Regimen Monograph

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

A - Regimen Name

VENE+OBIN Regimen

Venetoclax-Obinutuzumab

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

For treatment of patients with previously untreated CLL

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

Supplementary Public Funding

<u>oBINutuzumab</u>

New Drug Funding Program (Obinutuzumab - in Combination with Venetoclax for Previously Untreated Chronic Lymphocytic Leukemia) (NDFP Website)

venetoclax

Exceptional Access Program (venetoclax - In Combination with Obinutuzumab for Previously Untreated Chronic Lymphocytic Leukemia, based on criteria) (<u>EAP Website</u>)

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B - Drug Regimen

Cycle 1:

oBINutuzumab 1000 mg IV Days 1*, 8, 15

*Dose may be split over 2 days (100 mg IV on day 1, then 900 mg IV on day 2)

venetoclax¹ 20 mg PO Days 22 to 28

Cycle 2:

<u>oBlNutuzumab</u>	1000 mg	IV	Day 1
venetoclax ²	50 mg	PO	Days 1 to 7
venetoclax	100 mg	PO	Days 8 to 14
venetoclax	200 mg	PO	Days 15 to 21
<u>venetoclax</u>	400 mg	PO	Days 22 to 28

² Weeks 2 to 5 of venetoclax ramp-up occurs during cycle 2.

¹ Week 1 of venetoclax ramp-up period starts on cycle 1, day 22 and continues for 5 weeks (throughout cycle 2).

Cycles 3 to 6:

oBINutuzumab 1000 mg IV Day 1

venetoclax³ 400 mg PO Days 1 to 28

See <u>VENE(MNT)</u> for Cycles 7 to 12 (24 weeks of venetoclax monotherapy).

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C - Cycle Frequency

oBINutuzumab: REPEAT EVERY 28 DAYS for a usual total of 6 cycles, unless disease progression or unacceptable toxicity occurs.

venetoclax: CONTINUOUS treatment, with a 5-week ramp-up phase starting on day 22 of Cycle 1, followed by ten 28-day cycles starting with Cycle 3, unless disease progression or unacceptable toxicity occurs.

(Use regimen code <u>VENE(MNT)</u> for venetoclax treatment after stopping obinutuzumab.)

Refer to NDFP form for funding criteria for retreatment.

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D - Premedication and Supportive Measures

Antiemetic Regimen: Minimal

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³ Start of venetoclax maintenance dose.

J - Administrative Information

Venetoclax: Outpatient prescription for home administration

Obinutuzumab:

Approximate Patient Visit 4 hours

Pharmacy Workload (average time per visit) 18.249 minutes
Nursing Workload (average time per visit) 74.833 minutes

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K - References

Eichhorst B, Niemann CU, Kater AP, et al. First-line venetoclax combinations in chronic lymphocytic leukemia. N Engl J Med. 2023 May 11;388(19):1739-54.

Fischer K, Al-Sawaf O, Bahlo J, et al. Venetoclax and obinutuzumab in patients with CLL and coexisting conditions. N Engl J Med 2019;380:2225-36.

Fürstenau M, Kater AP, Robrecht S, et al. First-line venetoclax combinations versus chemoimmunotherapy in fit patients with chronic lymphocytic leukaemia (GAIA/CLL13): 4-year follow-up from a multicentre, open-label, randomised, phase 3 trial. Lancet Oncol. 2024 Jun;25(6):744-59.

Obinutuzumab drug monographs. Ontario Health (Cancer Care Ontario).

Reimbursement recommendation: venetoclax and obinutuzumab. Canadian Journal of Health Technologies 2024;4(12).

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

September 2025 Modified Rationale/uses and Cycle Frequency sections

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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.

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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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