Regimen Monograph

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

A - Regimen Name

IBRU+RITU Regimen

iBRUtinib-riTUXimab

Disease Site

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

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 the treatment of patients with previously treated refractory or relapsed Waldenström's macroglobulinemia (WM).
(Refer to the NDFP eligibility form for detailed funding criteria.)

Supplementary Public Funding

iBRUtinib
Exceptional Access Program (iBRUtinib - In Combination with Rituximab for

Previously Treated Waldenströms Macroglobulinemia) (EAP Website)

riTUXimab
New Drug Funding Program (Rituximab (Biosimilar IV) and Rituximab SC - In Combination with Ibrutinib for Previously Treated Waldenströms Macroglobulinemia) (NDFP Website)

riTUXimab (subcut)
New Drug Funding Program (Rituximab (Biosimilar IV) and Rituximab SC - In Combination with Ibrutinib for Previously Treated Waldenströms Macroglobulinemia) (NDFP Website)

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B - Drug Regimen

Note: Different rituximab products are **not interchangeable**.

Rituximab IV and subcutaneous formulations are **not interchangeable**. The dosing and concentrations of these products are different. Refer to Safety Considerations for the Implementation of Subcutaneous Rituximab Formulation.

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

iBRUtinib	420 mg	PO	Days 1 to 28
riTUXimab	375 mg /m²	IV	Day 1

THEN

Rituximab IV:

riTUXimab	375 mg /m²	IV	Day 8, 15, 22

OR

Rituximab (subcut):

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

riTUXimab (subcut)	1400 mg	Subcut	Day 8, 15, 22

Cycle 2 to 4:

iBRUtinib	420 mg	PO	Days 1 to 28

Cycle 5:

iBRUtinib	420 mg	PO	Days 1 to 28

PLUS,

Rituximab IV:

riTUXimab	375 mg /m²	IV	Day 1, 8, 15, 22

OR

Rituximab (subcut):

riTUXimab (subcut)	1400 mg	Subcut	Day 1, 8, 15, 22

Cycle 6 and onwards:

iBRUtinib	420 mg	PO	Days 1 to 28

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C - Cycle Frequency

CYCLES REPEAT **EVERY 28 DAYS**

iBRUtinib: Until disease progression or unacceptable toxicity occurs

riTUXimab IV/subcut: Weekly dosing during cycles 1 and 5 (up to a maximum of 8 doses), unless disease progression or unacceptable toxicity occurs

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D - Premedication and Supportive Measures

Antiemetic Regimen: Minimal

- Also refer to CCO Antiemetic Recommendations.

Screen for hepatitis B virus in all cancer patients starting systemic treatment. Refer to the hepatitis B virus screening and management guideline.

Other Supportive Care:

- Patients at risk of tumour lysis syndrome should have appropriate prophylaxis and be monitored closely.
- Consider prophylaxis for patients at an increased risk for opportunistic infections.

Pre-medication (prophylaxis for infusion/administration reactions)

Administer at least 30 minutes prior to rituximab:

- Oral antipyretic (e.g. acetaminophen)
- H1-receptor antagonist (e.g. diphenhydramine)
- Corticosteroid (e.g. methylprednisolone 80 mg IV) in patients with high bulk disease or pulmonary involvement if no corticosteroids are already being given as part of the chemotherapy regimen.
- In patients receiving **subcut** rituximab who experienced adverse effects with pre-medications, the omission of pre-medications can be considered.

Also refer to the CCO guideline for detailed description of Management of Cancer Medication-Related Infusion Reactions.

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J - Administrative Information

Approximate Patient Visit	3 to 5 hours (rituximab IV); 0.75 hour (rituximab subcut)
Pharmacy Workload (average time per visit)	rituximab IV or subcut: 20.946 minutes
Nursing Workload (average time per visit)	rituximab IV: 69.167 minutes; rituximab subcut: 35 minutes

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K - References

CADTH Reimbursement Recommendation: Ibrutinib (Imbruvica). Canadian Journal of Health Technologies. January 2024.

Dimopoulos MA, Tedeschi A, Trotman J, et al. Phase 3 Trial of Ibrutinib plus Rituximab in Waldenström's Macroglobulinemia. N Engl J Med. 2018 Jun 21;378(25):2399-2410.

Ibrutinib drug monograph. Ontario Health (Cancer Care Ontario).

Rituximab drug monograph. Ontario Health (Cancer Care Ontario).

Rituximab (subcut) drug monograph. Ontario Health (Cancer Care Ontario).

April 2025 new ST-QBP regimen

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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

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