

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

nelarabine (Atriance)

(Pediatric Oncology Group of Ontario (POGO))

Indication: Nelarabine (Atriance) for addition to front-line multi-agent therapy of pediatric, adolescent, and young adult (AYA) patients (aged 1-30 years at diagnosis) with intermediate- or high-risk T-cell acute lymphoblastic leukemia (T-ALL).

September 15, 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	PC0307-000
Brand name (generic)	Atriance (nelarabine)
Indication(s)	For addition to front-line multi-agent therapy of pediatric, adolescent, and young adult (AYA) patients (aged 130 years at diagnosis) with intermediate- or high-risk T-cell acute lymphoblastic leukemia (T-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"/>
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 <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
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 <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
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 <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
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 <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
If not, please provide details regarding the information that requires clarification.	
The Heme DAC would ask for some flexibility around the upper age limit of 30, as well as some flexibility with the chemotherapy backbone with what is commonly used in Ontario.	

^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	<i>Please state full name</i>			
Position	<i>Please state currently held position</i>			
Date	<i>Please add the date form was completed (DD-MM-YYYY)</i>			
<input type="checkbox"/>	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	<input type="checkbox"/>
			Yes	<input type="checkbox"/>
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	<input type="checkbox"/>
			Yes	<input type="checkbox"/>
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	<input type="checkbox"/>
			Yes	<input type="checkbox"/>
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
<i>Add company name</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Add company name</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Add or remove rows as required</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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	<input type="checkbox"/>
	Yes	<input checked="" type="checkbox"/>
If yes, please detail the help and who provided it. 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	<input type="checkbox"/>
	Yes	<input checked="" type="checkbox"/>
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	<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 Dr. Lee Mozessohn Dr. Pierre Villeneuve 		

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0307
Name of the drug and Indication(s)	Nelarabine for pediatric, adolescent, and young adult T-ALL
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 type="checkbox"/>
	No requested revisions <input checked="" 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.	

CADTH Reimbursement Review Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0307-000 Stakeholder Feedback on Draft Recommendation
Brand name (generic)	Atriance (nelarabine)
Indication(s)	T-cell acute lymphoblastic leukemia
Organization	Leukemia & Lymphoma Society of Canada
Contact information ^a	Name: Colleen McMillan [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"/>
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 as nelarabine offers a significant clinical benefit in patients and clinically meaningful improvement in disease free survival. This treatment meets an unmet need for more treatment options for T-ALL patients. This treatment improves the quality of life of patients with fewer and less severe side effects than currently available treatment options. We thank CADTH very much for this recommendation and we hope that any negotiations necessary can be negotiated expeditiously as patients have been waiting 5,000 days too long for reimbursement of nelarabine.	
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"/>
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 <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
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 <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
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 <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
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

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- Please see the [Procedures for CADTH Drug Reimbursement Reviews](#) for further details.

A. Patient Group Information				
Name	<i>Colleen McMillan</i>			
Position	<i>Advocacy Lead</i>			
Date	<i>15-09-2023</i>			
<input checked="" type="checkbox"/>	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	<input checked="" type="checkbox"/>
			Yes	<input type="checkbox"/>
If yes, please detail the help and who provided it.				
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<i>Add company name</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Add company name</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Add or remove rows as required</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

CADTH Reimbursement Review Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0307-000
Brand name (generic)	Atriance (Nelarabine)
Indication(s)	Nelarabine (Atriance) for addition to front-line multi-agent therapy of pediatric, adolescent, and young adult (AYA) patients (aged 1-30 years at diagnosis) with intermediate- or high-risk T-cell acute lymphoblastic leukemia (T-ALL).
Organization	Pediatric Oncology Group of Ontario (POGO)
Contact information ^a	Name: [REDACTED]
Stakeholder agreement with the draft recommendation	
1. Does the stakeholder agree with the committee's recommendation.	Yes <input checked="" type="checkbox"/>
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	No <input type="checkbox"/>
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 <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
<p>If not, please provide details regarding the information that requires clarification.</p> <p>"Patients are not eligible for treatment with nelarabine if they meet any of the following criteria: 2.1 have any prior cytotoxic chemotherapy, except for steroids and/or IT cytarabine"</p> <p>This comment is somewhat misleading. While it represents the eligibility for AALL 0434 study, it does not reflect the criteria for starting nelarabine. All patients in AALL 0434 received the classic aBFM 4 drug induction for 4 weeks prior to starting the first planned cycle of nelarabine. While we understand the goal to restrict to AALL 0434 eligible patients, we suggest this line be omitted or edited to reflect the reality at the time of planned nelarabine exposure.</p>	

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