Regimen Monograph

Regimen Name | Drug Regimen | Cycle Frequency | Premedication and Supportive Measures | Administrative Information | References | Other Notes | Disclaimer

A - Regimen Name

CYCLDEXA+RITU Regimen

Cyclophosphamide-dexamethasone-riTUXimab

Disease Site

Hematologic - Lymphoma - Non-Hodgkin's Low Grade
Waldenstrom's macroglobulinemia

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

For treatment of previously untreated, symptomatic patients with Waldenstrom's macroglobulinemia

Supplementary Public Funding

cyclophosphamide
ODB - General Benefit (cyclophosphamide - oral tablets) (ODB Formulary)

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

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.

dexamethasone[1]	20 mg	IV	Day 1
riTUXimab	375 mg /m²	IV	Day 1
cyclophosphamide	100 mg /m²	PO BID	Days 1 to 5

(Available as 25 mg and 50 mg tablets)

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

Rituximab IV:

riTUXimab	375 mg /m²	IV	Day 1

OR

Rituximab (subcut):
The subcutaneous formulation must only be given at the second or subsequent cycles, if the patient has previously received at least one full rituximab IV dose.

riTUXimab (subcut)	1400 mg	Subcut	Day 1

PLUS CYCLDEXA chemotherapy

dexamethasone[1]	20 mg	IV	Day 1

cyclophosphamide	100 mg /m²	PO BID	Days 1 to 5

(1) On Day 1 to be given as part of premedication before riTUXimab

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C - Cycle Frequency

REPEAT EVERY 21 DAYS for a usual total of 6 cycles unless disease progression or unacceptable toxicity occurs

For patients who have 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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D - Premedication and Supportive Measures

Antiemetic Regimen: Minimal
Consider prophylaxis daily for cyclophosphamide PO

Other Supportive Care:

Also refer to CCO Antiemetic Recommendations.

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J - Administrative Information

Approximate Patient Visit	First cycle: 5 hours; Subsequent cycles: 0.75 to 5 hours
Pharmacy Workload (average time per visit)	21.946 minutes
Nursing Workload (average time per visit)	69.833 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.

Dimopoulos MA, Anagnostopoulos A, Kyrtsonis MC, et al. Primary treatment of Waldenström macroglobulinemia With dexamethasone, rituximab, and cyclophosphamide. J Clin Oncol 2007;25:3344-9.

Kastritis E, Gavriatopoulou M, Kyrtsonis, MC, et al. Dexamethasone, rituximab, and cyclophosphamide as primary treatment of Waldenstrom macroglobulinemia: final analysis of a phase 2 study. Blood 2015 126: 1392-4.

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

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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

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