CADTH

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

Bevacuzimab and lomustine

Indication: Recurrent glioblastoma multiform

November 24, 2023

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PX0318
Name of the drug and Indication(s)	Bevacizumab in combination with lomustine for the treatment of patients with glioblastoma multiforme after relapse or disease progression, following prior therapy.
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	☐
	Minor revisions: A change in reimbursement **conditions** is requested	☐
No Request for Reconsideration	**Editorial revisions:** Clarifications in recommendation **text** are requested	☐
	No requested revisions	X

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.

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	PX0318
Brand name (generic)	Bevacizumab Solution in combination with Lomustine
Indication(s)	Glioblastoma Multiforme after disease relapse or disease progression following prior therapy
Organization	Brain Cancer Canada
Contact information[a]	Name: Anita Angelini, Executive Ambassador

Stakeholder agreement with the draft recommendation

1. **Does the stakeholder agree with the committee's recommendation.**	Yes	☒
	No	☐

We agree with:

- FMEC considered that there is a significant unmet need in the treatment of recurrent glioblastoma, considering the severity of the disease and the poor prognosis, as well as the lack of therapeutic options.

- FMEC acknowledged that the combination of bevacizumab and lomustine did not improve overall survival, the primary endpoint of the EORTC 26101 trial. However, in this context, given the significant unmet need, the benefit of the combination treatment on progression free survival (secondary outcome) was deemed clinically important.

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	☐

- Brain Cancer Canada is extremely grateful for the opportunity to contribute to the CADTH committee consideration, both in written and verbal form. We look forward to future opportunities to continue the dialogue with you.

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	☒

Excluding a Segment of Recurrent GBM Patients

- This is a positive reimbursement review, and absolutely a step in the right direction.
- In terms of application, it MAY still result in a lack of reimbursement or potential access to treatment options for recurrent GBM patients. We offer this perspective because health Canada has approved the use of bevacizumab in combination with lomustine, **for any patient with recurrent, previously treated glioblastoma, yet, t**he criteria as per the EORTC 260101 study **did not encompass the entire Health Canada indicated population**, and the CADTH recommendation as written indicates that initiation **should only include those that meet the criteria of EORTC 260101.**
- By following the criteria of the EORTC 260101, the recommendation may potentially neglect patients for whom this may be the only treatment option available, particularly if they are the patients that happen to fall outside of the EORTC criteria.

- At the Society for NeuroOncology Conference in Vancouver, November 16-29, 2023 oncologists and specialists publicly noted the distressing gap that arises in a number of settings (research and clinical) by relying solely on the scope of the EORTC criteria.

Ambiguity at the Provincial Implementation Level – Mode and Place of Delivery

- We are unclear if the reimbursement for the two medications in tandem applies only if the treatment is given in hospital, vs. in private medical clinic, or through take-home therapy (injection or oral).
- We believe it is imperative to make clear that reimbursement should be supported throughout every mode of delivery and location of administration so as to remove barriers to access and increase equity.

Ambiguity at the Provincial Implementation Level – The Question of Cost

- In the accompanying Review Report it was noted that the request for reimbursement review included a request for the inclusion of a cost-effectiveness analysis.

"As a cost-effectiveness analysis was not available, the cost-effectiveness of bevacizumab plus lomustine compared with lomustine alone or temozolomide for the treatment of patients with glioblastoma after relapse or disease progression, following prior therapy, could not be determined. Other costs such as administration costs were not considered as part of the cost comparison. To consider this alongside the healthcare resource implications associated with comparative clinical benefits, a cost-effectiveness analysis comparing bevacizumab plus lomustine to lomustine alone or to temozolomide would be required."

- While we recognize that resources may be limited and may account for why the analysis could not be completed during this review, we are unclear of where the responsibility for the cost-effectiveness analysis resides.
- If a cost effectiveness analysis was requested at the outset of the review as part of the review, but not completed, it presents enough of a data omission, that could lead decision-makers to not pursue or implement the reimbursement recommendation as presented. The lack of cost-effectiveness data may leave the door open for provinces to not pursue reimbursement which further exacerbates the access challenges for patients who have excruciatingly few options against an aggressive and fast paced disease.

5. **If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?**	Yes	☐
	No	☒

"Table 2, implementation guidance section, page 7/9 indicates:
…could also be given to additional specific populations, such as patients who receive high doses of corticosteroids, patients with substantial peritumour edema, patients with confirmed tumour progression within less than 3 months after the end of chemoradiotherapy, and patients with a WHO performance status greater than 2. Based on clinical expertise, it is possible that patients within these subpopulations may benefit from treatment."

