

Regimen Monograph

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A - Regimen Name

ALL-R3(INT) Regimen

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.

**Supplementary
Public Funding****[calaspargase pegol](#)**

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

[pegaspargase](#)

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

dexamethasone

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

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B - Drug Regimen**Intensification (Weeks 9 to 12):**

cytarabine	3000 mg /m ²	IV	q12h; Days 1, 2, 8, 9
dexamethasone	3 mg /m ²	PO	BID; Days 1-5
methotrexate	12 mg	IT	Days 1 and 22

Patients who have CNS disease at presentation should receive weekly doses until two clear CSF samples are obtained.

pegaspargase [^]	Refer to local protocols for dosing information		
vinCRISTine	1.5 mg /m ²	IV (maximum 2 mg)	Day 3
methotrexate	1000 mg /m ²	IV over 36 hours	Day 22
leucovorin	15 mg /m ²	IV	at 48 and 54 hours after start of methotrexate infusion

Followed by:

leucovorin	12 mg /m ²	IV	q6h until methotrexate level is ≤ 0.1 micromol/L
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[^]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 4-WEEK COURSE**[back to top](#)**D - Premedication and Supportive Measures**

Antiemetic Regimen: Moderate (D1, 2, 8, 9, 22)
Minimal (All other days)

Other Supportive Care:

Also refer to [CCO Antiemetic Recommendations](#).

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Pharmacy Workload (average time per visit) 21.077 minutes

Nursing Workload (average time per visit) 76.323 minutes

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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).

Masurekar AN, Parker CA, Shanyinde M, et al. Outcome of central nervous system relapses in childhood acute lymphoblastic leukaemia--prospective open cohort analyses of the ALLR3 trial. PLoS One 2014;9(10):e108107.

Masurekar A, Fong C, Hussein A, et al. The optimal use of PEG-asparaginase in relapsed ALL-lessons from the ALLR3 Clinical Trial. Blood Cancer J 2014;4:e203.

Parker C, Waters R, Leighton C, et al. Effect of mitoxantrone on outcome of children with first relapse of acute lymphoblastic leukaemia (ALL R3): an open-label randomised trial. *Lancet* 2010;376(9757):2009-17.

Sun W, Orgel E, Malvar J, et al. Treatment-related adverse events associated with a modified UK ALLR3 induction chemotherapy backbone for childhood relapsed/refractory acute lymphoblastic leukemia. *Pediatr Blood Cancer*. 2016 Nov;63(11):1943-8.

November 2024 Updated info on non-interchangeability of asparaginase products 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.

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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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