CADTH

CADTH REIMBURSEMENT REVIEW

# Stakeholder Feedback on Draft Recommendation

**glofitamab (Columvi)**

(Hoffmann-La Roche Limited)

**Indication:** Glofitamab is indicated for the 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 two or more lines of systemic therapy and are ineligible to receive or cannot receive CAR-T cell therapy or have previously received CAR-T cell therapy.

**January 18, 2024**

# CADTH Reimbursement Review
# Feedback on Draft Recommendation

| Stakeholder information | |
|---|---|
| CADTH project number | PC0320 |
| Brand name (generic) | Columvi (glofitamab) |
| Indication(s) | For the treatment of adult patients with relapsed or refractory DLBCL not otherwise specified, trFL, or PMBCL, who have received two or more lines of systemic therapy and are ineligible to receive or cannot receive CAR-T cell therapy or have previously received CAR-T cell therapy |
| Organization | Ontario Health (Cancer Care Ontario) Hematology Cancer Drug Advisory Committee |
| Contact information[a] | Name: |

| Stakeholder agreement with the draft recommendation | | |
|---|---|---|
| **1. Does the stakeholder agree with the committee's recommendation.** | Yes | ☒ |
| | No | ☐ |
| Please explain why the stakeholder agrees or disagrees with the draft recommendation. Whenever possible, please identify the specific text from the recommendation and rationale. | | |

| Expert committee consideration of the stakeholder input | | |
|---|---|---|
| **2. Does the recommendation demonstrate that the committee has considered the stakeholder input that your organization provided to CADTH?** | Yes | ☒ |
| | No | ☐ |
| If not, what aspects are missing from the draft recommendation? | | |

| Clarity of the draft recommendation | | |
|---|---|---|
| **3. Are the reasons for the recommendation clearly stated?** | Yes | ☒ |
| | No | ☐ |
| If not, please provide details regarding the information that requires clarification. | | |
| **4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?** | Yes | ☒ |
| | No | ☐ |
| If not, please provide details regarding the information that requires clarification. | | |
| **5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?** | Yes | ☒ |
| | No | ☐ |
| If not, please provide details regarding the information that requires clarification.<br><br>The DAC believes CT imaging should be flexible based on clinical situation, following guidance of the physician. | | |

[a] CADTH may contact this person if comments require clarification.

## Appendix 1. Conflict of Interest Declarations for Patient Groups

- To maintain the objectivity and credibility of the CADTH drug review programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest.
- This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the feedback from patient groups and clinician groups.
- CADTH may contact your group with further questions, as needed.
- Please see the *Procedures for CADTH Drug Reimbursement Reviews* for further details.

| **A. Patient Group Information** | |
|---|---|
| **Name** | *Please state full name* |
| **Position** | *Please state currently held position* |
| **Date** | *Please add the date form was completed (DD-MM-YYYY)* |
| ☐ | I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation. |

| **B. Assistance with Providing Feedback** | | |
|---|---|---|
| **1. Did you receive help from outside your patient group to complete your feedback?** | No | ☐ |
| | Yes | ☐ |
| If yes, please detail the help and who provided it. | | |
| **2. Did you receive help from outside your patient group to collect or analyze any information used in your feedback?** | No | ☐ |
| | Yes | ☐ |
| If yes, please detail the help and who provided it. | | |

| **C. Previously Disclosed Conflict of Interest** | | |
|---|---|---|
| **1. Were conflict of interest declarations provided in patient group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section D below.** | No | ☐ |
| | Yes | ☐ |

**D. New or Updated Conflict of Interest Declaration**

**3. List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.**

| **Company** | **Check Appropriate Dollar Range** | | | |
|---|---|---|---|---|
| | **$0 to 5,000** | **$5,001 to 10,000** | **$10,001 to 50,000** | **In Excess of $50,000** |
| *Add company name* | ☐ | ☐ | ☐ | ☐ |
| *Add company name* | ☐ | ☐ | ☐ | ☐ |
| *Add or remove rows as required* | ☐ | ☐ | ☐ | ☐ |

