

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

cenobamate (Xcopri)

(Paladin Labs Inc.)

Indication: As an adjunctive therapy for the management of partial-onset seizures in adults with epilepsy who are not satisfactorily controlled with conventional therapy.

August 3, 2023

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Ctalcabalder information			
Stakeholder information			
CADTH project number	SR0770-000 Stakeholder Feedback on Draft Recommendation	on	
Brand name (generic)	Xcopri		
Indication(s)	Epilepsy, partial-onset seizures (focal seizures)		
Organization	Canadian League Against Epilepsy		
Contact information ^a	Name: Juan Pablo Appendino		
Stakeholder agreement wi	th the draft recommendation		
. Does the stakeholder ag	ree with the committee's recommendation.	Yes No	
	eholder agrees or disagrees with the draft recommendation. W specific text from the recommendation and rationale.	/heneve	er
	e cost of Cenobamate for patients; therefore, if equivalent to otle ne market such as brivaracetam, eslicarbazepine, lacosamide;		is
 Varughese RT, Shah refractory focal-onse 2022;130:108679. do Elliott T, Ridley-Pryo 	ul in focal epilepsy (references below, and personal experience YD, Karkare S, Kothare SV. Adjunctive use of cenobamate for tepilepsy: A single-center retrospective study. Epilepsy Behavoi:10.1016/j.yebeh.2022.108679 r T, Gienapp AJ, Wheless JW. Initial Real-World Experience Wescents and Adults: A Single Center Experience. Pediatr Neuro	r pedia '.	atri
2022;129:19-23. doi: - Makridis KL, Bast T,	10.1016/j.pediatrneurol.2022.01.001 Prager C, et al. Real-World Experience Treating Pediatric Epil amate. Front Neurol. 2022;13:950171. Published 2022 Jul 12.	ol. epsy	
2022;129:19-23. doi: - Makridis KL, Bast T, Patients With Cenob doi:10.3389/fneur.20	10.1016/j.pediatrneurol.2022.01.001 Prager C, et al. Real-World Experience Treating Pediatric Epil amate. Front Neurol. 2022;13:950171. Published 2022 Jul 12.	ol. epsy	
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Yes

5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?				
If not, please provide details regarding the information that requires clarification.				

^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		
2. Did you receive help from outside your clinician group to complete this submission?	No	\boxtimes
	Yes	
If yes, please detail the help and who provided it.		
Did you receive help from outside your clinician group to collect or analyze any	No	\boxtimes
information used in this submission?	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	No	П
submitted at the outset of the CADTH review and have those declarations remained	Yes	
unchanged? If no, please complete section C below.	163	
If yes, please list the clinicians who contributed input and whose declarations have not changed:		
Clinician 1		
Clinician 2		
Add additional (as required)		

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				

	mpanies or organizations that ha who may have direct or indirect i				er the past two	
			Check Approx	oriate Dollar Ran	ge	
Company		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000	
Add compa	any name					
Add compa	any name	name				
Add or rem						
			1	1	1	
New or Up	dated Declaration for Clinician	2				
Name	Please state full name					
Position	Please state currently held pos	ition				
Date	Please add the date form was o	completed (DD-	-MM-YYYY)			
	I hereby certify that I have the	authority to dis	close all relevant	information with r	espect to any	
	matter involving this clinician or	clinician group	with a company,	organization, or e	entity that may	
	place this clinician or clinician g	roup in a real,	potential, or perce	eived conflict of in	terest situation.	
Conflict of	Interest Declaration					
List any co	mpanies or organizations that ha	ve provided voi	ır group with fina	ncial navment ove	er the past two	
	who may have direct or indirect i				ine past two	
		Check Appropriate Dollar Range				
Company		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000	
Add compa	any name					
Add compa	any name					
Add or rem	nove rows as required					
New or Up	dated Declaration for Clinician	3				
Name	Please state full name					
Position	Please state currently held pos	ition				
Date	Please add the date form was o		-MM-YYYY)			
\boxtimes	I hereby certify that I have the	authority to dis	close all relevant	information with r	espect to any	
	matter involving this clinician or	clinician group	with a company,	organization, or e	entity that may	
	place this clinician or clinician g	roup in a real,	potential, or perce	eived conflict of in	terest situation.	
Conflict of	Interest Declaration					
List any co	mpanies or organizations that ha	ve provided voi	ır group with fina	ncial payment ove	er the past two	
	who may have direct or indirect i				ino paor ino	
			Check Approp	riate Dollar Ranç	ge	
Company		\$0 to 5,000	\$5,001 to	\$10,001 to	In Excess of	
Add compa	any name		10,000	50,000	\$50,000	
Add compa						
-	nove rows as required					

