CADTH

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

Ruxolitinib (Jakavi)

(Novartis Pharmaceutical Canada Inc.)

Indication: For the treatment of treatment of steroid refractory or dependent acute graft-versus-host disease in patients aged 12 years and older.

September 2, 2022

CADTH

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0688-000
Brand name (generic)	Jakavi (ruxolitinib)
Indication(s)	Graft versus host disease
Organization	Ontario Health (Cancer Care Ontario) Complex Malignant Hematology
Contact information[a]	Name: Dr. Tom Kouroukis

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 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. Christopher Bredeson		

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR 0688
Brand name (generic)	JAKAVI (ruxolitinib)
Indication(s)	For the treatment of steroid refractory or dependent acute graft-versus-host disease (GVHD) in adult and pediatric patients 12 years and older
Organization	Cell Therapy Transplant Canada (CTTC)
Contact information[a]	Kirk R. Schultz – CTTC President

Stakeholder agreement with the draft recommendation		
6. Does the stakeholder agree with the committee's recommendation?	Yes	☒
	No	☒
Ruxolitinib has become the preferred second line therapy for both acute and chronic GvHD. The drug is well tolerated and has a high efficacy. It is now considered standard of care by a majority of adult and pediatric Hematopoietic Stem Cell Transplant (HSCT) centres in Canada. Overall, we agree with the recommendation. However, for the frequency of renewal, we would suggest re-evaluation every 6 months. Once the patient responds to therapy it is unlikely that ruxolitinib is stopped during the first 3 or even 6 months. Also, we do not agree with not adding JAKAVI to other therapies. It is common practice in treatment of aGVHD (or cGVHD) to add a therapy when current therapies are not working and then taper off the other therapies. Similarly, the discontinuation of JAKAVI if it is not working, is also likely going to be AFTER a different therapy is started. We don't know if the JAKAVI in this situation is providing partial help and an abrupt stop without giving time for next therapy to work could lead to a flare.		

Expert committee consideration of the stakeholder input		
7. 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		
8. Are the reasons for the recommendation clearly stated?	Yes	☒
	No	☐
9. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes	☒
	No	☐
10. 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

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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.
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- 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	☐
2. Did you receive help from outside your clinician group to collect or analyze any information used in this submission?	No	☒
	Yes	☐
All HSCT or BMT centre directors have had an opportunity to provide input on this response and it has been reviewed by the CTTC Board of Directors.		
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: • Kirk Schultz [redacted] [redacted]Imran Ahmad [redacted] • Mohamed Elemary [redacted] [redacted]Wilson Lam [redacted] • Jonas Mattsson [redacted] • Gizelle Popradi [redacted] [redacted]Mona Shafey [redacted]		

C. New or Updated Conflict of Interest Declarations

New or Updated Declaration for Clinician 1	
Name	Chris Bredeson
Position	Head, Malignant Hematology & Stem Cell Transplantation, The Ottawa Hospital
Date	30-08-2022

☒	**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**
Novartis	☒	☐	☐	☐

New or Updated Declaration for Clinician 2	
Name	Greg Guilcher
Position	Paediatric Oncologist, Alberta Children's Hospital; Associate Professor, University of Calgary
Date	31-08-2022
☒	**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**
None	☐	☐	☐	☐

New or Updated Declaration for Clinician 3	
Name	Terrance Comeau
Position	Director, New Brunswick Stem Cell Transplant Program, Horizon Health Network
Date	31-08-2022
☒	**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**
None	☐	☐	☐	☐

New or Updated Declaration for Clinician 4

Name	Mahmoud Elsawy
Position	Assistant Professor, Dalhousie University
Date	31-08-2022
☒	**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**
Kite/Gilead	☒	☐	☐	☐
Novartis	☒	☐	☐	☐
Bristol Myers Squibb	☒	☐	☐	☐

