)

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D - Premedication and Supportive Measures

Antiemetic Regimen: Moderate (Days 1, 8, 15, 36)
Low (Days 37-39, 43-46)
Minimal (Other treatment days)

Other Supportive Care:

- Also refer to [CCO Antiemetic Recommendations](#).
- Antiemetics should be given as per institutional guidelines.
- Consider PJP and other prophylaxis for infection based on institutional guidelines.

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J - Administrative Information

Pharmacy Workload (average time per visit) 31.424 minutes

Nursing Workload (average time per visit) 52.806 minutes

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K - References

Angiolillo AL, Schore RJ, Devidas M, et al. Pharmacokinetic and pharmacodynamic properties of calaspargase pegol Escherichia coli L-asparaginase in the treatment of patients with acute lymphoblastic leukemia: results from Children's Oncology Group Study AALL07P4. J Clin Oncol 2014 Dec 1;32(34):3874-82.

CADTH reimbursement recommendation: Calaspargase Pegol (Asparlas; acute lymphoblastic leukemia). Canadian Journal of Health Technologies 2024 January;4(1).

CADTH reimbursement review. Calaspargase Pegol (Asparlas; acute lymphoblastic leukemia). Canadian Journal of Health Technologies 2024 April;4(4).

CADTH reimbursement recommendation: Nelarabine (for addition to front-line multiagent therapy of pediatric, adolescent, and young adult patients (aged 1 year to 30 years at diagnosis) with intermediate- or high-risk T-cell acute lymphoblastic leukemia). October 2023.

Dunsmore KP, Winter SS, Devidas M, et al. Children's Oncology Group AALL0434: A phase III randomized clinical trial testing nelarabine in newly diagnosed T-cell acute lymphoblastic leukemia. J Clin Oncol. 2020 Oct 1;38(28):3282-93. doi: 10.1200/JCO.20.00256.

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M - Disclaimer

Regimen Abstracts

A Regimen Abstract is an abbreviated version of a Regimen Monograph and contains only top level information on usage, dosing, schedule, cycle length and special notes (if available). It is intended for healthcare providers and is to be used for informational purposes only. It is not intended to constitute or be a substitute for medical advice, and all uses of the Regimen Abstract are subject to clinical judgment. Such information is provided on an "as-is" basis, without any representation, warranty, or condition, whether express, or implied, statutory or otherwise, as to the information's quality, accuracy, currency, completeness, or reliability, and Cancer Care Ontario disclaims all liability for the use of this information, and for any claims, actions, demands or suits that arise from such use.

Information in regimen abstracts is accurate to the extent of the ST-QBP regimen master listings, and has not undergone the full review process of a regimen monograph. Full regimen monographs will be published for each ST-QBP regimen as they are developed.

Regimen Monographs

Refer to the [New Drug Funding Program](#) or [Ontario Public Drug Programs](#) websites for the most up-to-date public funding information.

The information set out in the drug monographs, regimen monographs, appendices and symptom management information (for health professionals) contained in the Drug Formulary (the "Formulary") is intended for healthcare providers and is to be used for informational purposes only. The information is not intended to cover all possible uses, directions, precautions, drug interactions or adverse effects of a particular drug, nor should it be construed to indicate that use of a particular drug is safe, appropriate or effective for a given condition. The information in the Formulary is not intended to constitute or be a substitute for medical advice and should not be relied upon in any such regard. All uses of the Formulary are subject to clinical judgment and actual prescribing patterns may not follow the information provided in the Formulary.

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Some Formulary documents, such as the medication information sheets, regimen information sheets and symptom management information (for patients), are intended for patients. Patients should always consult with their healthcare provider if they have questions regarding any information set out in the Formulary documents.

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