Regimen Monograph

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

A - Regimen Name

ACALBEND+RITU Regimen

Acalabrutinib-Bendamustine-Rituximab

ACAL+RITU(MNT) Regimen

Acalabrutinib-Rituximab (Maintenance)

Disease Site Hematologic

Lymphoma - Non-Hodgkin's Low Grade - Mantle Cell

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

First line treatment of mantle cell lymphoma (MCL) in patients who are ineligible for autologous stem cell transplant (ASCT)

(Refer to the NDFP eligibility form for detailed funding criteria. Refer to EAP for acalabrutinib funding details.)

Supplementary Public Funding

bendamustine

New Drug Funding Program (Bendamustine - First Line - Indolent Non-Hodgkin's Lymphoma and Mantle Cell Lymphoma) (NDFP Website)

acalabrutinib

Exceptional Access Program (acalabrutinib - In Combination with Bendamustine and Rituximab for Mantle Cell Lymphoma, based on criteria) (EAP Website)

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) (NDFP Website)

riTUXimab

New Drug Funding Program (Rituximab (Biosimilar IV) and Rituximab SC - Maintenance Treatment - Lymphoma) (NDFP Website)

riTUXimab (subcut)

New Drug Funding Program (Rituximab (Biosimilar IV) and Rituximab SC - Maintenance Treatment - Lymphoma) (NDFP Website)

B - Drug Regimen

Acalabrutinib tablets and capsules are bioequivalent and have equivalent oral bioavailability **except** when co-administered with acid reducing agents.

Note: Different rituximab products are NOT INTERCHANGEABLE.

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Cycle 1:

All patients must receive their first dose of rituximab by IV infusion

<u>riTUXimab</u> 375 mg /m² IV Day 1

bendamustine 90 mg /m² IV Days 1 and 2

acalabrutinib 100 mg PO BID

Cycles 2 to 6:

Rituximab IV:

<u>riTUXimab</u> 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:

bendamustine 90 mg /m² IV Days 1 and 2

<u>acalabrutinib</u> 100 mg PO BID

Maintenance (for patients who responded to induction)

acalabrutinib 100 mg PO BID (Continuous treatment)

treatment)

Plus RITU (IV or subcut):

riTUXimab¹ 375 mg /m² IV Day 1, Every 3

months

OR

riTUXimab (subcut)¹ 1400 mg Subcut Day 1, Every 3

months

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C - Cycle Frequency

Bendamustine: REPEAT EVERY 28 DAYS for a usual total of up to 6 cycles

Rituximab: REPEAT EVERY 28 DAYS during the first 6 cycles (induction phase), then administer

every **3 MONTHS** for 8 doses (maintenance phase)

Acalabrutinib: CONTINUOUS treatment

Unless disease progression or unacceptable toxicity.

For patients who responded to induction therapy, use maintenance acalabrutinib+rituximab regimen code - ACAL+RITU(MNT).

¹Dosing based on NDFP funding criteria. Rituximab maintenance was given starting cycle 8, q2 months for 12 doses in the clinical trial (Wang et al.)

D - Premedication and Supportive Measures

Antiemetic Regimen: Moderate (cycles 1 to 6)

Minimal (cycles 7 and onwards)

No routine prophylaxis for acalabrutinib

• Also refer to CCO Antiemetic Recommendations.

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

Pre-medication (prophylaxis for infusion 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.

Other Supportive Care:

- Hypertension should be controlled prior to starting bendamustine treatment.
- Consider withholding antihypertensive medication 12 hours prior to and during rituximab infusion as hypotension may occur during infusion.
- Consider prophylaxis for tumour lysis syndrome (TLS) in patients at higher risk of TLS.
- Consider prophylaxis in patients at increased risk for opportunistic infections (e.g. aspergillosis, fungal pneumonia, herpes zoster, and Pneumocystis Jiroveci Pneumonia).
- Consider the benefit-risk analysis of withholding acalabrutinib for at least 3 days pre- and postsurgery due to bleeding risk.

J - Administrative Information

Acalabrutinib – outpatient prescription for take-home administration

Approximate Patient Visit

ACALBEND+RITU 6 hours (first cycle); 1.75 to 4 hours (subsequent cycles);

ACAL+RITU(MNT) 0.75 to 5 hours

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K - References

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

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

Canada's Drug Agency. Reimbursement Recommendation: Acalabrutinib (Calquence). Canadian Journal of Health Technologies. October 2025.

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

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

Wang M, Salek D, Belada D, et al. Acalabrutinib Plus Bendamustine-Rituximab in Untreated Mantle Cell Lymphoma. J Clin Oncol. 2025 Jul 10;43(20):2276-2284.

December 2025 new ST-QBP regimen

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 <u>New Drug Funding Program</u> or <u>Ontario Public Drug Programs</u> 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.

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