### Input on Proposed Scope for Provisional Funding Algorithm

#### Instructions for Patient, Clinician, and Industry Groups

This form is for eligible patient, clinician, and industry groups to provide input on the proposed scope for a provisional funding algorithm. Input is sought before the project is initiated to help shape the direction and/or the scope of the funding algorithm, whereas feedback is collected when the funding algorithm is near completion (e.g., draft report of the provisional funding algorithm) for refinement.

As described in the <u>Procedures for Reimbursement Reviews</u>, the proposed scope documents for provisional algorithm projects are posted for input for 35 business days. If a rapid provisional funding algorithm is initiated, the proposed scope document will include the therapeutic area and a list of drugs likely to be impacted. If a panel provisional funding algorithm is initiated, the proposed scope document will include the therapeutic area, a list of drugs likely to be impacted, and the implementation issue(s).

We will only consider input received from eligible groups (as described in the <u>Procedures for Reimbursement Reviews</u>), including drug manufacturers, patient groups, clinician groups, and participating drug programs.

No extensive research is expected or needed to complete this form. Please provide input from the perspective and expertise of your group. Only complete the sections for which you have relevant input. For example:

- patient groups may comment on how the provisional funding algorithm may affect patients' access to therapy or other equity concerns for patients
- clinician groups may comment on how the provisional funding algorithm may be challenging to implement in the current clinical practice setting and whether there are current unmet needs in the therapeutic area
- drug manufacturers may identify market access concerns for drugs implicated by the algorithm
- drug programs may share implementation challenges anticipated within the therapeutic area.

If you have any questions regarding the process for provisional funding algorithms, please send an email to <a href="mailto:requests@cda-amc.ca">requests@cda-amc.ca</a> with the complete details of your question(s).

#### Before Completing This Form

Please review the following documents to ensure your understanding of our procedures:

- Procedures for Reimbursement Reviews
- Pharmaceutical Review Updates for any new applicable information.

#### **Completing This Form**

Input should be presented clearly and concisely. Use point form if possible. The issue(s) should be clearly stated and include specific reference to the section of the proposed scope document under consideration (i.e., page number, section title, and paragraph).

Comments should be restricted to the condition of interest and should not contain any language that could be considered disrespectful or inflammatory or could violate applicable defamation laws.

If comments in the Input section of this form exceed 3 pages in length, the input will not be accepted for review. References may be provided separately, preferably in *JAMA Oncology* citation format. Please use 11-point Arial font for all text and use generic drug names.

#### Submitting the Completed Form

You can upload the completed form by clicking **Submit Feedback** on the project webpage for the provisional funding algorithm of interest. To ensure fairness in our procedures, all input must be received by the deadline posted on the Canada's Drug Agency website.

#### Important Information About Providing Input for Provisional Funding Algorithms

As described in our <u>Procedures for Reimbursement Reviews</u>, the provisional funding algorithm process is used to assist jurisdictions in implementing reimbursement recommendations issued by our expert committees (e.g., pERC or FMEC) and/or making reimbursement policy decisions.

The scope of the provisional funding algorithm is confined to these reimbursement conditions and their related eligibility criteria. Examples of input that may be considered during this stage are comments related to how to implement the reimbursement recommendations effectively, fairly, and equitably or how other implementation challenges can be addressed.

Input related to the reimbursement of a drug should be submitted directly to the specific reimbursement review. New evidence should not be submitted during the input period for the provisional funding algorithm. For new evidence to be considered, it must have been previously reviewed (e.g., a resubmission) through the reimbursement review process and be assessed by an expert committee (i.e., pERC or FMEC).

### Input on Proposed Scope for Provisional Funding Algorithm

#### Patient, Clinician, or Industry Group Information

Project number: Enter project number

Condition (or indication) under review: Enter condition or indication

Organization name: Enter organization name

Contact information (if comments require clarification)

Full name: Enter first and last name of contact

Current position: Enter position or title of contact

**Email:** Enter email address of contact **Phone:** Enter phone number of contact

Contact information will not be included in any public posting of this document.

#### For Both Rapid and Panel Provisional Funding Algorithms (Required)

Q1: Based on the proposed scope of the provisional funding algorithm, the other drugs that could be impacted, and the current reimbursement setting, what factors do you think should be considered in the development of the provisional funding algorithm? Please provide your input:

Click here to provide your input

## For Panel Provisional Funding Algorithm Only (Not Required for Rapid Provisional Funding Algorithm)

Q2: Based on the implementation issues described in the proposed scope, what implementation issues could be addressed by the panel? Please provide your input:

Click here to provide your input

Q3: Are there any implementation issues that may not have been addressed in the proposed scope? Please provide your input:

Click here to provide your input

# Appendix 1: Conflict-of-Interest Declarations for Patient Groups

- To maintain the objectivity and credibility of the 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 input from patient groups.
- We may contact your group with further questions, as needed.