## Appendix 2. Conflict of Interest Declarations for Clinician Groups

- To maintain the objectivity and credibility of the CADTH drug review programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest.
- This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the feedback from patient groups and clinician groups.
- CADTH may contact your group with further questions, as needed.
- Please see the *Procedures for CADTH Drug Reimbursement Reviews* for further details.
- For conflict of interest declarations:
  - Please list any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.
  - Please note that declarations are required for each clinician that contributed to the input.
  - If your clinician group provided input at the outset of the review, only conflict of interest declarations that are new or require updating need to be reported in this form. For all others, please list the clinicians who provided input are unchanged
  - Please add more tables as needed (copy and paste).
  - All new and updated declarations must be included in a single document.

| **A. Assistance with Providing the Feedback** | | |
|---|---|---|
| **2. Did you receive help from outside your clinician group to complete this submission?** | No | ☐ |
| | Yes | ☒ |
| If yes, please detail the help and who provided it.<br>OH-CCO provided a secretariat function to the group. | | |
| **3. Did you receive help from outside your clinician group to collect or analyze any information used in this submission?** | No | ☒ |
| | Yes | ☐ |
| If yes, please detail the help and who provided it. | | |
| **B. Previously Disclosed Conflict of Interest** | | |
| **4. Were conflict of interest declarations provided in clinician group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section C below.** | No | ☐ |
| | Yes | ☒ |
| If yes, please list the clinicians who contributed input and whose declarations have not changed:<br>• Dr. Tom Kouroukis<br>• Dr. Pierre Villeneuve | | |

### C. New or Updated Conflict of Interest Declarations

| **New or Updated Declaration for Clinician 1** | |
|---|---|
| **Name** | *Please state full name* |
| **Position** | *Please state currently held position* |
| **Date** | *Please add the date form was completed (DD-MM-YYYY)* |
| ☐ | **I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation. |
| **Conflict of Interest Declaration** | |

List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

| Company | Check Appropriate Dollar Range | | | |
|---|---|---|---|---|
| | $0 to 5,000 | $5,001 to 10,000 | $10,001 to 50,000 | In Excess of $50,000 |
| *Add company name* | ☐ | ☐ | ☐ | ☐ |
| *Add company name* | ☐ | ☐ | ☐ | ☐ |
| *Add or remove rows as required* | ☐ | ☐ | ☐ | ☐ |

| New or Updated Declaration for Clinician 2 | |
|---|---|
| **Name** | *Please state full name* |
| **Position** | *Please state currently held position* |
| **Date** | *Please add the date form was completed (DD-MM-YYYY)* |
| ☐ | **I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation. |

**Conflict of Interest Declaration**

List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

| Company | Check Appropriate Dollar Range | | | |
|---|---|---|---|---|
| | $0 to 5,000 | $5,001 to 10,000 | $10,001 to 50,000 | In Excess of $50,000 |
| *Add company name* | ☐ | ☐ | ☐ | ☐ |
| *Add company name* | ☐ | ☐ | ☐ | ☐ |
| *Add or remove rows as required* | ☐ | ☐ | ☐ | ☐ |

CADTH

# CADTH Reimbursement Review

# Feedback on Draft Recommendation

| Stakeholder information | |
|---|---|
| CADTH project number | PC0320 |
| Name of the drug and Indication(s) | Glofitamab for the treatment of adult patients with relapsed or refractory DLBCL not otherwise specified, trFL, or PMBCL, who have received two or more lines of systemic therapy and are ineligible to receive or cannot receive CAR-T cell therapy or have previously received CAR-T cell therapy. |
| Organization Providing Feedback | PAG |

| 1. Recommendation revisions<br>Please indicate if the stakeholder requires the expert review committee to reconsider or clarify its recommendation. | | |
|---|---|---|
| **Request for Reconsideration** | **Major revisions:** A change in recommendation **category** or patient **population** is requested | ☐ |
| | **Minor revisions:** A change in reimbursement **conditions** is requested | ☐ |
| **No Request for Reconsideration** | **Editorial revisions:** Clarifications in recommendation **text** are requested | X |
| | **No requested revisions** | ☐ |

| 2. Change in recommendation category or conditions<br>Complete this section if major or minor revisions are requested |
|---|
| Please identify the specific text from the recommendation and provide a rationale for requesting a change in recommendation. |

| 3. Clarity of the recommendation<br>Complete this section if editorial revisions are requested for the following elements |
|---|
| **a) Recommendation rationale** |
| Please provide details regarding the information that requires clarification. |
| **b) Reimbursement conditions and related reasons** |
| Please provide details regarding the information that requires clarification. |
| **c) Implementation guidance** |
| Please provide high-level details regarding the information that requires clarification. You can provide specific comments in the draft recommendation found in the next section. Additional implementation questions can be raised here. |

- Under considerations for initiation of treatment, PAG asked for clarification on the 6-month disease free interval needed prior to re-treatment. If this time frame is included in the trial protocol, it can remain in this section. If not, the time frame will be removed.

