Regimen Monograph

A - Regimen Name

GLOF(RAMP) Regimen

Glofitamab (Ramp-up)

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.

Rationale and Uses

Treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL transformed from an indolent lymphoma, high grade B-cell lymphoma (HGBCL), primary mediastinal B-cell lymphoma (PMBCL), or follicular lymphoma grade 3b (FLG3b) after 2 or more lines of systemic treatment and who have previously received or are unable to receive CAR-T cell therapy.

Supplementary Public Funding	**glofitamab** New Drug Funding Program (Glofitamab (Outpatient) - Relapsed or Refractory Diffuse Large B-cell Lymphoma) (**Funding for obinutuzumab and glofitamab**) **glofitamab** High Cost Therapy Funding Program (Glofitamab (Inpatient) - Relapsed or Refractory Diffuse Large B-cell Lymphoma) (**Funding for obinutuzumab and glofitamab**)

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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

Then,

glofitamab	2.5 mg	IV	Day 8
glofitamab	10 mg	IV	Day 15

Cycle 2 and onwards:

glofitamab	30 mg	IV	day 1

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

Note: ST-QBP funding for ambulatory administration only

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C - Cycle Frequency

REPEAT EVERY 21 DAYS

Until disease progression or unacceptable toxicity, up to a maximum of 12 cycles.

Use regimen code GLOF(RAMP) for cycles 1 and 2, then GLOF for subsequent cycles.

Refer to the NDFP form for details on glofitamab retreatment.

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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.

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)

*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.

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***:**

- 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**

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

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.

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E - Dose Modifications

Doses should be modified according to the protocol by which the patient is being treated.

Do not start treatment with obinutuzumab or glofitamab in patients with active infection.

Must have tocilizumab available prior to starting glofitamab (Cycles 1 and 2).

Dosage with toxicity

Dose reductions are not recommended for glofitamab or obinutuzumab pre-treatment. Refer to oBINutuzumab drug monograph for additional details

Table 1 - CRS Toxicity Management

Recommendations below are based on the product monograph. Refer to Crombie et al. for alternative CRS management guidelines.

Toxicity	Grade[a]	Management / Action	Next dose[c]

CRS	Grade 1	• Hold until CRS has resolved.
		• Manage and treat symptoms as appropriate[b]. If CRS lasts more than 48 h after symptomatic management:
		  ◦ Consider corticosteroids (e.g. dexamethasone 10 mg IV, or equivalent)
		  ◦ Consider tocilizumab IV as per institutional guidelines.
		• Refer to Table 5 for recommendations on infusion rates, restart and re-challenge.
			Resume dose as recommended in Table 4.

	Grade 2	• Hold.
		• Manage and treat symptoms as appropriate[b]:
		  ◦ Corticosteroids (e.g. dexamethasone 10 mg IV, or equivalent)
		  ◦ Consider tocilizumab IV as per institutional guidelines.
		• Refer to Table 5 for recommendations on infusion rates, restart and re-challenge.
			Resume dose as recommended in Table 4.
			
			Monitor patient more frequently after dose; consider hospitalization.

	Grade 3	• Hold.
		• Manage and treat symptoms as appropriate[b]:
		  ◦ Corticosteroids (e.g. dexamethasone 10 mg IV, or equivalent)
		  ◦ Tocilizumab IV as per institutional guidelines.
			Resume dose as recommended in Table 4.
			
			Hospitalize for monitoring after dose.

		• Refer to Table 5 for recommendations on infusion rates, restart and re-challenge.	

	Recurrent Grade 3, or Grade 4	• Stop glofitamab.
		• Manage and treat symptoms as appropriate[b]:
		  ○ Corticosteroids (e.g. dexamethasone 10 mg IV, or equivalent)
		  ○ Tocilizumab IV as per institutional guidelines.
			Permanently discontinue.

[a] Grade based on American Society for Transplantation and Cellular Therapy (ASTCT) consensus grading (Lee et al 2019).

[b] Anticytokine therapy is recommended if ICANS occurs concurrently with CRS. Refer to local institutional guidelines for management of concurrent CRS and ICANS.

[c] Do not give next dose unless symptoms have resolved for at least 72 hours.

Table 2 - Neurologic Toxicity

Severity[a]	**Action[b,c]**
Grade 1	Continue glofitamab and monitor for neurologic toxicity.
Grade 2	Hold[d,e] until neurologic toxicity improves to Grade ≤ 1 or baseline. Manage and treat symptoms as appropriate. Consider neurology consultation.
Grade 3	Hold[d] until neurologic toxicity improves to Grade ≤ 1 or baseline for ≥ 7 days. Consider permanently discontinuing for Grade 3 events lasting > 7 days. Manage and treat symptoms as appropriate. Consider neurology consultation.
Grade 4	Permanently discontinue. Manage and treat symptoms as appropriate. Consider neurology consultation.