- We interpret this to mean that oncologists are given some opportunity to exercise discretion on a case by case basis about suggesting the two medications in tandem, but from a reimbursement perspective, it may mean that the oncologists will still have to help the patient fight for reimbursement (prove that it is suitable) or may themselves be required to spend time filling out additional paperwork to justify why the treatment is warranted and why it should be reimbursed.
- Given that not every patient or province has a neurooncologist, and that the reimbursement practice of every province and territory varies, different process challenges will likely surface in each province/territory. It would be helpful to remove ambiguity wherever possible at the implementation level.
- Implementation guidelines have not necessarily anticipated/resolved the questions of equity or access. If decisions are made case-by-case, is pre-authorization for reimbursement required? If so, this is unreasonable in a population whose life expectancy is short, particularly at recurrence.
- We must also note concern for the deployment of resources within each of the provincial health systems - if the neuro teams are needed to complete paperwork for authorizations for treatments for their patients, they are not able to be deployed to the work of seeing more patients or spending more time with patients.
- At point of discontinuation, #2 in Table 2, it is not clear when or if bevacizumab should be reimbursed if the decision is made to discontinue lomustine. The implementation guidelines only indicate that bevacizumab treatment could be continued if deemed appropriate, but does not indicate that reimbursement should remain intact in such circumstances.

[a] CADTH may contact this person if comments require clarification.

Appendix 1. Conflict of Interest Declarations for Patient Groups

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- 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	Anita Angelini, on behalf of Brain Cancer Canada
Position	Executive Ambassador
Date	November 20, 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. Assistance with Providing Feedback		
1. **Did you receive help from outside your patient group to complete your feedback?**	No	☒
	Yes	☐
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	☒
	Yes	☐
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	☒
	Yes	☐

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.** NONE

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	☐	☐	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PX0318-000
Brand name (generic)	bevacizumab and lomustine
Indication(s)	For the treatment of patients with glioblastoma after relapse or disease progression, following prior therapy
Organization	Amgen Canada Inc.
Contact information[a]	Arpit Chhabra, Health Economics & Market Access Manager.

Stakeholder agreement with the draft recommendation		
1. **Does the stakeholder agree with the committee's recommendation.**	Yes	☒
	No	☐

We agree with FMEC's draft recommendation that the combination of bevacizumab and lomustine be reimbursed for patients with recurrent glioblastoma multiforme. Additionally, we agree with the clinical criteria outlined for initiation and discontinuation. We particularly appreciate the considered guidance of the FMEC that the clinical decision on continuing bevacizumab should be made on a case-by-case basis in the event of a patient developing intolerance to or discontinuing lomustine.

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	☐

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	☒
	No	☐

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	☒
	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	☒
	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 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	*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 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	☐
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	☐
	Yes	☐
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	☐
	Yes	☐

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**
Add company name	☐	☐	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

Appendix 2. Conflict of Interest Declarations for Clinician Groups

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- 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	☐
	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 information used in this submission?**	No	☐
	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 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: • 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				
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	☐	☐	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

New or Updated Declaration for Clinician 2	
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				
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	☐	☐	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

New or Updated Declaration for Clinician 3	
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				
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	☐	☐	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

New or Updated Declaration for Clinician 4	
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

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	☐	☐	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

New or Updated Declaration for Clinician 5	
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

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Add company name	☐	☐	☐	☐
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CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PX0318
Brand name (generic)	Bevacizumab and lomustine
Indication(s)	For the treatment of adult patients with glioblastoma.
Organization	Ontario Health (Cancer Care Ontario) CNS Cancer Drug Advisory Committee
Contact information[a]	Name: Dr Sunit Das

Stakeholder agreement with the draft recommendation		
1. **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.

In clinical practice, bevacizumab and lomustine combination is often used after other treatment approaches at initial recurrence such as temozolomide rechallenge, repeat radiation or participation in a clinical trial. The CNS DAC would support consideration of bevacizumab and lomustine after these initial measures and not just at initial recurrence.

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	☐

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	☒
	No	☐

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	☒
	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	☒
	No	☐

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

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A. Patient Group Information	
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Position	*Please state currently held position*
Date	*Please add the date form was completed (DD-MM-YYYY)*
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B. Assistance with Providing Feedback		
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	Yes	☐
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	☐
	Yes	☐
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	☐
	Yes	☐

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.**

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Add company name	☐	☐	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

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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 information used in this submission?**	No	☐
	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 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. Sunit Das • Dr. Mary Jane Lim-Fat • Dr. Warren Mason • Dr. James Perry		

C. New or Updated Conflict of Interest Declarations

New or Updated Declaration for Clinician 1	
Name	*Dr. Seth Climans*
Position	*Ontario Health (Cancer Care Ontario) CNS Cancer Drug Advisory Committee member*
Date	*23-11-2023*
☒	**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				
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Add company name	☐	☐	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

New or Updated Declaration for Clinician 2	
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				
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Add company name	☐	☐	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

New or Updated Declaration for Clinician 3	
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				
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Add company name	☐	☐	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

New or Updated Declaration for Clinician 4	
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

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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	☐	☐	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

New or Updated Declaration for Clinician 5	
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

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	☐	☐	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