New or Updated Declaration for Clinician 5

Name	Geoffrey Cuvelier
Position	Section Head, Department of Pediatric Oncology-Hematology-BMT, CancerCare Manitoba
Date	31-08-2022
☒	**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**
None	☐	☐	☐	☐

New or Updated Declaration for Clinician 6

Name	David Mitchell
Position	Director, Pediatric Hematopoietic Stem Cell Transplantation, Montreal Children's Hospital
Date	31-08-2022
☒	**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
None	☐	☐	☐	☐

New or Updated Declaration for Clinician 7	
Name	Victor Lewis
Position	Associate Professor of Oncology and Pediatrics, University of Calgary, Alberta Children's Hospital
Date	31-08-2022
☒	**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
Novartis	☒	☐	☐	☐

New or Updated Declaration for Clinician 8	
Name	Kevin Song
Position	Interim Medical Director, Leukemia/BMT Program of BC, Vancouver General Hospital
Date	31-08-2022
☒	**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
None	☐	☐	☐	☐

New or Updated Declaration for Clinician 9	
Name	Anargyros Xenocostas
Position	Director, Hematopoietic Stem Cell Transplant Program, London Health Sciences-Victoria Hospital
Date	31-08-2022
☒	**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**
Novartis (Advisory boards)	☒	☐	☐	☐

New or Updated Declaration for Clinician 10	
Name	Jacob Rozmus
Position	Pediatric Hematologist-Oncologist, BMT Director, BC Children's Hospital; Clinical Assistant Professor, University of British Columbia
Date	31-08-2022
☒	**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**
None	☐	☐	☐	☐

New or Updated Declaration for Clinician 11	
Name	Joanne Hickey
Position	Associate Professor of Medicine (Hematology), Memorial University
Date	31-08-2022
☒	**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**
None	☐	☐	☐	☐

New or Updated Declaration for Clinician 12	
Name	Geneviève Gallagher
Position	Directrice médicale du Programme de Transplantation de cellules Hématopoiétiques et de Thérapie Cellulaire, CHU de Québec- Université Laval
Date	31-08-2022

☒	**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**
None	☐	☐	☐	☐

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0688
Name of the drug and Indication(s)	Ruxolitinib (Jakavi) for the treatment of treatment of steroid refractory or dependent acute graft-versus-host disease in patients aged 12 years and older
Organization Providing Feedback	FWG

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

Please identify the specific text from the recommendation and provide a rationale for requesting a change in recommendation.

3. Clarity of the recommendation
Complete this section if editorial revisions are requested for the following elements

a) Recommendation rationale

It would helpful to drug plans to differentiate 'systemic therapies' which may be used for alternative conditions, unrelated to immune suppression or treatment of aGvHD.

b) Reimbursement conditions and related reasons

In the prescribing conditions, (table item # 7) it would be helpful if 'systemic therapies' could be clarified to reflect systemic therapies for treatment of aGvHD.

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.

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. 2.
2. Please specify other implementation questions or issues that should be addressed by CADTH
1. 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 Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR 0688
Brand name (generic)	JAKAVI (ruxolitinib)
Indication(s)	For the treatment of steroid refractory or dependent acute graft-versus-host disease (GVHD) in adult and pediatric patients 12 years and older
Organization	The Leukemia & Lymphoma Society, CLL Canada, Lymphoma Canada
Contact information[a]	Name: Sabrina Hanna