# Outstanding Implementation Issues

In the event of a positive draft recommendation, drug programs can request further implementation support from CADTH on topics that cannot be addressed in the reimbursement review (e.g., concerning other drugs, without sufficient evidence to support a recommendation, etc.). Note that outstanding implementation questions can also be posed to the expert committee in Feedback section 4c.

| Algorithm and implementation questions |
|---|
| **1. Please specify sequencing questions or issues that should be addressed by CADTH (oncology only)** |
| 1. An update to the algorithm is needed (rapid algorithm)<br>2. |
| **2. Please specify other implementation questions or issues that should be addressed by CADTH** |
| 1.<br>2. |
| **Support strategy** |
| **3. Do you have any preferences or suggestions on how CADTH should address these issues?** |
| May include implementation advice panel, evidence review, provisional algorithm (oncology), etc. |

CADTH

# CADTH Reimbursement Review
# Feedback on Draft Recommendation

| Stakeholder information | |
|---|---|
| CADTH project number | PC0320-000 |
| Brand name (generic) | Columvi (Glofitamab) |
| Indication(s) | Indicated for the 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 two or more lines of systemic therapy and are ineligible to receive or cannot receive CAR-T cell therapy or have previously received CAR-T cell therapy. |
| Organization | Lymphoma Canada |
| Contact information[a] | Name: Gurjot Basra, Manager of Patient Programs, Research, and Advocacy |

| Stakeholder agreement with the draft recommendation | | |
|---|---|---|
| **1. Does the stakeholder agree with the committee's recommendation.** | Yes | ☒ |
| | No | ☐ |

Please explain why the stakeholder agrees or disagrees with the draft recommendation. Whenever possible, please identify the specific text from the recommendation and rationale.

We agree with the committee's recommendation that Glofitamab be reimbursed for the treatment of relapsed or refractory DLBCL. DLBCL patients have expressed the need for more effective treatments that extend survival, have fewer side effects, and improve quality of life. Survey patients specifically indicated that they were less satisfied with treatment options in the second and third line compared to the first line setting. Hence, it is important to patients that they have more choice of treatments that will be better tolerated and best suited to their personal clinical history. Overall, the patients we surveyed rated their experience with this treatment as good and very good, and would recommend it to other patients with R/R DLBCL. In this regard, Glofitamab has addressed patient preferences with respect to greater choice, and improved quality of life.

| Expert committee consideration of the stakeholder input | | |
|---|---|---|
| **2. Does the recommendation demonstrate that the committee has considered the stakeholder input that your organization provided to CADTH?** | Yes | ☒ |
| | No | ☐ |

If not, what aspects are missing from the draft recommendation?

Yes, the committee has demonstrated that it has recognized the importance of the preferences of the surveyed patient population, namely that patients would like access to more options in the relapsed/refractory setting that allow them to live longer, with less symptoms and an improved quality of life.

| Clarity of the draft recommendation | | |
|---|---|---|
| **3. Are the reasons for the recommendation clearly stated?** | Yes | ☒ |
| | No | ☐ |

If not, please provide details regarding the information that requires clarification.

The reasons for the recommendations are clearly stated. However, reimbursement condition 5 stating that Glofitamab should not be reimbursed when given in combination with other systemic anticancer drugs, is extremely limiting for patients as this may hinder the ability to tailer treatment plans to individual patient needs, compromising the chances of optimal outcomes. This is especially true as new studies are emerging recognizing the effectiveness of Glofitamab used in combination therapy. For example, a study published in the ASH Blood journal by Topp et al. (2022) indicates how Glofitamab can be safely combined with R-CHOP as a fixed-duration treatment for patients with first-line DLBCL. Hence, reimbursement condition 5 may lead to suboptimal disease management. Instead, the decision for combination therapy should be left to the discretion of the treating clinician (hematologists or oncologists) with expertise in the management of DLBCL.

| | | |
|---|---|---|
| **4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?** | Yes | ☒ |
| | No | ☐ |

If not, please provide details regarding the information that requires clarification.

| | | |
|---|---|---|
| **5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?** | Yes | ☐ |
| | No | ☒ |

If not, please provide details regarding the information that requires clarification.

