

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

brexucabtagene autoleucel (Tecartus)
(Gilead Sciences Inc.)

Indication: For treatment of adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

March 16, 2023

Disclaimer: The views expressed in this submission are those of the submitting organization or individual. As such, they are independent of CADTH and do not necessarily represent or reflect the view of CADTH. No endorsement by CADTH is intended or should be inferred.

By filing with CADTH, the submitting organization or individual agrees to the full disclosure of the information. CADTH does not edit the content of the submissions.

CADTH does use reasonable care to prevent disclosure of personal information in posted material; however, it is ultimately the submitter's responsibility to ensure no identifying personal information or personal health information is included in the submission. The name of the submitting stakeholder group and all conflicts of interest information from individuals who contributed to the content are included in the posted submission.

CADTH Reimbursement Review Feedback on Draft Recommendation

Stakeholder information		
CADTH project number	PG0304-000	
Brand name (generic)	TECARTUS (brexucabtagene autoleucel)	
Indication(s)	Acute lymphoblastic leukemia (ALL)	
Organization	Cell Therapy Transplant Canada (CTTC)	
Contact information ^a	Kirk R. Schultz – CTTC President	
Stakeholder agreement with the draft recommendation		
1. Does the stakeholder agree with the committee’s recommendation?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Brexucabtagene autoleucel is now considered a valuable salvage therapy for relapsed or refractory ALL. Based on the ZUMA-3 trial, a significantly higher portion of patients are being cured with brexucabtagene autoleucel therapy.		
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	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Clarity of the draft recommendation		
3. Are the reasons for the recommendation clearly stated?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>

^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	<input checked="" type="checkbox"/>
	Yes	<input type="checkbox"/>
2. Did you receive help from outside your clinician group to collect or analyze any information used in this submission?	No	<input checked="" type="checkbox"/>
	Yes	<input type="checkbox"/>
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	<input type="checkbox"/>
	Yes	<input checked="" type="checkbox"/>
If yes, please list the clinicians who contributed input and whose declarations have not changed: <ul style="list-style-type: none"> Christopher Bredeson Terrance Comeau Kevin Song 		

C. New or Updated Conflict of Interest Declarations

New or Updated Declaration for Clinician 1	
Name	Kevin Hay
Position	Assistant Professor, Department of Medicine, University of British Columbia
Date	07-03-2023
<input checked="" type="checkbox"/>	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	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Novartis	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BMS	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Jazz Pharmaceuticals	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Janssen	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

New or Updated Declaration for Clinician 2

Name	Victor Lewis
Position	Associate Professor of Oncology and Pediatrics, University of Calgary
Date	13-03-2023

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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

New or Updated Declaration for Clinician 3

Name	Nicole Prokopishyn
Position	Director at Large, Regulatory and Quality, CTTC; Cellular Therapy Lab Director, Alberta Precision Labs, Alberta
Date	13-03-2023

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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

CADTH Reimbursement Review Feedback on Draft Recommendation

Stakeholder information		
CADTH project number	PG0304-000	
Brand name (generic)	brexucabtagene autoleucl (Tecartus)	
Indication(s)	for treatment of adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)	
Organization	Ontario Health (Cancer Care Ontario) Hematology Cancer Drug Advisory Committee	
Contact information ^a	Name: Dr. Tom Kouroukis	
Stakeholder agreement with the draft recommendation		
1. Does the stakeholder agree with the committee's recommendation.	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
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	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Clarity of the draft recommendation		
3. Are the reasons for the recommendation clearly stated?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
N/A		

^a CADTH may contact this person if comments require clarification.

