Regimen Monograph

Regimen Name | Drug Regimen | Cycle Frequency | Premedication and Supportive Measures | Administrative Information | References | Other Notes | Disclaimer

A - Regimen Name

AALL1131(CONS) Regimen

Methotrexate (IT)-Cyclophosphamide-Mercaptopurine-Cytarabine-Vincristine-Pegaspargase

Disease Site

Hematologic
Leukemia - Acute Lymphoblastic (ALL)

Intent

Curative
Palliative

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.

Supplementary Public Funding

mercaptopurine
ODB - General Benefit (mercaptopurine) (ODB Formulary)

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

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

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B - Drug Regimen

methotrexate	15 mg	IT	Days 1, 8, 15, 22
cyclophosphamide	1000 mg /m²	IV	Days 1 and 29
cytarabine	75 mg /m²	Subcut	Days 1-4, 8-11, 29-32, 36-39
mercaptopurine	60 * mg /m²	PO	Days 1-14, 29-42

(*Suggested starting dose. Adjust dose based on thiopurine S-methyltransferase (TPMT) status)

pegaspargase^	Refer to local protocols for dosing information		
vinCRIStine	1.5 mg /m²	IV (maximum 2 mg)	Days 15, 22, 43, 50

^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

SINGLE 56-DAY CYCLE

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D - Premedication and Supportive Measures

Antiemetic Regimen: Moderate (D1, 29)
Minimal (All other days)

Other Supportive Care:

Also refer to CCO Antiemetic Recommendations.

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J - Administrative Information

Pharmacy Workload (average time per visit)	15.561 minutes
Nursing Workload (average time per visit)	45.083 minutes

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K - References

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).

Children's Oncology Group AALL1131 Protocol

Salzer WL, Burke MJ, Devidas M, et al. Toxicity associated with intensive postinduction therapy incorporating clofarabine in the very high-risk stratum of patients with newly diagnosed high-risk B-lymphoblastic leukemia: A report from the Children's Oncology Group study AALL1131. Cancer. 2018 Mar 15;124(6):1150-9.

November 2024 Updated info on non-interchangeability of asparaginase formulations in section B

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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.

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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