To an extent, most conditions have been listed clearly, however, condition 6 seems to suggest that despite durable responses and prolonged survival in patients that have received Glofitamab, the feasibility of adoption is solely dependent on the submitted price. We feel the feasibility of adoption should not be tied strictly to budgetary impacts and rather that the focus be on the manageable toxicity profile, improvement in QoL and prolonged response should take precedence. Additionally, it is not clear/unfair for the price reduction of Glofitamab to be compared to that of chemotherapy, instead it should also factor in other treatments used in this line such as Pola-BR, to reduce access delays for patients. Condition 7 further states feasibility concerns, which may contribute to further delays in access. For r/r DLBCL patients, delays to accessing this therapy can be detrimental to their overall survival, especially if they are ineligible for CAR-T. We would like to stress the urgency for this group of patients, hence, condition 5,6, and 7 should be re-evaluated.

[a] CADTH may contact this person if comments require clarification.

## Appendix 1. Conflict of Interest Declarations for Patient Groups

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- This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the feedback from patient groups and clinician groups.
- CADTH may contact your group with further questions, as needed.
- Please see the *Procedures for CADTH Drug Reimbursement Reviews* for further details.

| **A. Patient Group Information** | |
|---|---|
| **Name** | *Gurjot Basra* |
| **Position** | *Manager of Patient Programs, Research, and Advocacy* |
| **Date** | *January 18, 2024* |
| ☒ | I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation. |

| **B. Assistance with Providing Feedback** | | |
|---|---|---|
| **1. Did you receive help from outside your patient group to complete your feedback?** | No | ☒ |
| | Yes | ☐ |
| If yes, please detail the help and who provided it. | | |
| **2. Did you receive help from outside your patient group to collect or analyze any information used in your feedback?** | No | ☒ |
| | Yes | ☐ |
| If yes, please detail the help and who provided it. | | |

| **C. Previously Disclosed Conflict of Interest** | | |
|---|---|---|
| **1. Were conflict of interest declarations provided in patient group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section D below.** | No | ☐ |
| | Yes | ☒ |

**D. New or Updated Conflict of Interest Declaration**

**3. List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.**

| **Company** | **Check Appropriate Dollar Range** | | | |
|---|---|---|---|---|
| | **$0 to 5,000** | **$5,001 to 10,000** | **$10,001 to 50,000** | **In Excess of $50,000** |
| *Roche* | ☐ | ☐ | ☒ | ☐ |
| *Gilead* | ☐ | ☐ | ☐ | ☒ |
| *Incyte* | ☐ | ☐ | ☒ | ☐ |
| *Novartis* | ☐ | ☐ | ☒ | ☐ |
| *BMS* | ☐ | ☐ | ☐ | ☒ |

CADTH

# CADTH Reimbursement Review
# Feedback on Draft Recommendation

| Stakeholder information | |
|---|---|
| CADTH project number | PC0320-000-000 |
| Brand name (generic) | Columvi (glofitamab) |
| Indication(s) | For the treatment of adult patients with relapsed or refractory DLBCL not otherwise specified, trFL, or PMBCL, who have received two or more lines of systemic therapy and are ineligible to receive or cannot receive CART cell therapy or have previously received CAR-T cell therapy. |
| Organization | The Leukemia & Lymphoma Society of Canada (LLSC) |
| Contact information[a] | Name: Colleen McMillan, Advocacy Lead |

| Stakeholder agreement with the draft recommendation | | |
|---|---|---|
| **1. Does the stakeholder agree with the committee's recommendation.** | Yes | ☒ |
| | No | ☐ |
| Our organization agrees with the committee's recommendation. We agree that this treatment could meet patients' need for additional treatments that result in longer disease remission, improved survival, disease symptom control and improvements in health related quality of life. | | |

