Regimen Monograph

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

A - Regimen Name

PENT+ALEM Regimen

Pentostatin-Alemtuzumab

Disease Site Hematologic - Lymphoma - T-cell

Hematologic - Rare Diseases

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.

Rationale and Uses

For the treatment of T-Cell neoplasms.

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| R- | Drug | Rec | mir | ۵n |
|------------|------|-----|-------|-----|
| D - | Diuq | Ver | 41111 | CI. |

pentostatin 4 mg /m² IV Day 1; Q7 Days x 4 doses

(This drug is not currently publicly funded for this regimen and intent)

THEN

pentostatin 4 mg/m² IV Days 1 and 15

(This drug is not currently publicly funded for this regimen and intent)

Q28 Days

AND

Week 1:

| <u>alemtuzumab</u> ^{a, b, c} | 3 mg | IV / Subcut * | (first dose) |
|---------------------------------------|-------|---------------|---------------|
| alemtuzumab ^{a, b, c} | 10 mg | IV / Subcut * | (second dose) |

<u>alemtuzumab</u>^{a, b, c} 30 mg IV / Subcut * (third dose)

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

Weeks 2+:

alemtuzumab^{a, b, c} 30 mg IV / Subcut * 3 times per week

(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

Alemtuzumab: Until CR or best response, for a usual total of up to 13 weeks, unless disease progression or unacceptable toxicity occurs.

Pentostatin: Until CR or best response, for a usual total of up to 14 doses (weekly for 4 weeks then every 2 weeks for up to 10 doses), unless disease progression or unacceptable toxicity occurs.

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D - Premedication and Supportive Measures

Antiemetic Regimen: Minimal (Alemtuzumab)

Low (Pentostatin)

Other Supportive Care:

Premedication (prophylaxis for infusion reactions):

Administer 30 minutes prior to IV/SC alemtuzumab*:

- H1-receptor antagonist (e.g. diphenhydramine 50 mg IV)
- Acetaminophen 650 mg PO

Other supportive care:

- 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 is ≥ 200 cells/microL.
- Consider antifungal prophylaxis (e.g. fluconazole)
- Allopurinol and hydration to reduce the risk of tumour lysis syndrome are recommended.
- Irradiated blood products should be used.

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J - Administrative Information

Approximate Patient Visit PENT: 1.5 to 2.5 hours; ALEM (IV): 2.5 to 3 hours; ALEM

(SC): 0.5 to 1 hour

Pharmacy Workload (average time per visit) 8.33 minutes

Nursing Workload (average time per visit) 32.33 minutes

^{*}Can consider corticosteroids (methylprednisolone 1g) on the first 3 days

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K - References

Alemtuzumab drug monograph, Cancer Care Ontario.

Ravandi F, Aribi A, O'Brien S, et al. Phase II study of alemtuzumab in combination with pentostatin in patients with T-cell neoplasms. J Clin Oncol 2009;27:5425-5430.

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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 <u>New Drug Funding Program</u> or <u>Ontario Public Drug Programs</u> websites for the most up-to-date public funding information.

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