[a] Grade for ICANS based on American Society for Transplantation and Cellular Therapy (ASTCT) consensus grading (Lee et al 2019).

[b] If ICANS, manage as per institutional guidelines. Refer also to Crombie et. al for alternative ICANS management guidelines.

[c] Anticytokine therapy is recommended if ICANS occurs concurrently with CRS. Refer to local institutional guidelines for management of concurrent CRS and ICANS.

[d] Resume at dose described in Table 4.

[e] Consider the type of neurologic toxicity before deciding to withhold glofitamab.

Table 3 - Other Toxicities

Toxicity	Severity	Action
Active Infection	Grade 1 to 3	Hold* until infection resolves.
	Grade 4	Hold* until infection resolves, OR Consider discontinue.
Tumour flare	Grade 1	Monitor for signs and symptoms of compression or obstruction due to mass effect**.
	Grade 2 to 4	Hold* until tumour flare resolves. Monitor for signs and symptoms of compression or obstruction due to mass effect**. Initiate appropriate treatment (e.g. antihistamine and corticosteroids). Consider discontinue for Grade 4.
Neutropenia	ANC < 0.5 × 10^9/L	Hold* until ANC ≥ 0.5 × 10^9/L.
Thrombocytopenia	Platelets < 50 × 10^9/L	Hold* until platelets ≥ 50 × 10^9/L.
Other adverse effects	Grade ≥ 3	Hold* until toxicity improves to Grade ≤ 1 or baseline.

*Resume at dose described in Table 4.

**Especially in patients with bulky tumours located in close proximity to airways and/or vital organs.

Table 4 - Restarting After Dose Delay

Last Administered Dose	Time since Last Dose	Action for Next Dose
Obinutuzumab pre-treatment (Cycle 1, Day 1)	≤ 2 weeks	Administer glofitamab 2.5 mg, then resume the planned treatment schedule.
	> 2 weeks	Repeat pre-treatment with obinutuzumab, then resume the planned treatment schedule.
Glofitamab 2.5 mg (Cycle 1, Day 8)	≤ 2 weeks	Administer glofitamab 10 mg, then resume the planned treatment schedule.
	> 2 to ≤ 6 weeks	Repeat glofitamab 2.5 mg, then resume the planned treatment schedule.
	> 6 weeks	Repeat pre-treatment with obinutuzumab and glofitamab 2.5 mg, then resume the planned treatment schedule.
Glofitamab 10 mg (Cycle 1, Day 15)	≤ 2 weeks	Administer glofitamab 30 mg, then resume the planned treatment schedule.
	> 2 to ≤ 6 weeks	Repeat glofitamab 10 mg, then resume the planned treatment schedule.
	> 6 weeks	Repeat pre-treatment with obinutuzumab and step-up doses, then resume the planned treatment schedule.
Glofitamab 30 mg (Cycle 2 onwards)	≤ 6 weeks	Administer glofitamab 30 mg, then resume the planned treatment schedule.
	> 6 weeks	Repeat pre-treatment with obinutuzumab and step-up doses, then resume the planned treatment schedule.

Table 5 - Management of Infusion-related reactions (including CRS):

Also refer to the CCO guideline for detailed description of Management of Cancer Medication-Related Infusion Reactions.

Grade	Management		Re-challenge*	
	Glofitamab	**Obinutuzumab**	**Glofitamab**	**Obinutuzumab**
1	• Stop the infusion. • Manage the symptoms. **Restart:** • After symptoms resolve, restart infusion at a slower rate (up to 50% slower, or up to 8 hr duration).	• Stop or slow the infusion rate. • Manage the symptoms. **Restart:** • Once symptoms have resolved, continue infusion. • If IR does not recur, may escalate the infusion rate at increments appropriate for the treatment dose (see administration section).	• Consider slower infusion rate (up to 50% slower, or up to 8 hr duration).	N/A
2	• Stop the infusion. • Manage the symptoms. • Do not restart.	• See Grade 1.	• Consider slower infusion rate (up to 50% slower, or up to 8 hr duration). • Monitor patients post-infusion.	
3	• Stop the	• Stop	• Consider slower infusion	

	infusion. • Aggressively manage the symptoms. • Do not restart.	treatment. • Aggressively manage symptoms. **Restart:** • Once symptoms have resolved, restart the infusion at no more than half the previous rate (at which the IR occurred). • If IR does not recur, may escalate the infusion rate as outlined above for grade 1-2 IRs.	rate (up to 50% slower, or up to 8 hr duration). • Monitor patients post-infusion. • If Grade ≥ 3 CRS recurs, stop infusion immediately and permanently discontinue (do not re-challenge).	
4	• Stop treatment. • Aggressively manage the symptoms. • Do not restart.	• Stop treatment. • Aggressively manage the symptoms. • Do not restart.	• Permanently discontinue (do not re-challenge).	