Stakeholder agreement with the draft recommendation		
1. Does the stakeholder agree with the committee's recommendation.	Yes	X
	No	☐
We agree with the CDEC recommendation that ruxolitinib be reimbursed for the treatment of steroid refractory or dependent acute graft-versus-host disease (aGvHD) in adult and pediatric patients aged 12 years and older only if the conitions listed in Table 1 are met. As noted by the committee, AGvHD is associated with substantial morbidity and mortality and currently there is a significant unmet need for additional effective treatments for patients. There are currently no standard of care treatments available and consequently availability of ruxolitinib is of utmost importance in fulfilling that patient need. Further, aGvHD symptoms significantly impacts patients' daily QoL. According to patients surveyed, Ruxolitinib was an effective treatment that improved their QoL as reported in the patient input provided to CADTH.		
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	X
	No	☐
While the report provides a good summary of the input provided, we feel it is important to highlight that many patients must be seen by multiple healthcare professionals before being properly diagnosed and must also take many treatments that complicate symptoms and require multiple visits to the hospital In addition to the above, ruxolitinib can be administered as an outpatient treatment which is preferred by patients surveyed.		
Clarity of the draft recommendation		
3. **Are the reasons for the recommendation clearly stated?**	Yes	X
	No	☐
We feel the reasons for recommendations have been clearly stated and support the needs of patients.		
4. **Have the implementation issues been clearly articulated and adequately**	Yes	X

addressed in the recommendation?	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	X
	No	
The reimbursement conditions have been clearly stated and the rationale has been provided, however, we are concerned with the rationale that a 65% reduction in price is necessary to meet CADTH QALY and WTP. While we fully agree with a negotiated and appropriate price review for this therapy, we feel that the unmet need for these patients must be considered as a top priority in supporting the reimbursement conditions for the reasons listed above.		

[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	*Sabrina Hanna*
Position	*Advocacy Lead*
Date	*31.08.2022*
X	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	X
CLL Canada and Lymphoma Canada		
2. Did you receive help from outside your patient group to collect or analyze any information used in your feedback?	No	☐
	Yes	X☐
Lymphoma Canada (LC), Lymphoma and Leukemia Society of Canada (LLSC), CLL Canada, Myeloma Canada, Aplastic Anemia & Myelodysplasia Association of Canada (AAMAC), Canadian MPN Research Foundation (CMPNRF), CML Network, MPN Canadian Research Foundation, Cell Therapy Transplant Canad (CTTC)		

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 remaine unchanged? If no, please complete section D below.	No	☐
	Yes	X

D. New or Updated Conflict of Interest Declaration

3. List any companies or organizations that have provided your group with financial payment over th 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**
Novartis	☐	X	☐	☐

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0688
Brand name (generic)	Ruxolitinib
Indication(s)	Acute GvHD
Organization	Novartis
Contact information[a]	[redacted]

Stakeholder agreement with the draft recommendation		
11. 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.

- Novartis agrees with the CADTH Canadian Drug Expert Committee (CDEC) to recommend that "that ruxolitinib be reimbursed for the treatment of steroid refractory or dependent acute graft-versus-host disease (aGvHD) in adult and pediatric patients aged 12 years and older." (Recommendation, page 3)
- Novartis also agrees with CDEC on the "rarity of steroid refractory and steroid dependent aGvHD and the significant unmet need for additional treatment options in this setting given the severe nature of this disease with substantial morbidity and mortality." (Rational for recommendation, page 3)
- Novartis agrees also with the clinical experts consulted by CADTH who «believed that the efficacy results from the REACH 2 trial were clinically meaningful and supportive of the reported response outcomes in the REACH 1 trial." (Discussion points, page 8)
- Novartis agrees with CADTH on the safety profile: "no unexpected safety concerns were observed with ruxolitinib and patients could be adequately managed in clinical practice." (Discussion points, page 8)
- Novartis agrees with CDEC on the similar treatment effect and safety profile among adults and adolescents aged 12 to 18 years. (Discussion points, page 8)

Expert committee consideration of the stakeholder input		
12. 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?
While Novartis agrees with the clinical evaluation and conclusions by CDEC, it is incomprehensible to Novartis how price reductions can be requested with a CADTH ICER of $21,057/QALY. Indeed, this ICER, based on CADTH reanalysis and assumptions, is still well below the willingness to pay threshold of $50,000/QALY.

Clarity of the draft recommendation		
13. Are the reasons for the recommendation clearly stated?	Yes	☒
	No	☐

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

14. 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.		
15. 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.