Regimen Monograph

A - Regimen Name

CLAD Regimen

Cladribine

Disease Site	Hematologic - Leukemia - Hairy Cell Hematologic - Lymphoma - Non-Hodgkin's Low Grade
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.
Rationale and Uses	Treatment of hairy cell leukemia

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B - Drug Regimen

cladribine	0.12-0.14 mg /kg	IV over 2 hours	Days 1 to 5

Alternative Schedules:

cladribine	0.09-0.1 mg /kg/day	IV over 24 hours as continuous infusion	Days 1 to 5 OR Days 1 to 7
cladribine	0.14 mg /kg	IV	Weekly for 6 weeks

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C - Cycle Frequency

SINGLE COURSE (DAILY SCHEDULE)

EVERY 7 DAYS X 6 WEEKS (WEEKLY SCHEDULE)

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D - Premedication and Supportive Measures

Antiemetic Regimen: Minimal

Other Supportive Care:
Prophylaxis of neutropenia with filgrastim may be used following the single cycle.

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E - Dose Modifications

Dosage with toxicity

Toxicity	Cladrabine dose
Myelosuppression	No adjustment required. Consider delay until recovery to baseline counts.
Neurotoxicity	Delay or discontinue, depending on severity
Nephrotoxicity	Delay or discontinue, depending on severity. See dosage with renal impairment table.

Hepatic Impairment

Exercise caution. No formal recommendations found.

Renal Impairment

Creatinine clearance	Cladribine (% dose)
≥ 50	100%
10-50	75%
≤ 10	50%

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F - Adverse Effects

Refer to cladribine drug monograph(s) for additional details of adverse effects

Most Common Side Effects	Less Common Side Effects, but may be Severe or Life-Threatening
• Myelosuppression ± infection (including opportunistic), bleeding (may be severe) • Fever • Fatigue • Nausea, vomiting • Rash (may be severe) • Headache • Injection site reaction • Abdominal pain • Anorexia • Constipation • Diarrhea • Dizziness, insomnia	• Venous thromboembolism • Hypersensitivity • Hemolysis • Nephrotoxicity • Neurotoxicity (more common with high doses) • Pneumonitis • Tumour lysis syndrome • Secondary malignancy

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G - Interactions

Refer to cladribine drug monograph(s) for additional details

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H - Drug Administration and Special Precautions

Refer to cladribine drug monograph(s) for additional details

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I - Recommended Clinical Monitoring

Treating physicians may decide to monitor more or less frequently for individual patients but should always consider recommendations from the product monograph.

Recommended Clinical Monitoring

- CBC; Baseline, at each visit and as clinically indicated, especially during the first 4 to 8 weeks after treatment
- Renal and liver function tests; Baseline, at each visit and as clinically indicated, especially with underlying renal or hepatic impairment
- Uric acid; Baseline and as clinically indicated, especially when treatment is initiated and in patients at risk of tumour lysis syndrome
- Clinical toxicity assessment for fever, infection, bleeding, rash, neurotoxicity, fatigue and GI toxicity; At each visit

- Grade toxicity using the current NCI-CTCAE (Common Terminology Criteria for Adverse Events) version

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J - Administrative Information

Approximate Patient Visit	Cladribine CIV: 0.5 hour; daily infusion: 2 hours
Pharmacy Workload (average time per visit)	14.184 minutes
Nursing Workload (average time per visit)	35 minutes

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K - References

Cladribine drug monograph, Cancer Care Ontario.

Else M, Dearden CE, Matutes E, et al. Long-term follow-up of 233 patients with hairy cell leukaemia, treated initially with pentostatin or cladribine, at a median of 16 years from diagnosis. British Journal of Haematology 2009; 145: 733–40.

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Morton J, Taylor K, Bunce I, et al. High response rates with short infusional 2-chlorodeoxyadenosine in novo and relapsed low-grade lymphoma. Australian and New Zealand Lymphoma Study Group. Br

J Haematol. 1996 Oct; 95(1): 110-5.

Piro L, Carrera C, Carson D et al. Lasting remissions in hairy cell leukemia induced by a single infusion of 2-chlordeoxyadenosine. N Engl J Med. 1990 Apr 10; 322 (16): 1117-21.

Robak T, Jamroziak K, Gora-Tybor J, et al. Cladribine in a weekly versus daily schedule for untreatedactive hairy cell leukemia: final report from the Polish Adult Leukemia Group (PALG) of a prospective, randomized, multicenter trial. Blood. 2007 May 1;109(9):3672-5.

Saven A, Piro LD. Treatment of hairy cell leukemia. Blood, 1992; 79: 1111-1120.

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January 2018 aligned disease site to ST-QBP

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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.

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