	place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.							
Conflict of Interest Declaration								
	mpanies or organizations that ha who may have direct or indirect i				r the past two			
	Check Appropriate Dollar Range							
Company		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000			
Add compa	nny name							
Add compa	nny name							
Add or rem	ove rows as required							
New or Up	dated Declaration for Clinician	5						
Name	Please state full name							
Position	Please state currently held pos	ition						
Date	Please add the date form was of							
	I hereby certify that I have the matter involving this clinician or place this clinician or clinician g	clinician group	with a company,	organization, or e	entity that may			
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.							
				riate Dollar Rang				
Company		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000			
Add compa	nny name							
Add compa	nny name							
Add or rem	Add or remove rows as required							

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

New or Updated Declaration for Clinician 4

Please state full name

Please state currently held position

Please add the date form was completed (DD-MM-YYYY)

Name

Date

Position



CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0770
Name of the drug and	Cenobamate (Xcopri) for epilepsy
Indication(s)	
Organization Providing	FWG
Feedback	

1. Recommendate Please indicate if the recommendation.	ion revisions ne stakeholder requires the expert review committee to reconsider or clarit	fy its
Request for	Major revisions: A change in recommendation category or patient population is requested	
Reconsideration	Minor revisions: A change in reimbursement conditions is requested	
No Request for	Editorial revisions: Clarifications in recommendation text are requested	Х□
Reconsideration	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

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

CADTH Reimbursement REcommendation cenobamate (Xcopri)



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.

