CADTH

CADTH Feedback on Draft Recommendation

Instructions for Stakeholders

This template is for eligible stakeholders to provide feedback and comments on draft recommendations. Draft recommendations are available for feedback for 10 business days.

CADTH will consider feedback received from eligible stakeholders, including the sponsor, the payers, patient groups, and clinician groups. Individuals interested in providing feedback should contact the relevant patient and clinician organizations. This template may also be used by eligible industry stakeholders to provide feedback on draft recommendations.

The sponsor may use this form to provide general feedback on the draft recommendation if they are not filing a request for reconsideration. If the sponsor is filing a request for reconsideration, they must complete the <u>reconsideration template</u> and should not complete this template.

All submitted feedback must be disclosable and will be posted on the CADTH website.

If you have questions, please email <u>requests@cadth.ca</u> with the complete details of your question(s).

Completing the Template:

Feedback should be presented clearly and succinctly in point form, whenever possible. The issue(s) should be clearly stated and specific reference must be made to the section of the recommendation document under discussion (i.e., page number, section title, and paragraph).

Comments should be restricted to the content of the draft recommendation and should not contain any language that could be considered disrespectful, inflammatory or could be found to violate applicable defamation law.

Feedback must be based on the information that was considered by the expert committee in making the draft recommendation. No new evidence will be considered at this part of the review process.

Feedback must not exceed 3 pages in length, using a minimum 11-point font on 8.5" by 11" paper. If comments exceed 3 pages, the feedback will not be accepted by CADTH. References may be provided separately; however, these cannot be related to new evidence.

Patient groups must complete Appendix 1.

Clinician groups must complete Appendix 2.

Filing the Completed Template:

The feedback must be provided in Microsoft Word format. In order to ensure fairness in CADTH's procedures, all stakeholder feedback must be received by the deadline posted on the CADTH website.

CADTH Feedback on Draft Recommendation

Stakeholder information			
CADTH project number			
Brand name (generic)			
Indication(s)			
Organization			
Contact information ^a	Name:		
Stakeholder agreement wi	th the draft recommendation		
1. 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.	henev	er
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 mise	sing from the draft recommendation?		
Clarity of the draft recomm	nendation		
2 Are the recency for the	recommendation clearly stated?	Yes	
5. Are the reasons for the	recommendation clearly stated?	No	
If not, please provide details	regarding the information that requires clarification.		
4. Have the implementation	n issues been clearly articulated and adequately	Yes	
addressed in the recom		No	
If not, please provide details	regarding the information that requires clarification.		
5. If applicable, are the reir	nbursement conditions clearly stated and the rationale	Yes	
	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

- To maintain the objectivity and credibility, all participants in the 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.

A. Patient Group Information							
Name	Please state full name						
Position	Please state currently held posi	tion					
Date	Please add the date form was c	ompleted (DD-	MM-YYYY)				
□ 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	B. Assistance with Providing Feedback						
1. Did you receive help from outside your patient group to complete your feedback?					No Yes		
If yes, please	e detail the help and who provide	d it.			103		
	receive help from outside you	r patient grou	p to collect or a	inalyze any	No		
informa	tion used in your feedback?				Yes		
	e detail the help and who provide						
	ly Disclosed Conflict of Interes		·····	4.41			
	onflict of interest declarations ped at the outset of the CADTH				No		
	ged? If no, please complete se			ations remained	d Yes		
D. New or U	pdated Conflict of Interest Dec	laration					
				priate Dollar Rai	nge		
Company		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Exces \$50,000	ss of	
Add compan	ny name				I		
Add compan	ny name				[
Add or remo	ve rows as required						

Appendix 2. Conflict of Interest Declarations for Clinician Groups

- To maintain the objectivity and credibility, all participants in the 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.
- 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 device 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	
	Yes	
If yes, please detail the help and who provided it.		
3. Did you receive help from outside your clinician group to collect or analyze any	No	
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	
submitted at the outset of the CADTH review and have those declarations remained	Yes	Π
unchanged? If no, please complete section C below.		
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 Up	dated 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	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 device under review.

		Check Approp	oriate Dollar Rang	ge
Company	\$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				

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.

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 device under review.

	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 company name					
Add company name					
Add or remove rows as required					

New or Up	dated Declaration for Clinician	3			
Name	Please state full name				
Position	Please state currently held posi	ition			
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				
List any co	T <mark>Interest Declaration</mark> mpanies or organizations that hav who may have direct or indirect i				er the past two
List any co	mpanies or organizations that hav		evice under revie		
List any co	mpanies or organizations that hav		evice under revie	W.	
List any coi years AND	mpanies or organizations that hav who may have direct or indirect i	nterest in the de	evice under revie Check Approp \$5,001 to	w. riate Dollar Rang \$10,001 to	ge In Excess of
List any coi years AND Company	mpanies or organizations that hav who may have direct or indirect i ny name	nterest in the do \$0 to 5,000	evice under revie Check Approp \$5,001 to 10,000	w. riate Dollar Rang \$10,001 to 50,000	ge In Excess of \$50,000

New or Up	dated Declaration for Clinician	4			
Name	Please state full name				
Position	Please state currently held posi	tion			
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 hav who may have direct or indirect i				r the past two
			Check Approp	riate Dollar Rang	je
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	5			
Name	Please state full name				
Position	Please state currently held posi	ition			
Date	Please add the date form was o	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 hav who may have direct or indirect i				r the past two
			Check Approp	riate Dollar Rang	10
Company		¢0.4~ 5.000			
Company		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Add company	any name				In Excess of
			10,000		In Excess of \$50,000