A. Patient Group Information
Full name: Enter first and last name
Current position: Enter current position or title
Date form completed (dd-mm-yyyy): Select or enter date
☐ 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
Did you receive help from outside your patient group to complete your input?
□ No □ Yes
If yes, please detail the help that was received and who provided it:
Enter details about help received
Did you receive help from outside your patient group to collect or analyze any information used in you input?
□ No □ Yes
If yes, please detail the help that was received and who provided it:
Enter details about help received

#### C. New or Updated Conflict-of-Interest Declaration

List any companies or organizations that have provided your group with financial payment over the past 2 years AND that may have direct or indirect interest in the drug under review.

Table 1: Conflict-of-Interest Declaration for Patient Group

	Approximate amount received			
Company	≤ \$5,000	\$5,001 to \$10,000	\$10,001 to \$50,000	> \$50,000
Enter company name				
Enter company name				
Enter company name				



# Appendix 2: Conflict-of-Interest Declarations for Clinician Groups

- To maintain the objectivity and credibility of the 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 clinician groups.
- We may contact your group with further questions, as needed.
- For conflict-of-interest declarations:
  - list any companies or organizations that have provided your group with financial payment over the past 2 years AND that may have direct or indirect interest in the drug under review
  - o provide declarations for each clinician that contributed to the input
  - include only new conflict-of-interest declarations or ones that require updating if your clinician group provided input at the beginning of the outset of the review; for all others, please list the clinicians whose provided input is unchanged
  - o add more tables as needed (copy and paste)
  - o include all new and updated declarations in a single document.

#### A. Assistance With Providing the Feedback

Did you receive help from outside your clinician group to complete your input?
□ No
□ Yes
f yes, please detail the help that was received and who provided it:
Enter details about help received
Did you receive help from outside your clinician group to collect or analyze any information used in vour input?
vour input?
vour input? □ No

#### **B. Conflict-of-Interest Declarations**

List any companies or organizations that have provided your group or member(s) of your group with financial payment over the past 2 years AND that may have direct or indirect interest in the drug under review. This is required for each clinician that contributed to the input — please add more tables as needed (copy and paste). It is preferred that all declarations be included in a single document.

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Full name: Enter first and last name

Current position: Enter current position or title

Date form completed (dd-mm-yyyy): Select or enter date

☐ 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 you or your group with financial payment over the past 2 years AND that may have direct or indirect interest in the drug under review.

Table 2: Conflict-of-Interest Declaration for Clinician 1

	Approximate amount received			
Company	≤ \$5,000	\$5,001 to \$10,000	\$10,001 to \$50,000	> \$50,000
Enter company name				
Enter company name				
Enter company name				

Full name: Enter first and last name

Current position: Enter current position or title

Date form completed (dd-mm-yyyy): Select or enter date

☐ 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 you or your group with financial payment over the past 2 years AND that may have direct or indirect interest in the drug under review.

Table 3: Conflict-of-Interest Declaration for Clinician 2

	Approximate amount received			
Company	≤ \$5,000	\$5,001 to \$10,000	\$10,001 to \$50,000	> \$50,000
Enter company name				
Enter company name				
Enter company name				

Full name: Enter first and last name

Current position: Enter current position or title

Date form completed (dd-mm-yyyy): Select or enter date

☐ 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 you or your group with financial payment over the past 2 years AND that may have direct or indirect interest in the drug under review.

Table 4: Conflict-of-Interest Declaration for Clinician 3

	Approximate amount received			
Company	≤ \$5,000	\$5,001 to \$10,000	\$10,001 to \$50,000	> \$50,000
Enter company name				
Enter company name				
Enter company name				

Full name: Enter first and last name

Current position: Enter current position or title

Date form completed (dd-mm-yyyy): Select or enter date

☐ 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 you or your group with financial payment over the past 2 years AND that may have direct or indirect interest in the drug under review.

Table 5: Conflict-of-Interest Declaration for Clinician 4

	Approximate amount received			
Company	≤ \$5,000	\$5,001 to \$10,000	\$10,001 to \$50,000	> \$50,000
Enter company name				
Enter company name				
Enter company name				

Full name: Enter first and last name

Current position: Enter current position or title

Date form completed (dd-mm-yyyy): Select or enter date

☐ 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 you or your group with financial payment over the past 2 years AND that may have direct or indirect interest in the drug under review.

Table 6: Conflict-of-Interest Declaration for Clinician 5

	Approximate amount received			
Company	≤ \$5,000	\$5,001 to \$10,000	\$10,001 to \$50,000	> \$50,000
Enter company name				
Enter company name				
Enter company name				