

## Regimen Monograph

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## A - Regimen Name

# ALEM Regimen

Alemtuzumab

**Disease Site** Hematologic - Lymphoma - T-cell  
Hematologic - Rare Diseases  
(for Mycosis Fungoides/Sézary syndrome)

**Intent** 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.

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**B - Drug Regimen****Week 1:**

<a href="#">alemtuzumab</a> <sup>a, b, c</sup>	3 mg	IV / Subcut *	(first dose)
<a href="#">alemtuzumab</a> <sup>a, b, c</sup>	10 mg	IV / Subcut *	(second dose)
<a href="#">alemtuzumab</a> <sup>a, b, c</sup>	30 mg	IV / Subcut *	(third dose)

(This drug is not publicly funded. Universal compassionate access program is available. )

**Weeks 2 to 13:**

<a href="#">alemtuzumab</a> <sup>a, b, c</sup>	30 mg	IV / Subcut *	3 times per week
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(This drug is not publicly funded. Universal compassionate access program is available. )

a. Although not approved by Health Canada, alemtuzumab has been given subcutaneously instead of intravenously; the incidence of infusion reactions may be lower.

b. Gradual dose escalation is required at the initiation of therapy and after treatment interruptions of 7 days or more. In most patients, escalation to 30mg can be accomplished in 3-7 days. Initial doses can be administered in various ways; sequentially (daily on days 1 to 3) and on alternate days (i.e. days 1, 3, and 5). Both schedules were used in clinical trials.

c. Single doses of alemtuzumab greater than 30 mg or cumulative weekly doses of greater than 90 mg should not be administered since higher doses are associated with an increased incidence of pancytopenia.

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**C - Cycle Frequency**

For a usual total of 13 weeks (1 week dose escalation, 12 weeks maintenance), unless disease progression or unacceptable toxicity occurs.

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**D - Premedication and Supportive Measures**

**Antiemetic Regimen:** Minimal

**Other Supportive Care:**

- Diphenhydramine 50mg PO and acetaminophen 650mg PO 30 minutes before infusion; add meperidine 25mg IV and hydrocortisone 200mg IV with  $\geq$  grade 3 reaction with prior infusion
- Trimethoprim/sulfamethoxazole DS twice daily three times per week and famciclovir (or equivalent) 250mg bid during treatment and for 2 months after or until CD4+ count  $\geq$  200 cell/uL
- Allopurinol and hydration to reduce the risk of tumour lysis syndrome are recommended.

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**J - Administrative Information**

Approximate Patient Visit	IV: 3 hours; SC: 1 hour
Pharmacy Workload (average time per visit)	8.334 minutes
Nursing Workload (average time per visit)	32.33 minutes

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**K - References**

Alemtuzumab drug monograph, Cancer Care Ontario.

Lundin J, Hagberg H, Repp R, et al. Phase 2 study of alemtuzumab (anti-CD52 monoclonal antibody) in patients with advanced mycosis fungoides/Sézary syndrome. *Blood* 2003;101(11) 4267-4272.

**September 2019** New ST-QBP regimen

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**M - Disclaimer****Regimen Abstracts**

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*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.*

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