Regimen Monograph

A - Regimen Name

EPCO Regimen

Epcoritamab

Disease Site

Hematologic
Lymphoma - Non-Hodgkin's High Grade
Lymphoma - Non-Hodgkin's Intermediate Grade

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

Treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, DLBCL transformed from indolent lymphoma, high grade B-cell lymphoma (HGBCL), primary mediastinal B-cell lymphoma (PMBCL) or follicular lymphoma Grade 3B (FLG3b), after two or more lines of systemic treatment and who have

previously received or are unable to receive CAR-T cell therapy

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B - Drug Regimen

Cycle 1:

epcoritamab	0.16 mg	Subcut	Day 1

(This drug is not publicly funded. Universal compassionate access program is available.)

epcoritamab	0.8 mg	Subcut	Day 8

(This drug is not publicly funded. Universal compassionate access program is available.)

epcoritamab	48 mg	Subcut	Days 15 and 22

(This drug is not publicly funded. Universal compassionate access program is available.)

Cycles 2 to 3:

epcoritamab	48 mg	Subcut	Days 1, 8, 15, 22

(This drug is not publicly funded. Universal compassionate access program is available.)

Cycles 4 to 9:

epcoritamab	48 mg	Subcut	Days 1 and 15

(This drug is not publicly funded. Universal compassionate access program is available.)

Cycles 10 and onwards:

epcoritamab	48 mg	Subcut	Day 1

(This drug is not publicly funded. Universal compassionate access program is available.)

Inpatient admission may be required for cytokine release syndrome monitoring.

Note: ST-QBP funding for ambulatory administration only

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C - Cycle Frequency

REPEAT EVERY 28 DAYS

Until disease progression or unacceptable toxicity

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D - Premedication and Supportive Measures

Antiemetic Regimen: Minimal

- Also refer to CCO Antiemetic Summary.

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

Premedication (prophylaxis of cytokine release syndrome (CRS))

Cycle 1 (All patients):

- Prednisolone 100 mg PO/IV (or equivalent), 30-120 minutes **before and** 3 consecutive days **after** each epcoritamab dose
- Diphenhydramine 50 mg PO/IV (or equivalent), 30-120 minutes before each epcoritamab dose
- Acetaminophen 650-1000 mg PO, 30-120 minutes before each epcoritamab dose

Cycle 2 and onwards (Patients who experienced Grade 2 or 3* CRS with previous dose):

- Prednisolone 100 mg PO/IV (or equivalent), 30-120 minutes **before and** 3 consecutive days **after** each epcoritamab dose, until ≥ Grade 2 CRS does not occur subsequently.

*Epcoritamab is discontinued after Grade 4 CRS.

Other Supportive Care:

- Consider prophylaxis against Pneumocystis jirovecii pneumonia (PJP) and herpes virus

infections.
- Consider other antimicrobial prophylaxis as per local guidelines.
- Epcoritamab should be administered to adequately hydrated patients.
- Patients at risk of tumour lysis syndrome should have appropriate prophylaxis and be monitored closely.

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J - Administrative Information

Pharmacy Workload (average time per visit) 17.00 minutes
Nursing Workload (average time per visit) 44.833 minutes

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K - References

Product monograph: Epcoritamab (Epkinly™). AbbVie Corporation, October 2023.

Thieblemont C, Phillips T, Ghesquieres H, et al. Epcoritamab, a novel, subcutaneous CD3xCD20 Bispecific T-Cell-Engaging antibody, in relapsed or refractory large B-cell lymphoma: dose expansion in a phase I/II Trial. J Clin Oncol 2023 Apr 20;41(12):2238-47.

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M - Disclaimer

Regimen Abstracts

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QBP regimen as they are developed.

Regimen Monographs

Refer to the New Drug Funding Program or Ontario Public Drug Programs 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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