#### Regimen Monograph

Regimen Name | Drug Regimen | Cycle Frequency | Administrative Information | References | Other Notes | Disclaimer

# A - Regimen Name

# **CLAD+RITU Regimen**

Cladribine-riTUXimab

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.

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.

## Supplementary Public Funding

## riTUXimab

New Drug Funding Program (Rituximab (Biosimilar IV) and Rituximab SC in Combination with Chemotherapy - Indolent B-cell Lymphoma) (Funded for Biosimilar IV only )

#### riTUXimab

New Drug Funding Program (Rituximab (Biosimilar IV) and Rituximab SC - Maintenance Treatment - Lymphoma)

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# **B** - Drug Regimen

**Note:** Different rituximab products are NOT INTERCHANGEABLE.

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

riTUXimab<sup>1,2</sup> 375 mg /m<sup>2</sup> IV weekly x 4 to 8 weeks

## **Alternative Schedule:**

<u>cladribine</u> 0.09-0.1 mg /kg/day IV over 24 hours as Days 1 to 5 OR Days

continuous infusion 1 to 7

riTUXimab<sup>1,2</sup> 375 mg /m<sup>2</sup> IV weekly x 4 to 8 weeks

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# C - Cycle Frequency

## SINGLE COURSE (cladribine)

**WEEKLY FOR 4 TO 8 WEEKS (rituximab)** 

Maintenance rituximab (responding "rituximab-naïve" patients only): REPEAT EVERY 3 MONTHS for maximum 2 years (8 doses total) of rituximab maintenance treatment in the absence of unacceptable toxicity or disease progression.

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<sup>&</sup>lt;sup>1</sup> rituximab can be given concurrently or following cladribine

<sup>&</sup>lt;sup>2</sup> only rituximab IV is funded via NDFP

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## J - Administrative Information

Approximate Patient Visit CLAD CIV: 0.5 hour; daily infusion: 2 hours; RITU: 3 to 5

hours

Pharmacy Workload (average time per visit) 24.63 minutes

Nursing Workload (average time per visit) 62.333 minutes

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## K - References

Cladrabine and rituximab drug monographs, 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.

Else M, Osuji N, Francesco F, et al. The role of rituximab in combination With pentostatin or cladribine for the treatment of recurrent/refractory hairy cell leukemia. Cancer 2007; 110: 2240-7.

Lauria F, Cencini E, Forconi F. Alternative methods of cladribine administration. Leuk Lymphoma. 2011 Jun;52 Suppl 2:34-7.

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.

Nieva J, Bethel K, Saven A, et al.: Phase II study of rituximab in the treatment of cladribine-failed patients with hairy cell leukemia. Blood 2003 Aug 1;102(3):810-3.

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.

Zinzani PL, Pellegrini C, Stefoni V, et al. Hairy cell leukemia: evaluation of the long-term outcome in 121 patients. Cancer. 2010 Oct 15;116(20):4788-92.

#### **PEBC Advice Documents or Guidelines**

Rituximab in Lymphoma and Chronic Lymphocytic Leukemia

August 2020 Updated NDFP forms and interchangeability information in Drug Regimen section

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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 <u>New Drug Funding Program</u> or <u>Ontario Public Drug Programs</u> 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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