CADTH

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

mogamulizumab (Poteligeo)

(Kyowa Kirin Canada)

Indication: For the treatment of adult patients with relapsed or refractory mycosis fungoides (MF) or Sézary syndrome (SS) after at least one prior systemic therapy.

July 28, 2022

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0244-000
Brand name (generic)	Mogamulizumab (TBC)
Indication(s)	The treatment of adult patients with mycosis fungoides (MF) or Sézary syndrome (SS) who have received at least one prior systemic therapy.
Organization	Ontario Health (CCO) Hematology Cancer Drug Advisory Committee
Contact information[a]	[redacted]

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

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	☐

Clarity of the draft recommendation		
3. Are the reasons for the recommendation clearly stated?	Yes	☒
	No	☐
4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes	☒
	No	☐
5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	☒
	No	☐

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

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		
1. Did you receive help from outside your clinician group to complete this submission?	No	☐
	Yes	☒
Ontario Health (CCO) provided secretariat function to the DAC.		
2. Did you receive help from outside your clinician group to collect or analyze any information used in this submission?	No	☒
	Yes	☐
B. Previously Disclosed Conflict of Interest		
3. 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: • Dr. Tom Kouroukis • Dr. Mark Brown • Dr. Lee Mozessohn • Dr. Jordan Herst		

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0277
Name of the drug and Indication(s)	Mogamulizumab for MF/SS
Organization Providing Feedback	PAG

1. Recommendation revisions 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 Complete this section if major or minor revisions are requested
None.

3. Clarity of the recommendation Complete this section if editorial revisions are requested for the following elements
a) Recommendation rationale
In Table 3 Cost and Cost-effectiveness, in the treatment row, PAG is requesting adding the dosing schedule, since cost will be dependent upon patient weight/vial wastage
b) Reimbursement conditions and related reasons
None.
c) Implementation guidance
In Table 2, under the heading “Care provision issues” PAG is requesting adding the following text “*Preparation of mogamulizumab requires a sterile compounding pharmacy and has very limited final product stability (fewer than 4 hours from preparation to end of infusion). As such, administration of mogamulizumab is likely to be restricted to facilities/locations with access to a sterile compounding pharmacy on site*.”

CADTH

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0244-000
Brand name (generic)	Poteligeo (Mogamulizumab)
Indication(s)	for the treatment of adult patients with mycosis fungoides (MF) or Sézary syndrome (SS) who have received at least one prior systemic therapy
Organization	Lymphoma Canada, Canadian Skin Patient Alliance (CSPA) and Cutaneous Lymphoma Foundation (CLF)
Contact information[a]	[redacted]

Stakeholder agreement with the draft recommendation		
1. Does the stakeholder agree with the committee's recommendation.	Yes	☒
	No	☐
Yes, Lymphoma Canada, in collaboration with CSPA and CLF, agree with CADTH's recommendation that mogamulizumab be reimbursed for this indication, only if the conditions listed in Table 1 of the Recommendation are met. A diagnosis of MF or SS greatly impacts the quality of life and wellbeing of the patients due to the significant symptom burden of the disease. Consequently the availability of mogamulizumab, which according to patients surveyed, is able to manage the major symptoms experienced by MF/SS patients including skin itchiness, red skin patches/rash and skin pain, is thus of utmost importance.		

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, according to the rationale for the recommendation our patient group submission was considered particularly when noting the following: -pERC acknowledged the unmet need for this rare patient population in this setting given the severe nature of this disease with substantial morbidity and lack of effective available therapies. -69% of patients responded they had a good to excellent experience with this therapy; -that 81% of survey respondents cited the importance of having an increased number of treatment options available;		

Clarity of the draft recommendation		
3. Are the reasons for the recommendation clearly stated?	Yes	☒
	No	☐
Yes, the reasons are clearly stated.		
4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes	☐
	No	☒

No. Although pERC acknowledged the unmet need for this rare patient population in this setting given the severe nature of this disease with substantial morbidity and lack of effective available therapies, the implementation guidance noted for reimbursement condition number 1.has introduced a barrier to access to mogamulizumab by requiring patients with a CD30+ immunohistochemical expression to be treated with brentuximab vedotin where available. This can potentially eliminate mogamulizumab as a treatment option for some patients, despite the positive experience (good to excellent) that patients have expressed with this therapy and despite the fact that 81% of the patients we surveyed cited the importance of having an increased number of treatment options available. Treating clinicians should be able to determine the best course of treatment to prescribe a MF or SS patient based on the medical history and individual disease status of the patient rather than on a jurisdictional availability basis.

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

Yes, Table 1 “Reimbursement Conditions and Reasons” clearly states this information. However, under the Initiation Section (Implementation Guidance) of Table 1, Lymphoma Canada recommends that additional guidance be provided so as to avoid barriers to access to mogamulizumab based on jurisdictional availability of other therapies. As noted in both our patient submission as well as the pERC recommendation, there is an unmet need for this patient demographic that mogamulizumab addresses. In that regard, access to it should be based on clinical need rather than jurisdictional considerations. Equitable access to therapies that are successful in treating MF/SS patients is of utmost importance.

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

Appendix 1. Conflict of Interest Declarations for Patient Groups

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- Please see the *Procedures for CADTH Drug Reimbursement Reviews* for further details.

A. Patient Group Information	
Name	*Antonella Rizza*
Position	*CEO*
Date	*July 21, 2022*
☒	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	☒
Yes. Susan Thornton from the Cutaneous Lymphoma Foundation (CLF) and Rachael Manion from the Canadian Skin Patient Alliance (CSPA) both contributed to the review of the "feedback on draft recommendation" submission.		
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	☐	☐	☐	☐