Appendix 2. Conflict of Interest Declarations for Clinician Groups

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 - 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	<input type="checkbox"/>
	Yes	<input checked="" type="checkbox"/>
Ontario Health provided secretariat assistance to the DAC.		
2. Did you receive help from outside your clinician group to collect or analyze any information used in this submission?	No	<input checked="" type="checkbox"/>
	Yes	<input type="checkbox"/>
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	<input type="checkbox"/>
	Yes	<input checked="" type="checkbox"/>
If yes, please list the clinicians who contributed input and whose declarations have not changed: <ul style="list-style-type: none"> Dr. Tom Kouroukis 		

C. New or Updated Conflict of Interest Declarations

New or Updated Declaration for Clinician 1	
Name	Dr. Pierre Villeneuve
Position	Member, Ontario Health (Cancer Care Ontario) Hematology Cancer Drug Advisory Committee
Date	16-03-2023
<input checked="" type="checkbox"/>	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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

New or Updated Declaration for Clinician 2

Name	Dr Selay Lam
Position	Member, Ontario Health (Cancer Care Ontario) Hematology Cancer Drug Advisory Committee
Date	16-03-2023
<input checked="" type="checkbox"/>	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	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

New or Updated Declaration for Clinician 3

Name	Dr Lee Mozessohn
Position	Member, Ontario Health (Cancer Care Ontario) Hematology Cancer Drug Advisory Committee
Date	16-03-2023
<input checked="" type="checkbox"/>	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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

New or Updated Declaration for Clinician 4

Name	Dr. Guillaume Richard-Carpentier
Position	Member, Ontario Health (Cancer Care Ontario) Hematology Cancer Drug Advisory Committee
Date	16-03-2023
<input checked="" type="checkbox"/>	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.

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PG0304
Name of the drug and Indication(s)	Brexucabtagene autoleucel for acute lymphoblastic leukemia
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 <input type="checkbox"/>
	Minor revisions: A change in reimbursement conditions is requested <input type="checkbox"/>
No Request for Reconsideration	Editorial revisions: Clarifications in recommendation text are requested <input checked="" type="checkbox"/>
	No requested revisions <input type="checkbox"/>
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	
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.	
PAG is requesting the following editorial revisions:	

- In Table 2 under consideration for initiation of therapy (which exclusion criteria for ZUMA-3) should be applied in determining eligibility, PAG would like to indicate that while for patients with prior CD19-targeted therapy could be eligible for the treatment with brexucabtagene autoleucl: **that it is specified that it is indicated for patients with prior non-cellular CD19-targeted therapy that could be eligible for the treatment with brexucabtagene autoleucl.**
- In Table 2 under consideration for initiation of therapy, the statement referring to uncontrolled CNS disease, PAG would like to consider adding “active” to uncontrolled CNS disease. Some jurisdictions refer “uncontrolled” to infection status (viral, fungal, bacetiral) vs. active CNS involvement.
- PAG would like to know if there was a discussion on CD19 tumour expression. In ZUMA-3 trial where patients previously treated with blinatumomab, the CD19 tumour expression must be documented after the completion of the most recent prior line of therapy. If CD19 expression is quantified, then blasts must be ≥90%CD19 positive. For comparison, the Kymriah criteria (25 years or younger ALL) does not require a specific level of CD19 positivity. PAG would like to include a clarification if this has been discussed.

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. Update the ALL Rapid Algorithm (to distinguish by age) 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	PG0304-000	
Brand name (generic)	TECARTUS (brexucabtagene autoleucl)	
Indication(s)	for treatment of adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)	
Organization	Gilead Sciences Canada, Inc	
Contact information ^a	[REDACTED]	
Stakeholder agreement with the draft recommendation		
1. Does the stakeholder agree with the committee's recommendation.	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Gilead Sciences Canada, Inc (Gilead) agrees with pERC's Initial Recommendation to reimburse brexucabtagene autoleucl for the treatment of adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL). Gilead is pleased that CADTH and pERC have recognized the need for brexucabtagene autoleucl to be funded for these patients, which have limited treatment options available to them.		
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	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
N/A		
Clarity of the draft recommendation		
3. Are the reasons for the recommendation clearly stated?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
N/A		
4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
N/A		
5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
N/A		

^a CADTH may contact this person if comments require clarification.