Stakeholder information

CADTH project number	SR0770-000		
Brand name (generic)	Cenobamate		
Indication(s)	Adjunctive therapy in the management of partial-onset seizure		ults
	with epilepsy who are not satisfactorily controlled with conver	ntional	
	therapy		
Organization	Canadian Epilepsy Alliance		
Contact information ^a	Name: Laura Dickson, President		
Stakeholder agreement w	ith the draft recommendation		
1. Does the stakeholder aç	gree with the committee's recommendation.	Yes No	
possible, please identify the Whenever a new therapy is	ceholder agrees or disagrees with the draft recommendation. Verspecific text from the recommendation and rationale. available to people with epilepsy who have seizures not satisfied means, it brings new hope for a better life and ability to live we	actorily	
	the fear of being held back by chronic disease.		
pursue one's goals without because committee considerations. 2. Does the recommendations.	the fear of being held back by chronic disease. eration of the stakeholder input ion demonstrate that the committee has considered the	Yes	
Expert committee considers. 2. Does the recommendation stakeholder input that y	the fear of being held back by chronic disease.		
Expert committee considers. 2. Does the recommendation stakeholder input that y	eration of the stakeholder input on demonstrate that the committee has considered the our organization provided to CADTH? sing from the draft recommendation?	Yes	
Expert committee considerate committee considerate. 2. Does the recommendation stakeholder input that your lift not, what aspects are mis clarity of the draft recommendation.	eration of the stakeholder input on demonstrate that the committee has considered the our organization provided to CADTH? sing from the draft recommendation? mendation	Yes	
Expert committee considerate. 2. Does the recommendation stakeholder input that your life not, what aspects are mister committee. Clarity of the draft recommittee. Are the reasons for the	the fear of being held back by chronic disease. Pration of the stakeholder input Ion demonstrate that the committee has considered the our organization provided to CADTH? Ising from the draft recommendation? Internation The commendation clearly stated?	Yes No	
Expert committee considerate. 2. Does the recommendation stakeholder input that your life not, what aspects are mister committee. Clarity of the draft recommittee. Are the reasons for the	eration of the stakeholder input on demonstrate that the committee has considered the our organization provided to CADTH? sing from the draft recommendation? mendation	Yes No	
Expert committee conside 2. Does the recommendati stakeholder input that y If not, what aspects are mis Clarity of the draft recomm 3. Are the reasons for the If not, please provide details	the fear of being held back by chronic disease. Pration of the stakeholder input Ion demonstrate that the committee has considered the our organization provided to CADTH? Ising from the draft recommendation? Internation The commendation clearly stated?	Yes No	
Expert committee conside 2. Does the recommendati stakeholder input that y If not, what aspects are mis Clarity of the draft recommands. Are the reasons for the If not, please provide details	cration of the stakeholder input ion demonstrate that the committee has considered the our organization provided to CADTH? sing from the draft recommendation? mendation recommendation clearly stated? s regarding the information that requires clarification. In issues been clearly articulated and adequately	Yes No Yes No	
Expert committee conside 2. Does the recommendati stakeholder input that y If not, what aspects are mis Clarity of the draft recommand. Are the reasons for the If not, please provide details 4. Have the implementatio addressed in the recommand.	cration of the stakeholder input ion demonstrate that the committee has considered the our organization provided to CADTH? sing from the draft recommendation? mendation recommendation clearly stated? s regarding the information that requires clarification. In issues been clearly articulated and adequately	Yes No Yes No	
Expert committee consider. 2. Does the recommendation stakeholder input that your life not, what aspects are misted to the common stakeholder input that you life not, what aspects are misted to the common stakeholder input that you life not, what aspects are misted to the common stakeholder input that you life not, what aspects are misted to the common stakeholder in the recommon stakeholder in the recommon life not, please provide details the common stakeholder in the recommon stakeholder in the rec	the fear of being held back by chronic disease. Peration of the stakeholder input on demonstrate that the committee has considered the our organization provided to CADTH? sing from the draft recommendation? mendation recommendation clearly stated? s regarding the information that requires clarification. In issues been clearly articulated and adequately mendation?	Yes No Yes No	

^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 G	roup Information						
Name	Please state full name Laura Di						
Position	Please state currently held position President, Canadian Epilepsy Alliance						
Date	Please add the date form was completed (DD-MM-YYYY) 21-07-2023						
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. Assistan	ce with Providing Feedback						
1 Did you	receive help from outside you	r notiont arou	n to complete v	our foodbook?	No	\boxtimes	
1. Did you	receive help from outside you	r patient grou	p to complete y	our reedback?	Yes		
If yes, please	e detail the help and who provide	d it.					
2. Did you	receive help from outside you	r patient grou	p to collect or a	nalyze any	No	\boxtimes	
informa	tion used in your feedback?				Yes		
	e detail the help and who provide						
	ly Disclosed Conflict of Interes						
	onflict of interest declarations				No		
	ed at the outset of the CADTH ged? If no, please complete se			ations remained	d Yes	\boxtimes	
D. New or U	pdated Conflict of Interest Dec	laration					
	r companies or organizations t o years AND who may have dir					over the	
			Check Appro	priate Dollar Raı	nge		
Company	Company \$0 to 5,000 \$5,001 to \$10,001 to In Excess of 10,000 50,000 \$50,000					s of	
Add compar	ny name						
Add compar	ny name						
Add or remo	ve rows as required						

