Regimen Monograph

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

A - Regimen Name

CHLO+RITU Regimen

Chlorambucil-riTUXimab

Disease Site 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.

Rationale and Uses Treatment of follicular lymphoma or other indolent histology, CD20-positive B-cell lymphoma (**excluding** small lymphocytic lymphoma, CLL), in patients who:

- Have not received previous treatment with rituximab for indolent B-cell lymphoma
- Have previously received rituximab (including combination rituximab-chemotherapy and/or rituximab monotherapy or maintenance rituximab) and have sustained a response and remained disease-free for at least 6 months after the last dose of rituximab

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Refer to the NDFP eligibility forms for detailed funding criteria.

Supplementary Public Funding

riTUXimab
New Drug Funding Program (Rituximab (Biosimilar IV) and Rituximab SC in Combination with Chemotherapy - Indolent B-cell Lymphoma) (NDFP Website)

riTUXimab
New Drug Funding Program (Rituximab (Biosimilar IV) and Rituximab SC - Retreatment - Indolent Lymphoma) (NDFP Website) (in combination with chemotherapy)

chlorambucil
ODB - General Benefit (chlorambucil) (ODB Formulary)

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

riTUXimab (subcut)
New Drug Funding Program (Rituximab (Biosimilar IV) and Rituximab SC - Retreatment - Indolent Lymphoma) (in combination with chemotherapy)

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B - Drug Regimen

Note: Different rituximab products are NOT INTERCHANGEABLE.

Cycle 1: All patients must receive their first dose of rituximab by IV infusion

riTUXimab	375 mg /m²	IV	Day 1
chlorambucil	6 mg /m²	PO	Daily for 14 days

(Outpatient presription in multiples of 2mg tablets)

Cycle 2 and onwards (up to 6-8 cycles in total, including initial IV rituximab cycle(s))

riTUXimab	375 mg /m²	IV	Day 1

OR

Rituximab subcutaneous:

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The subcutaneous formulation must only be given at the second or subsequent cycles, and only after at least 1 full rituximab IV dose.

riTUXimab (subcut)	1400 mg	Subcut	Day 1

Plus CHLO chemotherapy

chlorambucil	6 mg /m²	PO	Daily for 14 days

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C - Cycle Frequency

REPEAT EVERY 28 DAYS For a total of 6-8 cycles in absence of disease progression or unacceptable toxicity

For patients who responded to induction therapy, and were rituximab-naïve prior to induction, refer to maintenance rituximab regimen - RITU(MNT) or RITU(MNT-SC).

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J - Administrative Information

Chlorambucil: Outpatient prescription for home administration

Approximate Patient Visit	0.75 to 5 hours
Pharmacy Workload (average time per visit)	20.946 minutes
Nursing Workload (average time per visit)	69.167 minutes

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K - References

Bauwens D, Maerevoet M, Michaux L, et al. Activity and safety of combined rituximab with chlorambucil in patients with mantle cell lymphoma. Br J Haematol. 2005 Nov;131(3):338-40.

Chlorambucil and rituximab drug monographs, Cancer Care Ontario.

Laszlo D, Rabascio C, Andreola G, et al. Chlorambucil-rituximab as first-line combination therapy in follicular non-Hodgkin's lymphoma: a clinical and biological analysis. Leukemia & Lymphoma 2007; 48(2): 437–8.

Martinelli G, Laszlo D, Bertolini F, et al. Chlorambucil in combination with induction and maintenance rituximab is feasible and active in indolent non-Hodgkin's lymphoma. Br J Haematol 2003; 123(2): 271-7.

Salar A, Casao D, Cervera M, et al. Rapid infusion of rituximab with or without steroid-containing chemotherapy: 1-yr experience in a single institution. Eur J Haematol 2006: 77: 338–340.

Sehn LH, Donaldson J, Filewich A, et . al. Rapid Infusion Rituximab in Combination with Steroid Containing Chemotherapy Can Be Given Safely and Substantially Reduces Resource Utilization. Blood 2004; 104(11): A1407.

Davies A, Merli F, Mihaljević B, et al. Efficacy and safety of subcutaneous rituximab versus

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intravenous rituximab for first-line treatment of follicular lymphoma (SABRINA): a randomised, open-label, phase 3 trial. Lancet Haematol. 2017 Jun;4(6):e272-e282

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 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.

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Some Formulary documents, such as the medication information sheets, regimen information sheets and symptom

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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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