Regimen Monograph

Regimen Name | Drug Regimen | Cycle Frequency | Premedication and Supportive Measures | Dose Modifications | Adverse Effects | Interactions | Drug Administration and Special Precautions | Recommended Clinical Monitoring | Administrative Information | References | Other Notes | Disclaimer

A - Regimen Name

CLAD Regimen

Cladribine

Disease Site	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.
Rationale and Uses	Treatment of aggressive systemic mastocytosis

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B - Drug Regimen

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

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C - Cycle Frequency

REPEAT EVERY 28 DAYS

Up to 9 cycles

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D - Premedication and Supportive Measures

Antiemetic Regimen: Minimal

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E - Dose Modifications

Doses should be modified according to the protocol by which the patient is being treated.

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 cycle 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.

Barete S, Lortholary O, Damaj G, et al. Long-term efficacy and safety of cladribine (2-CdA) in adult patients with mastocytosis. Blood. 2015 Aug 20;126(8):1009-16.

Lim KH, Pardanani A, Butterfield JH, et al. Cytoreductive therapy in 108 adults with systemic mastocytosis: Outcome analysis and response prediction during treatment with interferon-alpha, hydroxyurea, imatinib mesylate or 2-chlorodeoxyadenosine. Am J Hematol 2009;84(12):790-4.

Marlies EHM, Van Hoef. Cladribine in the Treatment of Systemic Mastocytosis, a Review of the Literature. Int J Rare Dis Disord 2019;2:007. Am J Hematol .

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July 2021 new ST-QBP regimen

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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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