| Expert committee consideration of the stakeholder input | | |
|---|---|---|
| **2. Does the recommendation demonstrate that the committee has considered the stakeholder input that your organization provided to CADTH?** | Yes | ☐ |
| | No | ☐ |
| LLSC did not submit original input regarding the review for this treatment, however our organization supports the input provided by Lymphoma Canada and the clinicians | | |

| Clarity of the draft recommendation | | |
|---|---|---|
| **3. Are the reasons for the recommendation clearly stated?** | Yes | ☒ |
| | No | ☐ |
| If not, please provide details regarding the information that requires clarification. | | |
| **4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?** | Yes | ☒ |
| | No | ☐ |
| If not, please provide details regarding the information that requires clarification. | | |
| **5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?** | Yes | ☒ |
| | No | ☐ |
| If not, please provide details regarding the information that requires clarification. | | |

[a] CADTH may contact this person if comments require clarification.

## Appendix 1. Conflict of Interest Declarations for Patient Groups

- To maintain the objectivity and credibility of the CADTH drug review programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest.
- This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the feedback from patient groups and clinician groups.
- CADTH may contact your group with further questions, as needed.
- Please see the *Procedures for CADTH Drug Reimbursement Reviews* for further details.

| **A. Patient Group Information** | |
|---|---|
| **Name** | *Colleen McMillan* |
| **Position** | *Advocacy Lead, LLSC* |
| **Date** | *09-01-2024* |
| ☒ | I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation. |

| **B. Assistance with Providing Feedback** | | |
|---|---|---|
| **1. Did you receive help from outside your patient group to complete your feedback?** | No | ☒ |
| | Yes | ☐ |
| If yes, please detail the help and who provided it. | | |
| **2. Did you receive help from outside your patient group to collect or analyze any information used in your feedback?** | No | ☒ |
| | Yes | ☐ |
| If yes, please detail the help and who provided it. | | |

| **C. Previously Disclosed Conflict of Interest** | | |
|---|---|---|
| **1. Were conflict of interest declarations provided in patient group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section D below.** | No | ☐ |
| | Yes | ☐ |

**D. New or Updated Conflict of Interest Declaration**

**3. List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.**

| **Company** | **Check Appropriate Dollar Range** | | | |
|---|---|---|---|---|
| | **$0 to 5,000** | **$5,001 to 10,000** | **$10,001 to 50,000** | **In Excess of $50,000** |
| *NOTHING TO DECLARE* | ☐ | ☐ | ☐ | ☐ |
| *Add company name* | ☐ | ☐ | ☐ | ☐ |
| *Add or remove rows as required* | ☐ | ☐ | ☐ | ☐ |

# CADTH Reimbursement Review
# Feedback on Draft Recommendation

| Stakeholder information | |
|---|---|
| CADTH project number | PC0320 |
| Brand name (generic) | COLUMVI (glofitamab) |
| Indication(s) | For the treatment of adult patients with relapsed or refractory DLBCL not otherwise specified, trFL, or PMBCL, who have received two or more lines of systemic therapy and are ineligible to receive or cannot receive CAR-T cell therapy or have previously received CAR-T cell therapy. |
| Organization | Hoffmann-La Roche Limited |
| Contact information[a] | Primary Contact<br>[redacted] |

| Stakeholder agreement with the draft recommendation | | |
|---|---|---|
| **1. Does the stakeholder agree with the committee's recommendation.** | Yes | ☒ |
| | No | ☐ |

Roche agrees with the draft recommendation.

Rationale: Glofitamab offers clinically meaningful improvements in median overall survival and progression-free survival, and is associated with a clinically meaningful complete response (CR) rate and durable response. Glofitamab is a much needed treatment option that can lead to better outcomes for R/R DLBCL patients.

| Expert committee consideration of the stakeholder input | | |
|---|---|---|
| **2. Does the recommendation demonstrate that the committee has considered the stakeholder input that your organization provided to CADTH?** | Yes | ☒ |
| | No | ☐ |

Yes, in general, the recommendation demonstrates that the committee has considered the input Hoffmann-La Roche Limited has provided to CADTH.

| Clarity of the draft recommendation | | |
|---|---|---|
| **3. Are the reasons for the recommendation clearly stated?** | Yes | ☒ |
| | No | ☐ |

Yes, the reasons for the recommendation are clearly stated.

