Regimen Monograph

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

A - Regimen Name

BAC+RITU Regimen

Bendamustine-Cytarabine-Rituximab

Disease Site Hematologic - Lymphoma - Non-Hodgkin's Low Grade

Mantle cell lymphoma

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 previously untreated (age \geq 65 years) or relapsed/refractory mantle cell lymphoma (MCL) patients after one previous immunochemotreatment (+/- stem cell transplant; age \geq 18 years).

Supplementary <u>riTUXimab</u>
Public Funding New Drug F

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) (in 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) (in combination with chemotherapy)

back to top

B - Drug Regimen

Note: Different rituximab products are NOT INTERCHANGEABLE.

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

<u>riTUXimab</u> 375 mg /m² IV Day 1

bendamustine 70 mg /m² IV Days 2 and 3

(Prior authorization is required for PDRP funding of this drug within this regimen)

cytarabine 500 to 800 mg/m² IV Days 2 to 4

Cycle 2 and onwards: (For a usual total of 4 to 6 cycles including initial IV rituximab cycle(s))

Rituximab IV:

<u>riTUXimab</u> 375 mg /m² IV Day 1

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) 1400 mg Subcut Day 1

Plus BAC Chemotherapy:

bendamustine 70 mg /m² IV Days 2 and 3

(Prior authorization is required for PDRP funding of this drug within this regimen)

cytarabine 500 to 800 mg/m² IV Days 2 to 4

back to top

C - Cycle Frequency

REPEAT EVERY 28 DAYS for a usual total of 4 to 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).

back to top

D - Premedication and Supportive Measures

Antiemetic Regimen: Minimal (D1)

Moderate (D2-4)

Other Supportive Care:

Also refer to CCO Antiemetic Recommendations.

back to top

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, openlabel, phase 3 trial. Lancet Haematol. 2017 Jun;4(6):e272-e282.

Visco C, Finotto S, Zambello R et al. Combination of rituximab, bendamustine, and cytarabine for patients with mantle-cell non-hodgkin lymphoma ineligible for intensive regimens or autologous

transplantation. 2013 J Clin Oncol 31:1442-1449.

PEBC Advice Documents or Guidelines

Rituximab in Lymphoma and Chronic Lymphocytic Leukemia

August 2020 Updated NDFP forms and interchangeability information in Drug Regimen section

back to top

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 <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.

The format and content of the drug monographs, regimen monographs, appendices and symptom management information contained in the Formulary will change as they are reviewed and revised on a periodic basis. The date of last revision will be visible on each page of the monograph and regimen. Since standards of usage are constantly evolving, it is advised that the Formulary not be used as the sole source of information. It is strongly recommended that original references or product monograph be consulted prior to using a chemotherapy regimen for the first time.

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.

While care has been taken in the preparation of the information contained in the Formulary, 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.

CCO and the Formulary's content providers shall have no liability, whether direct, indirect, consequential, contingent, special, or incidental, related to or arising from the information in the Formulary or its use thereof, whether based on breach of contract or tort (including negligence), and even if advised of the possibility thereof. Anyone using the information in the Formulary does so at his or her own risk, and by using such information, agrees to indemnify CCO and its content providers from any and all liability, loss, damages, costs and expenses (including legal fees and expenses) arising from such person's use of the information in the Formulary.

back to top