Regimen Monograph

A - Regimen Name

ABFM(INTERIM MNT) Regimen

Augmented Berlin-Frankfurt-Münster regimen (Interim Maintenance)

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

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B - Drug Regimen

Based on the AALL0434 protocol:

vinCRIStine	1.5 mg /m²	IV	Days 1, 11, 21, 31, 41
(maximum 2 mg per dose)			
methotrexate	100 mg /m²	IV	Day 1, 11, 21, 31, 41

* Dose escalated by 50 mg/m^2 every 10 days, adjusted for toxicity

methotrexate	15 mg	IT	Days 1, 31
pegaspargase	2500 units /m²	IV / IM	Days 2, 22

In the AALL0434 study, select patients received high-dose methotrexate (in-patient) as part of a different arm for interim maintenance. Refer to the protocol for details.

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C - Cycle Frequency

One 8-week cycle, followed by the Delayed Maintenance phase

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D - Premedication and Supportive Measures

Antiemetic Regimen: Low (Days 1, 11, 21 – methotrexate < 250 mg/m2)
Moderate (Days 31, 41 - if methotrexate escalated to ≥ 250 mg/m2)
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)	17.604 minutes
Nursing Workload (average time per visit)	38.611 minutes

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K - References

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.

April 2024 new ST-QBP regimen

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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.

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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.

The format and content of the drug monographs, regimen monographs, appendices and symptom management information contained in the Formulary will change as they are reviewed and revised on a periodic basis. The date of last revision will be visible on each page of the monograph and regimen. Since standards of usage are constantly evolving, it is advised that the Formulary not be used as the sole source of information. It is strongly recommended that original references or product monograph be consulted prior to using a chemotherapy regimen for the first time.

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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