Regimen Monograph

A - Regimen Name

GLOF Regimen

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 adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL arising from follicular lymphoma (trFL), or primary mediastinal B-cell lymphoma (PMBCL), who have received ≥ 2 lines of systemic therapy and are ineligible to receive or cannot receive CAR-T cell therapy or have previously received CAR-T cell therapy

back to top

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 publicly funded. Universal compassionate access program is available.)

Then,

glofitamab	2.5 mg	IV	Day 8

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

glofitamab	10 mg	IV	Day 15

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

Cycle 2 on onwards:

glofitamab	30 mg	IV	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

back to top

C - Cycle Frequency

REPEAT EVERY 21 DAYS

For a maximum of 12 cycles or until disease progression or unacceptable toxicity, whichever occurs first

back to top

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, Days 8 and 15; Cycles 2 to 3 (All patients):

- IV glucocorticoid (e.g. dexamethasone 20 mg or equivalent), completed at least 1 hour before each glofitamab dose
- Antihistamine (e.g. diphenhydramine 50 mg PO/IV), at least 30 minutes before each glofitamab dose
- Antipyretic (e.g. acetaminophen 1000 mg PO), at least 30 minutes before each glofitamab dose

All subsequent doses:

- **All Patients -** Give at least 30 minutes before each glofitamab dose:
  - Antihistamine
  - Antipyretic
- **Patients who experienced CRS with previous doses:**
  - Add IV glucocorticoid, completed at least 1 hour before each glofitamab dose

Other Supportive Care:

- Consider prophylaxis against Pneumocystis jirovecii pneumonia (PJP) and herpes virus infections.
- Consider other antimicrobial prophylaxis as per local guidelines.
- Glofitamab should be administered to adequately hydrated patients.
- Patients at risk of tumour lysis syndrome should have appropriate prophylaxis and be monitored closely.

back to top

J - Administrative Information

Pharmacy Workload (average time per visit)	23.250 minutes
Nursing Workload (average time per visit)	44.833 minutes

back to top

K - References

Dickinson MJ, Carlo-Stella C, et al. Glofitamab for Relapsed or Refractory Diffuse Large B-Cell Lymphoma. N Engl J Med. 2022 Dec 15;387(24):2220-31.

Prescribing information: Glofitamab (Columvi). Genentech Inc. (USA), June 2023.

Product monograph: Glofitamab (Columvi). Hoffmann-La Roche Limited, March 2023.

April 2024 Updated to reflect the availability of a universal compassionate program for drug costs

back to top

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 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.

The format and content of the drug monographs, regimen monographs, appendices and symptom management information contained in the Formulary will change as they are reviewed and revised on a periodic basis. The date of last revision will be visible on each page of the monograph and regimen. Since standards of usage are constantly evolving, it is advised that the Formulary not be used as the sole source of information. It is strongly recommended that original references or product monograph be consulted prior to using a chemotherapy regimen for the first time.

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.

While care has been taken in the preparation of the information contained in the Formulary, 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.

CCO and the Formulary's content providers shall have no liability, whether direct, indirect, consequential, contingent, special, or incidental, related to or arising from the information in the Formulary or its use thereof, whether based on breach of contract or tort (including negligence), and even if advised of the possibility thereof. Anyone using the information in the Formulary does so at his or her own risk, and by using such information, agrees to indemnify CCO and its content providers from any and all liability, loss, damages, costs and expenses (including legal fees and expenses) arising from such person's use of the information in the Formulary.

back to top