* Ensure symptoms are resolved for at least 72 hours prior to next infusion of glofitamab.

Hepatic Impairment

The safety and efficacy of **obinutuzumab** have not been established in patients with hepatic impairment.

No **glofitamab** dose adjustment is necessary for mild hepatic impairment based on

pharmacokinetic studies (no clinically significant differences observed). Glofitamab has not been studied in patients with moderate to severe hepatic impairment (total bilirubin > 1.5 x ULN and any AST).

Renal Impairment

Patients who have a creatinine clearance < 50mL/min in the **obinutuzumab** pivotal studies (in combination with chemotherapy) experienced more serious adverse events, including fatal ones, than those with creatinine ≥ 50 mL/min.

Creatinine Clearance (mL/min)	Obinutuzumab Dose
> 50	No dose adjustment
30-50	No dose adjustment; use with caution
< 30	No data

No **glofitamab** dose adjustment is necessary in patients with mild or moderate renal impairment (CrCl 30 to < 90 mL/min). No clinically significant changes in the pharmacokinetics of glofitamab were observed based on mild to moderate renal impairment. The effects of severe renal impairment (CrCl 15 to < 30 mL/min) and end-stage renal disease (CrCl < 15 mL/min) on the pharmacokinetics of glofitamab are unknown.

Dosage in the Elderly

No obinutuzumab or glofitamab dose adjustments are required in patients ≥ 65 years of age. No differences in efficacy of glofitamab or obinutuzumab were observed between older and younger patients.

NHL patients ≥ 65 years of age experienced more serious adverse effects with obinutuzumab and chemotherapy than younger patients.

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F - Adverse Effects

Refer to oBINutuzumab, glofitamab drug monograph(s) for additional details of adverse effects.

The table below lists the adverse effects of glofitamab only. Refer to oBINutuzumab drug monograph for adverse effects of obinutuzumab.

Very common (≥ 50%)	Common (25-49%)	Less common (10-24%)	Uncommon (< 10%), but may be severe or life-threatening
• Infusion related reactions, including cytokine release syndrome (may be severe)	• Myelosuppression ± infection, bleeding (may be severe)	• Fatigue • Fever • Abnormal electrolyte(s) • Rash, pruritus • Constipation • Edema • Tumour flare	• Immune effector cell-associated neurotoxicity syndrome • QT interval prolonged • GI hemorrhage • ↑ LFTs • Hypogammaglobulinemia • Tumour lysis syndrome

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G - Interactions

Refer to oBINutuzumab, glofitamab drug monograph(s) for additional details.

- Caution with obinutuzumab and drugs that cause immunosuppression (e.g. leflunomide, etanercept, clozapine, other antineoplastics); monitor closely or avoid, if possible.
- Glofitamab may cause transient suppression of CYP450 enzymes. Monitor and adjust doses of CYP450 substrates with narrow therapeutic index (e.g. warfarin, cyclosporine) as necessary.

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H - Drug Administration and Special Precautions

Refer to oBINutuzumab, glofitamab drug monograph(s) for additional details.

Administration

Obinutuzumab:

- Obinutuzumab should be administered only as an IV infusion through a dedicated line. **Do not administer as an IV push or bolus.**
- Infuse IV at 50 mg/h. The rate of infusion can be escalated in 50 mg/h increments every 30 minutes to a maximum of 400 mg/h.
- Withdraw required amount of diluent from vial and dilute in a 250 mL bag containing 0.9% sodium chloride. See product monograph for details.
- Gently invert the IV bag to mix. Do not shake.
- Compatible with sodium chloride 0.9%. Do not mix with other IV solutions.
- Also compatible with the following IV bags and sets:
  - PVC, non-PVC polyolefin, polyethylene, polypropylene bags
  - PVC, polyurethane or polyethylene infusion sets
  - polyetherurethane catheters
  - optional inline filters with polyethersulfone product contact surfaces
  - 3-way stopcock infusion aid made from polycarbonate
- Store vials between 2° to 8°C; protect from light.

Also refer to the CCO guideline for detailed description of Management of Cancer Medication-Related Infusion Reactions.

Glofitamab:

- Infuse IV through a dedicated line. Do NOT administer as an IV push or bolus.
- Do not mix with other drugs.
- Dilute in a 50mL or 100mL 0.9% or 0.45% sodium chloride infusion bag.
- Final drug concentration after dilution should be 0.1 mg/mL to 0.6 mg/mL.
- Gently invert infusion bag to mix. Do not shake.
- Compatible with polyvinyl chloride (PVC), polyethylene (PE), polypropylene (PP), or non-PVC polyolefin 0.9% NS IV bags and PVC 0.45% sodium chloride IV bags.
- Compatible with infusion sets with product-contacting surfaces of polyurethane, PVC, PE, and in-line filter membranes made of polyethersulfone or polysulfone
- Infuse IV over 4 hours (2.5 mg, 10mg and first 30mg dose).
- May infuse over 2 hours (Cycle 3 and onwards) if previous dose well tolerated.
- Monitor patients during infusion, for 10 hours after the first glofitamab dose (2.5mg, Cycle 1, Day 8) and after subsequent doses as necessary, for signs and symptoms of CRS or ICANS.
- Store unopened vials refrigerated (2°C to 8°C) and protect from light.

