Regimen Monograph

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

A - Regimen Name

GEMOX+GLOF Regimen

Gemcitabine-Oxaliplatin-Glofitamab

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 patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL)

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B - Drug Regimen

Cycle 1:

Start with obinutuzumab pre-treatment, to minimize the risk of cytokine release syndrome (CRS):

oBINutuzumab 1000 mg IV Day 1

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

gemcitabine 1000 mg /m² IV Day 2

oxaliplatin 100 mg /m² IV Day 2

glofitamab 2.5 mg IV Day 8

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

glofitamab 10 mg IV Day 15

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

Cycles 2 to 8:

glofitamab 30 mg IV Day 1

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

gemcitabine 1000 mg /m² IV Day 1

oxaliplatin 100 mg /m² IV Day 1

Inpatient admission may be required for cytokine release syndrome (CRS) monitoring.

Note: ST-QBP funding for ambulatory administration only

In the clinical trial, prophylactic granulocyte colony-stimulating factor was required during cycles 1–2, and was optional thereafter based on physician discretion.

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C - Cycle Frequency

REPEAT EVERY 21 DAYS

For up to 8 cycles, followed by glofitamab monotherapy (GLOF(MNT)), unless disease progression or unacceptable toxicity

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D - Premedication and Supportive Measures

Antiemetic Regimen: Minimal (Cycle 1 on days 1, 8, 15)

Moderate (Cycle 1, day 2; Cycles 2 to 8)

Also refer to <u>CCO Antiemetic Summary</u>.

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

Pre-medications for Obinutuzumab (prophylaxis for infusion-related reactions):

Give at least 30 min to 1 hr prior to each obinutuzumab infusion:

- IV corticosteroid* (e.g. dexamethasone 20 mg or equivalent)
- Antihistamine (e.g. 50 mg diphenhydramine PO/IV)
- Analgesic/antipyretic (e.g. acetaminophen 1000 mg PO/IV)

Pre-medications for Glofitamab (prophylaxis for CRS):

Cycles 1 to 3:

Give at least 30 min to 1 hr prior to each glofitamab infusion*:

- IV glucocorticoid* (e.g. dexamethasone 20 mg or equivalent)
- Antihistamine (e.g. diphenhydramine 50 mg PO/IV)
- Antipyretic (e.g. acetaminophen 1000 mg PO)

Cycle 4 and beyond:

Give at least 30 min prior to each glofitamab infusion*:

^{*}Corticosteroid to be completed at least 1 hr prior to infusion. Hydrocortisone should not be used as it has not been effective in reducing IR rates.

- Antihistamine (e.g. diphenhydramine 50 mg PO/IV)
- Antipyretic (e.g. acetaminophen 1000 mg PO)
- Add IV glucocorticoid* for patients who experienced CRS with previous doses

Oxaliplatin premedication (prophylaxis for infusion reactions):

- There is insufficient evidence that routine prophylaxis with pre-medications reduces IR rates.
- Consider corticosteroids and H1-receptor antagonists ± H2-receptor antagonists in high-risk patients (i.e. ≥ cycle 6, younger age, female gender, prior platinum exposure, platinum-free interval ≥ 3 years).

Other Supportive Care:

- Consider prophylaxis against Pneumocystis jirovecii pneumonia (PJP) and herpes virus infections.
- Consider other antimicrobial prophylaxis as per local guidelines.
- Obinutuzumab and glofitamab should be administered to adequately hydrated patients.
- Patients at risk of tumour lysis syndrome should have appropriate prophylaxis and be monitored closely.
- Consider withholding antihypertensives (if applicable) 12 hours prior to obinutuzumab infusion, during infusion and for the first hour after administration.
- Consider withholding concomitant medications that increase bleeding risk with obinutuzumab.
- Patients should be counselled about cold avoidance prior to receiving oxaliplatin, since cold temperatures can precipitate or exacerbate acute neurological symptoms.

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J - Administrative Information

Pharmacy Workload (average time per visit) 26.181 minutes

Nursing Workload (average time per visit) 46.667 minutes

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K - References

Abramson JS, Ku M, Hertzberg M, et al. Glofitamab plus gemcitabine and oxaliplatin (GemOx) versus rituximab-GemOx for relapsed or refractory diffuse large B-cell lymphoma (STARGLO): a global phase 3, randomised, open-label trial. Lancet. 2024 Nov 16;404(10466):1940-1954. doi: 10.1016/S0140-6736(24)01774-4.

^{*}Glucocorticoid to be completed at least 1 hour before glofitamab infusion.

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

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

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

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

May 2025 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.

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.

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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.

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