Under Rationale for Recommendation (pg. 3), CADTH stated: *"Using the sponsor submitted price for glofitamab and publicly listed prices for all other drug costs, the incremental cost-effectiveness ratio (ICER) for glofitamab was $230,682 per quality-adjusted life-year (QALY) compared with salvage*

*chemotherapy. At this ICER, glofitamab is not cost-effective at a $50,000 per QALY gained willingness to pay (WTP) threshold for patients with R/R DLBCL after at least two prior lines of therapy. A price reduction is required for glofitamab to be considered cost-effective at a $50,000 per QALY gained threshold."*

There is no mention of the incremental cost-effectiveness of glofitamab relative to Pola-BR – a relevant publicly funded comparator for glofitamab. This is not in line with pERC's recommendation as part of the Pharmacoeconomic Review Report (pg. 2) dated November 23, 2023, where "CADTH notes that a price reduction may still be required for glofitamab to be no more costly than Pola-BR". Roche requests that CADTH please include the following wording:

- "Glofitamab is associated with lower costs and similar QALYs when compared to Pola-BR. A price reduction may be required for glofitamab to be no more costly than Pola-BR as the price of polatuzumab was based on public list price."

| **4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?** | Yes | ☒ |
|---|---|---|
| | No | ☐ |

Yes, the implementation issues have been clearly articulated and adequately addressed in the recommendation. Roche requests clarification in the following:

**Responses to Questions from Drug Programs, under Considerations for Initiation of Therapy in Table 2 (pg. 11)**

The drug program inquired on whether or not patients with other types of indolent lymphomas besides FL that have transformed into DLBCL be eligible for glofitamab treatment, specifically follicular lymphoma grade 3B and high grade B cell lymphoma. Given that clinical experts and pERC agreed that "these patients, i.e., patients with Grade 3B FL, HGBCL, and transformed lymphomas from any type of indolent lymphoma, should be eligible for treatment with glofitamab", Roche proposes the inclusion of these lymphoma types to be incorporated into the following sections for further clarity:

1. Under Recommendation (pg. 3): "The CADTH pCODR Expert Review Committee (pERC) recommends that glofitamab be reimbursed for the treatment of adult patients with relapsed or refractory diffuse-large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL arising from follicular lymphoma (trFL), **high-grade B cell lymphoma (HGBCL), follicular lymphoma Grade 3B (FLG3B)**, or primary mediastinal B-cell lymphoma (PMBCL), who have received two or more lines of systemic therapy and are ineligible to receive or cannot receive CAR-T cell therapy or have previously received CAR-T cell therapy only if the conditions listed in Table 1 are met."
2. Under Table 1. Reimbursement Conditions and Reasons (pg. 4): "1.1 Relapsed or refractory DLBCL not otherwise specified, trFL, **HGBCL, FLG3B,** or PMBCL"

**Other**

Roche notes that under Table 3 "Should patients with other types of indolent lymhomas besides FL that have transformed into DLBCL be eligible?" in the response section (pg. 11), CADTH has spelled HGBCL "HCBCL".

| 5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation? | Yes | ☒ |
|---|---|---|
| | No | ☐ |

Yes, in general, the reimbursement conditions are clearly stated and the rationale for the conditions are provided in the recommendation. However, Roche requests further clarification or consideration on the following:

**Reimbursement Conditions and Reasons, Pricing Section in Table 1 (pg. 5)**

CADTH has stated the following as a reimbursement condition: *"The ICER for glofitamab is $230,682 per QALY gained when compared with salvage chemotherapy. A price reduction of 82% would be required for glofitamab to achieve an ICER of $50,000 per QALY gained compared to salvage chemotherapy."*

There is no mention of the incremental cost-effectiveness of glofitamab relative to Pola-BR – a relevant publicly funded comparator for glofitamab. This is not in line with pERC's recommendation as part of the Pharmacoeconomic Review Report (pg. 2) dated November 23, 2023, where "CADTH notes that a price reduction may still be required for glofitamab to be no more costly than Pola-BR". Roche requests that CADTH please include the following wording:
"Glofitamab is associated with lower costs and similar QALYs when compared to Pola-BR. A price reduction may be required for glofitamab to be no more costly than Pola-BR as the price of polatuzumab was based on public list price."

[a] CADTH may contact this person if comments require clarification.