**Clinician Group Input Template**

Instructions

Input from clinicians is submitted to Canada’s Drug Agency (CDA-AMC) by **groups or associations of health care professionals**. Individual clinicians who wish to provide input are encouraged to work with a group that represents their profession to prepare a group submission. CDA-AMC will accept input from individual clinicians only when there is no relevant group or association that could provide input for the drug under review. Individuals who wish to submit input for a drug review should first [contact us](https://www.cda-amc.ca/contact-us) to confirm the absence of a relevant group or association.

Completing the Template

Please complete all applicable sections of the clinician input template. Ensurethat all contributing clinicians have completed the conflict of interest declaration in the clinician input template. Input **will not be accepted** **without the conflict of interest section** completed for all contributors.

Accessibility Instructions

When completing the template ensure text is compliant with below accessibility legislation:

* The [Accessibility for Ontarians with Disabilities Act (AODA)](https://www.ontario.ca/laws/statute/05a11), states all public documents must now be compliant with Ontario’s accessibility guidelines to ensure that screen readers and people with reading disabilities can access and read documents. Microsoft Word provides an [Accessibility Checker](https://support.microsoft.com/en-us/office/rules-for-the-accessibility-checker-651e08f2-0fc3-4e10-aaca-74b4a67101c1) for identifying and repairing accessibility issues, which is located under the Review tab and Check Accessibility sub-tab.
* Tips to ensure accessibility when completing your submission include the following:
* **For tables**: add a table title, designate row and/or column headers, do not add tables within other tables, and cells should not be blank. See below pre-formatted AODA-compliant table as an example.

 Table #: Table Title Example

|  |  |  |  |
| --- | --- | --- | --- |
| <Table Heading> | <Table Heading> | <Table Heading> | <Table Heading> |
| <Table Body Copy> | <Table Body Copy> | <Table Body Copy> | <Table Body Copy> |

abb = abbreviation

* **For figures, graphs, or images:** include 1 to 2 lines of alternative text (**Alt text**: *short description of image*) to describe the contents of the figure/image for screen reader function.
* **For links:** use descriptive hyperlinks (ex., [Canada's Drug Agency (CDA-AMC) Website](https://cda-amc.ca))
* **Colour** should not be used as the sole method for conveying content or distinguishing visual elements.

Filing the Completed Template

**Delete** first page of this template and all red font instructions once document is complete.

**Send**the completed template by using the Submit link next to the drug listed on the [Open Calls](https://www.cadth.ca/provide-input/open-calls) page. The input must be filed as a Microsoft Word document by the posted deadline date.

Reimbursement Review

Clinician Group Input

Project Number: <Enter Response here>

Generic Drug Name (Brand Name): <Enter Response here>

Indication: <Enter Response here>

Name of Clinician Group: <Enter Response here>

Author of Submission: <Enter Response here>

1. About Your Clinician Group

Please describe the purpose of your organization. Include a link to your website (if applicable).

<Enter Response Here>

2. Information Gathering

Please describe how you gathered the information included in the submission.

<Enter Response Here>

3. Current Treatments and Treatment Goals

Please describe the current treatment paradigm for the disease.

* Focus on the Canadian context.
* Please include drug and non-drug treatments.
* Drugs without Health Canada approval for use in the management of the indication of interest may be relevant if they are routinely used in Canadian clinical practice. Treatments available through special access programs are relevant. Are such treatments supported by clinical practice guidelines?
* Do current treatments modify the underlying disease mechanism? Target symptoms?
* What are the most important goals that an ideal treatment would address?
* **Examples:** Prolong life, delay disease progression, improve lung function, prevent the need for organ transplant, prevent infection or transmission of disease, reduce loss of cognition, reduce the severity of symptoms, minimize adverse effects, improve health-related quality of life, increase the ability to maintain employment, maintain independence, reduce burden on caregivers.

<Enter Response Here>

4. Treatment Gaps (unmet needs)

4.1. Considering the treatment goals in Section 3, please describe goals (needs) that are not being met by currently available treatments.

Please describe goals (needs) that are not being met by currently available treatments. Examples of unmet needs:

* Not all patients respond to available treatments
* Patients become refractory to current treatment options
* No treatments are available to reverse the course of disease
* No treatments are available to address key outcomes
* Treatments are needed that are better tolerated
* Treatments are needed to improve compliance
* Formulations are needed to improve convenience

Please describe limitations associated with current treatments (e.g., adverse events, administration, etc., if applicable).

