Regimen Monograph

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

A - Regimen Name

FC+R Regimen

Fludarabine-Cyclophosphamide-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* after disease progression following first-line treatment, 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

*__excluding__ small lymphocytic lymphoma, CLL

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) (with combination chemotherapy)

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

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

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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[1]	375 mg /m²	IV	Day 1
(1) Give on day 1 before FC			
fludarabine	25 mg /m²	IV	Days 1 to 3
cyclophosphamide	250 mg /m²	IV	Days 1 to 3

Cycle 2 and onwards: (For a usual total of 6 cycles, including initial IV rituximab cycle(s))

Rituximab IV:

riTUXimab[1, 2]	375 mg /m²	IV	Day 1

OR

Rituximab subcutaneous:

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 FC chemotherapy

fludarabine	25 mg /m²	IV	Days 1 to 3
cyclophosphamide	250 mg /m²	IV	Days 1 to 3

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C - Cycle Frequency

REPEAT EVERY 28 DAYS until evidence of desired disease response or for usual total of 6 cycles.

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

Approximate Patient Visit	Day 1: 2-6 hours; Days 2-3: 1 hour
Pharmacy Workload (average time per visit)	26.889 minutes
Nursing Workload (average time per visit)	54.389 minutes

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K - References

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

Eucker J,Schille C,Schmid P, et al. The combination of fludarabine and cyclophosphamide results in a high remission rate with moderate toxicity in low-grade non-Hodgkin's lymphomas. Anti-Cancer Drugs 2002;13:907–13.

Fludarabine, cyclophosphamide, rituximab drug monographs, Cancer Care Ontario.

Sacchi S, Pozzi S, Marcheselli R, et al. Rituximab in combination with fludarabine and cyclophosphamide in the treatment of patients with recurrent follicular lymphoma. Cancer 2007 Jul 1;110(1):121-8.

Tam CS, Wolf M, Prince HM, Januszewicz EH, et al. Fludarabine, cyclophosphamide, and rituximab for the treatment of patients with chronic lymphocytic leukemia or indolent non-Hodgkin lymphoma. Cancer. 2006 Jun 1;106(11):2412-20.

Thomas DW, Owen RG, Johnson SAN, et al. Superior quality and duration of responses among patients with mantle cell lymphoma treated with fludarabine and cyclophosphamide with or without rituximab compared with prior responses to CHOP. Leukemia & Lymphoma 2005;46(4):549 – 52.

PEBC Advice Documents or Guidelines

- Rituximab in Lymphoma and Chronic Lymphocytic Leukemia

June 2021 removed fludarabine NDFP funding info

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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.

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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