Contraindications

- Patients who have a hypersensitivity to these drugs or any of their components.

Warnings / Precautions

- Obinutuzumab and glofitamab should not be given in the presence of an active infection.
- Avoid live vaccines during treatment with obinutuzumab and glofitamab. Following vaccination, do not start obinutuzumab until protective antibody titres have been reached. The safety of immunization with live vaccines during or after glofitamab treatment has not been studied.
- Use obinutuzumab with extreme caution in patients who are positive for hepatitis
- Use caution in patients with:
  - a history of recurring or chronic infections;
  - underlying conditions that may predispose them to infections;
  - significant prior immunosuppressive treatment.
- Patients with a history of cardiovascular or respiratory disease should be monitored closely during and after obinutuzumab infusion. Use caution when hydrating patients with history of cardiovascular disease, to prevent fluid overload
- Patients at acute risk of hypertensive crisis should be assessed for the risk vs benefit of withholding anti-hypertensives. If deemed clinically appropriate, hold antihypertensive medications for 12 hours prior to, during, and for the first hour after obinutuzumab infusion.
- Serious and life-threatening CRS have occurred with glofitamab, ensure step-up schedule is followed and infusions are administered where there is immediate access to medications and equipment required to manage CRS.
- Symptoms of CRS (e.g. tachycardia, hypotension, hypoxia) or neurological effects may affect ability to drive or operate machinery. Patients should avoid driving or operating machinery until symptoms resolve.
- Patients with high tumour burden, rapidly proliferative tumours, renal dysfunction or dehydration are at greater risk of tumour lysis syndrome.
- Patients with conditions such as central nervous system lymphoma, prior allogeneic HSCT and autoimmune disease (requiring immunosuppressive therapy) were excluded from clinical trials; assess benefit-risk of glofitamab treatment in these patients.

Pregnancy and Lactation

- This regimen is not recommended for use in pregnancy. IgG1 antibodies are known to cross placenta. Adequate contraception should be used by patients and their partners while on treatment and after the last treatment dose. Recommended methods and duration of contraception may differ depending on the treatment. Refer to the drug monograph(s) for more information.
- Breastfeeding is not recommended during this treatment and after the last treatment dose. Refer to the drug monograph(s) for recommendations after the last treatment dose (if available).

- Fertility effects: Unknown

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I - Recommended Clinical Monitoring

Treating physicians may decide to monitor more or less frequently for individual patients but should always consider recommendations from the product monograph.

Refer to the hepatitis B virus screening and management guideline for monitoring during and after treatment.

Recommended Clinical Monitoring

- CBC; Baseline and before each dose; more frequently if clinically indicated
- Clinical toxicity assessment for CRS; At each visit and for 10 hours after the first glofitamab infusion
- Renal function tests; Baseline and as clinically indicated
- Liver function tests; Baseline and as clinically indicated
- CRP, ferritin, coagulation tests (e.g. aPTT, INR, PT, fibrinogen); Baseline and as clinically indicated
- Electrolytes (e.g. PO4, K, Ca and Mg), uric acid levels; Baseline and as clinically indicated, especially for patients at risk of TLS
- Clinical toxicity assessment for infection, hypersensitivity, TLS, rash, bleeding, thromboembolism, tumour flare, neurologic (including ICANS), pulmonary, GI and cardiac effects; At each visit

- Grade toxicity using the current NCI-CTCAE (Common Terminology Criteria for Adverse Events) version

Suggested Clinical Monitoring

- Cardiac tests for all patients with cardiac risk factors before starting obinutuzumab; Baseline and as clinically indicated

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J - Administrative Information

Pharmacy Workload **(average time per visit)**
GLOF 23.250 minutes

Nursing Workload **(average time per visit)**
GLOF 44.833 minutes

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K - References

Crombie JL, Graff T, Falchi L, et al. Consensus recommendations on the management of toxicity associated with CD3×CD20 bispecific antibody therapy. *Blood* 2024; 143 (16): 1565–1575.

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Lee W, Santomasso BD, Locke FL, et al. ASTCT consensus grading for cytokine release Syndrome and neurologic toxicity associated with immune effector cells. Biol Blood Marrow Transplant. 2019;25:625-38.

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

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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 New Drug Funding Program or Ontario Public Drug Programs 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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