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
### B - Drug Regimen

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>Route</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cladribine</td>
<td>0.12-0.14 mg/kg</td>
<td>IV over 2 hours</td>
<td>Days 1 to 5</td>
</tr>
</tbody>
</table>

**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

### C - Cycle Frequency

**SINGLE COURSE (DAILY SCHEDULE)**

**EVERY 7 DAYS X 6 WEEKS (WEEKLY SCHEDULE)**

### D - Premedication and Supportive Measures

**Antiemetic Regimen:** Minimal

**Other Supportive Care:**

Prophylaxis of neutropenia with filgrastim may be used following the single cycle.
E - Dose Modifications

Dosage with toxicity

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>Cladrabine dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myelosuppression</td>
<td>No adjustment required. Consider delay until recovery to baseline counts.</td>
</tr>
<tr>
<td>Neurotoxicity</td>
<td>Delay or discontinue, depending on severity</td>
</tr>
<tr>
<td>Nephrotoxicity</td>
<td>Delay or discontinue, depending on severity. See dosage with renal impairment table.</td>
</tr>
</tbody>
</table>

Hepatic Impairment

Exercise caution. No formal recommendations found.

Renal Impairment

<table>
<thead>
<tr>
<th>Creatinine clearance</th>
<th>Cladribine (% dose)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥ 50</td>
<td>100%</td>
</tr>
<tr>
<td>10-50</td>
<td>75%</td>
</tr>
<tr>
<td>≤ 10</td>
<td>50%</td>
</tr>
</tbody>
</table>

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### F - Adverse Effects

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

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

### G - Interactions

Refer to cladribine drug monograph(s) for additional details

### H - Drug Administration and Special Precautions

Refer to cladribine drug monograph(s) for additional details
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

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

K - References

Cladribine drug monograph, Cancer Care Ontario.


**January 2018** aligned disease site to ST-QBP
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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