Regimen Monograph

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

A - Regimen Name

FLUD(PO)+R Regimen

Fludarabine (oral)-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)

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

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) (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
fludarabine	40 mg /m²	PO	Days 1 to 5

(This drug is not currently publicly funded for this regimen and intent)

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

Rituximab IV:

riTUXimab	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 FLUD chemotherapy

fludarabine	40 mg /m²	PO	Days 1-5

(This drug is not currently publicly funded for this regimen and intent)

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C - Cycle Frequency

REPEAT EVERY 28 DAYS for a total of 6 cycles, or 2 cycles beyond maximum response in the 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

Fludarabine: Outpatient prescription for home administration

Approximate Patient Visit	1-5 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

Czuczman M, Koryzna A, Mohr A, et al. Rituximab in combination with fludarabine chemotherapy in

low-grade or follicular lymphoma. J Clin Oncol. 2005 Feb 1;23(4):694-704.

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.

Fludarabine and rituximab drug monographs, Cancer Care Ontario.

Tobinai K, Watanabe T, Ogura M, et al. Phase II study of oral fludarabine phosphate in relapsed indolent B-cell non-Hodgkin's lymphoma. J Clin Oncol 2006; 24:174-80.

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.

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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

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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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