Stakeholder information						
CADTH project number	SR0770-000					
Brand name (generic)	Xcopri (cenobamate)					
Indication(s)	Epilepsy, partial-onset seizures					
Organization	Epilepsy Southwestern Ontario					
Contact information ^a						
Stakeholder agreement wi	th the draft recommendation					
1. Does the stakeholder ag	ree with the committee's recommendation.	Yes No				
possible, please identify the Any new medication provide	Please explain why the stakeholder agrees or disagrees with the draft recommendation. Whenever possible, please identify the specific text from the recommendation and rationale. Any new medication provides hope to those living with epilepsy who have not been successful with previous anti seizure medications or treatment types.					
Expert committee conside	ration of the stakeholder input					
	on demonstrate that the committee has considered the our organization provided to CADTH?	Yes No				
If not, what aspects are miss	sing from the draft recommendation?					
Clarity of the draft recomn	nendation					
3 Are the reasons for the	recommendation clearly stated?	Yes	\boxtimes			
3. Are the reasons for the i	econiniendation clearly stated:	No				
If not, please provide details	regarding the information that requires clarification.					
	n issues been clearly articulated and adequately	Yes	\boxtimes			
addressed in the recomi		No				
If not, please provide details	regarding the information that requires clarification.					
	nbursement conditions clearly stated and the rationale	Yes	X			
<u> </u>	ded in the recommendation?	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

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- Please see the <u>Procedures for CADTH Drug Reimbursement Reviews</u> 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)							
⊠								
B. Assistan	ce with Providing Feedback							
4 Did vou	receive help from enteide ver	tiont	n 40 00mmle4e v	aur faadhaak?	No	\boxtimes		
1. Did you	receive help from outside you	r patient grou	p to complete y	our reedback?	Yes			
If yes, pleas	e detail the help and who provide	ed it.						
	receive help from outside you	r patient grou	p to collect or a	ınalyze any	No	\boxtimes		
informa	tion used in your feedback?				Yes			
If yes, pleas	e detail the help and who provide	d it.						
	ly Disclosed Conflict of Interes							
	onflict of interest declarations				No	\boxtimes		
	ed at the outset of the CADTH ged? If no, please complete se			rations remained	d Yes			
D. New or U	lpdated Conflict of Interest Dec	laration						
	o companies or organizations t o years AND who may have dir					over the		
				priate Dollar Rai	_			
Company		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Exces \$50,000	s of		
Paladin Lab	S							
Add compar	ny name							
Add or remo	ve rows as required							

Stakeholder information			
CADTH project number	SR0770		
Brand name (generic)	Xcopri (Cenobamate)		
Indication(s)	As adjunctive therapy in the management of partial-onset seizures in		
	adults with epilepsy who are not satisfactorily controlled with		
	conventional therapy		
Organization	Paladin Labs Inc.		
Contact information ^a			
Stakeholder agreement with the draft recommendation			
1. Does the stakeholder agree with the committee's recommendation.		Yes	\boxtimes
		No	
Paladin Labs Inc. agrees with the positive recommendation to reimburse cenobamate. Following a			
comprehensive review of cenobamate's efficacy, safety, and cost-effectiveness in treating uncontrolled epilepsy, Paladin is pleased that CADTH came to a conclusion that will benefit Canadian			
patients with uncontrolled epilepsy.			
Expert committee consideration of the stakeholder input			
2. Does the recommendation demonstrate that the committee has considered the			\boxtimes
stakeholder input that your organization provided to CADTH?			
Clarity of the draft recommendation			
3. Are the reasons for the recommendation clearly stated?		Yes	\boxtimes
		No	
		Yes	
4. Have the implementation issues been clearly articulated and adequately			
addressed in the recommendation?		No	
E If applicable are the rein	where amount conditions also when stated and the retionals	Yes	
5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?			
for the conditions provided in the recommendation? No No No No No No No No			
recommendation/reason to price at the negotiated price of the least costly comparator was not			
supported by CADTH's own reanalysis. In the detailed pharmacoeconomic report, CADTH concluded			
that cenobamate is cost effective (99.4% probability at \$50K ICER). As such, no price reduction was			
deemed necessary based on CADTH's reanalysis. However, it is worth noting that the			
recommendation to price cenobamate at the negotiated price of the least costly comparator lacks support from CADTH's own analysis. The detailed PE report did not include any examination or			
reference to negotiated prices, making this assertion a surprising element of the recommendation.			
The primary driver of cost savings with cenobamate is the reduction in seizures and seizure freedom			

rates. Consequently, it is anticipated that cenobamate would continue to dominate comparators even

if negotiated prices were assumed for other comparators.

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