Regimen Monograph

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

A - Regimen Name

ACAL+OBIN Regimen

Acalabrutinib - 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-naive, symptomatic chronic lymphocytic leukemia (CLL)

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B - Drug Regimen

Cycle 1:

acalabrutinib	100 mg	PO	BID (Continuous)

(This drug is not currently publicly funded for this regimen and intent)

Cycle 2:

acalabrutinib	100 mg	PO	BID (Continuous)

(This drug is not currently publicly funded for this regimen and intent)

oBINutuzumab	1000* mg	IV	Days 1, 8 and 15

(This drug is not currently publicly funded for this regimen and intent)

*Cycle 2 first dose of obinutuzumab may be split over 2 days (100 mg IV day 1 and 900 mg IV day 2).

THEN,

Cycles 3 to 7:

acalabrutinib	100 mg	PO	BID (Continuous)

(This drug is not currently publicly funded for this regimen and intent)

oBINutuzumab	1000 mg	IV	Day 1

(This drug is not currently publicly funded for this regimen and intent)

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C - Cycle Frequency

REPEAT EVERY 28 DAYS

Start with acalabrutinib for one cycle, then give up to a usual total of 6 cycles of ACAL+OBIN (cycles 2 to 7) unless disease progression or unacceptable toxicity occurs; acalabrutinib monotherapy continues (see ACAL(MNT))

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D - Premedication and Supportive Measures

Antiemetic Regimen: Minimal

Obinutuzumab:

Hepatitis B screening should be performed prior to treatment for all patients.

Patients at risk for tumour lysis syndrome should receive adequate hydration and uricostatics or alternative starting 12 to 24 hours prior to infusion.

Consider withholding antihypertensives (if applicable) 12 hours prior to infusion, during infusion and for the first hour after drug administration, and withholding concomitant medications that increase bleeding risk, especially in the first cycle.

Premedication recommendations:

Treatment cycle, day	Patients	Premedication
Cycle 1, Day 1	All	IV corticosteroid* completed at least 1 hr prior to infusion & PO analgesic/antipyretic** & antihistamine*** at least 30 min prior to infusion
Subsequent infusions	Patients with no prior IR during previous infusion	PO analgesic/antipyretic** at least 30 min prior to infusion
	Patients with grade 1 or 2 IR with previous infusion	PO analgesic/antipyretic** & antihistamine*** at least 30 min prior to infusion
	Patients with grade 3 IR with previous infusion OR patients with lymphocyte counts > 25 x 10^9/L prior to next treatment	IV corticosteroid* completed at least 1 hr prior to infusion & PO analgesic/antipyretic** & antihistamine*** at least 30 min prior to infusion

*e.g. 100 mg prednisone or 20 mg dexamethasone. Hydrocortisone should not be used as it has not been effective in reducing IR rates.

**e.g. 1000 mg acetaminophen

***e.g. 50 mg diphenhydramine

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J - Administrative Information

Outpatient prescription for home administration (acalabrutinib)

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K - References

Acalabrutinib and obinutuzumab drug monographs, Cancer Care Ontario.

Sharman JP, Egyed M, Jurczak W, et al. Acalabrutinib with or without obinutuzumab versus chlorambucil and obinutuzmab for treatment-naive chronic lymphocytic leukaemia (ELEVATE TN): a randomised, controlled, phase 3 trial. Lancet 2020;395:1278-91.

October 2020 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.

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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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