<Enter Response Here>

5. Place in Therapy

5.1. How would the drug under review fit into the current treatment paradigm?

Is there a mechanism of action that would complement other available treatments, and would it be added to other treatments?

Is the drug under review the first treatment approved that will address the underlying disease process rather than being a symptomatic management therapy?

Would the drug under review be used as a first-line treatment, in combination with other treatments, or as a later (or last) line of treatment?

Would the drug under review be reserved for patients who are intolerant to other treatments or in whom other treatments are contraindicated?

Is the drug under review expected to cause a shift in the current treatment paradigm?

Please indicate whether or not it would be appropriate to recommend that patients try other treatments before initiating treatment with drug under review. Please provide a rationale for your perspective.

<Enter Response Here>

5.2. Which patients would be best suited for treatment with the drug under review? Which patients would be least suitable for treatment with the drug under review?

Which patients are most likely to respond to treatment with drug under review?

Which patients are most in need of an intervention?

Would this differ based on any disease characteristics (e.g., presence or absence of certain symptoms, stage of disease)?

How would patients best suited for treatment with drug under review be identified (e.g., clinician examination/judgement, laboratory tests (specify), diagnostic tools (specify))

Are there any issues related to diagnosis?

Is a companion diagnostic test required?

Is it likely that misdiagnosis occurs in clinical practice (e.g., underdiagnosis)?

Is it possible to identify those patients who are most likely to exhibit a response to treatment with drug under review?

<Enter Response Here>

5.3 What outcomes are used to determine whether a patient is responding to treatment in clinical practice? How often should treatment response be assessed?

Are outcomes used in clinical practice aligned with the outcomes typically used in clinical trials?

What would be considered a clinically meaningful response to treatment? Consider the magnitude of the response to treatment. Is this likely to vary across physicians?

Examples: improved survival; reduction in the frequency/severity of symptoms (provide specifics regarding changes in frequency, severity, etc.); attainment of major motor milestones; ability to perform activities of daily living; improvement of symptoms; and stabilization (no deterioration) of symptoms.

<Enter Response Here>

5.4 What factors should be considered when deciding to discontinue treatment with the drug under review?

Examples: disease progression (specify, e.g. loss of lower limb mobility); certain adverse events occur (specify type/frequency/severity); or additional treatment becomes necessary (specify).

<Enter Response Here>

5.5 What settings are appropriate for treatment with [drug under review]? Is a specialist required to diagnose, treat, and monitor patients who might receive [drug under review]?

Examples: Community setting, hospital (outpatient clinic), specialty clinic

If a specialist is required, which specialties would be relevant?

<Enter Response Here>

6. Additional Information

Is there any additional information you feel is pertinent to this review?

<Enter Response Here>

7. Conflict of Interest Declarations

To maintain the objectivity and credibility of the CDA-AMC 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 clinician group input. CDA-AMC may contact your group with further questions, as needed. Please see the *Procedures for Drug Reimbursement Reviews* (section 6.3) for further details.

1. Did you receive help from outside your clinician group to complete this submission? If yes, please detail the help and who provided it.

<Enter Response Here>

1. Did you receive help from outside your clinician group to collect or analyze any information used in this submission? If yes, please detail the help and who provided it.

<Enter Response Here>

1. 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 this is required for each clinician who contributed to the input — please add more tables as needed (copy and paste). It is preferred for all declarations to be included in a single document.**

Declaration for Clinician 1

**Name:** <Enter full name>

**Position:** <Enter currently held position>

**Date:** <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.

**Table 1: Conflict of Interest Declaration for Clinician 1**

|  |  |
| --- | --- |
| **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 |  |  |  |  |

\* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 2

Name: <Enter full name>

Position: <Enter currently held position>

Date: <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.

**Table 2: Conflict of Interest Declaration for Clinician 2**

|  |  |
| --- | --- |
| **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 |  |  |  |  |

\* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 3

Name: <Enter full name>

Position: <Enter currently held position>

Date: <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.

**Table 3: Conflict of Interest Declaration for Clinician 3**

|  |  |
| --- | --- |
| **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 |  |  |  |  |

\* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 4

Name: <Enter full name>

Position: <Enter currently held position>

Date: <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.

**Table 4: Conflict of Interest Declaration for Clinician 4**

|  |  |
| --- | --- |
| **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 |  |  |  |  |

\* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 5

Name: <Enter full name>

Position: <Enter currently held position>

Date: <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.

**Table 5: Conflict of Interest Declaration for Clinician 5**

|  |  |
| --- | --- |
| **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 |  |  |  |  |

\* Place an X in the appropriate dollar range cells for each company.