

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 - Leukemia - Chronic Lymphocytic (CLL)

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 anti-CD20 antibody-naïve previously untreated or second-line relapsed or refractory CLL patients, in whom fludarabine-based therapy is considered appropriate. There is insufficient evidence for the use of maintenance rituximab in CLL patients.

Supplementary Public Funding [riTUXimab](#)
New Drug Funding Program (Rituximab - Previously Untreated Chronic Lymphocytic Leukemia)

riTUXimab

New Drug Funding Program (Rituximab - Second Line - Chronic Lymphocytic Leukemia)

riTUXimab (subcut)

New Drug Funding Program (Rituximab (SC) - Previously Untreated Chronic Lymphocytic Leukemia)

riTUXimab (subcut)

New Drug Funding Program (Rituximab (SC) - Second Line - Chronic Lymphocytic Leukemia)

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B - Drug Regimen

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

riTUXimab	375 mg /m ²	IV *	Day 1
fludarabine	25 mg /m ²	IV	Days 1 to 3
cyclophosphamide	250 mg /m ²	IV	Days 1 to 3

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

Rituximab IV:

riTUXimab	500 mg /m ²	IV *	Day 1
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OR

Rituximab (subcut):

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)	1600** mg	Subcut	Day 1
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PLUS FC chemotherapy:

fludarabine	25 mg /m ²	IV	Days 1 to 3
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<u>cyclophosphamide</u>	250 mg /m ²	IV	Days 1 to 3
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* Consider slower infusion rate or split dosing over days 1-2 (± corticosteroids) for any cycle where high tumour load or WBC > 25 x 10⁹/L.

** Note: Rituximab subcut dosing is higher in CLL compared to other indications. Ensure the proper dose is administered.

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C - Cycle Frequency

REPEAT EVERY 28 DAYS

For a usual total of 6 cycles in the absence of disease progression or unacceptable toxicity

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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

Assouline S, Buccheri V, Delmer A, et al. Pharmacokinetics, safety, and efficacy of subcutaneous versus intravenous rituximab plus chemotherapy as treatment for chronic lymphocytic leukaemia (SAWYER): a phase 1b, open-label, randomised controlled non-inferiority trial. *Lancet Haematol* 2016;3(3):e128-38.

Hallek M, Fischer K, Fingerle-Rowson G, et al. Addition of rituximab to fludarabine and cyclophosphamide in patients with chronic lymphocytic leukaemia: a randomised, open-label, phase 3 trial. *Lancet* 2010;376(9747):1164-74.

Keating MJ, O'Brien S, Albitar M, et al. Early results of a chemoimmunotherapy regimen of fludarabine, cyclophosphamide, and rituximab as initial therapy for chronic lymphocytic leukemia. *J Clin Oncol* 2005; 23: 4079-88.

Robak T, Dmoszynska A, Solal-Celigny P, et al. Rituximab plus fludarabine and cyclophosphamide prolongs progression-free survival compared with fludarabine and cyclophosphamide alone in

previously treated chronic lymphocytic leukemia. J Clin Oncol 2010;28:1756-65.

Tam CS, O'Brien S, Wierda W, et al. Long-term results of the fludarabine, cyclophosphamide, and rituximab regimen as initial therapy of chronic lymphocytic leukemia. Blood 2008; 112(4): 975-80.

PEBC Advice Documents or Guidelines

- [Rituximab in Lymphoma and Chronic Lymphocytic Leukemia](#)

March 2019 Updated with ritux(subcut) option

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M - Disclaimer

Regimen Abstracts

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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.

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