Regimen Monograph

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 previously untreated CLL in patients who are ineligible for fludarabine-based regimens, require treatment, and have good performance status

Supplementary Public Funding

oBINutuzumab
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) (EAP Website)

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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)

venetoclax[1]	20 mg	PO	Days 22 to 28

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

Cycle 2:

oBINutuzumab	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
venetoclax	400 mg	PO	Days 22 to 28

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

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Cycles 3 to 6:

oBINutuzumab	1000 mg	IV	Day 1
venetoclax[3]	400 mg	PO	Days 1 to 28

[3] Start of venetoclax maintenance dose

Cycles 7 to 12 (24 weeks):

venetoclax	400 mg	PO	Daily

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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 for a usual total of 12 cycles (starting on cycle 1 day 22), unless disease progression or unacceptable toxicity occurs.

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D - Premedication and Supportive Measures

Antiemetic Regimen: Minimal

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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

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.

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

June 2023 Added descriptions for venetoclax ramp-up 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.

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