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**CADTH Reimbursement Review**

**Drug Program Input on Implementation Issues**

**Instructions**

This form provides CADTH with a summary of potential implementation issues for the drug(s) under review from the perspective of the participating drug programs. Early identification of these issues will help ensure that the recommendation meets the needs of the participating drug programs.

Completing the Template:

In accordance with the [*Procedures for CADTH Reimbursement Reviews*](https://cadth.ca/sites/default/files/Drug_Review_Process/CADTH_Drug_Reimbursement_Review_Procedures.pdf), a lead jurisdiction (discussant) prepares a draft of the potential implementation issues for discussion and finalization by the CADTH Pharmaceutical Advisory Committee working groups (i.e., Formulary Working Group for non-oncology drugs and Provincial Advisory Group for oncology drugs).

The finalized input from the drug programs is summarized and incorporated into the CADTH review reports for consideration by the expert committee in their deliberations.

All sections of the template should be completed (if applicable) as follows:

* **Table 1:** Drug programs are asked to raise any issues with the comparator drugs that have been used in the sponsor’s submission.
* **Table 2:** Drug programs are to specify issues related to potential reimbursement criteria regarding the drug under review.
* **Table 3:** Drug programs are to identify special implementation issues to be considered and addressed by the research team and/or expert committee but could fall outside the scope of CADTH’s recommendation. Issues may have practical or economic implications. These aspects may be addressed in a separate section of the reports or by a supplemental implementation advice panel (if required).
* **Table 4:** Drug programs can formulate direct questions related to implementation issues that they would like the experts and/or committee to address.

Filing the Completed Template:

Send the completed template to the CADTH support team who will include as part of the next monthly CADTH advisory group meeting material.

At the meeting, the discussant will provide a summary of their input to the group and other members will provide input from the perspectives of their jurisdictions. Based on the discussion, the drug program input will be revised and finalized for inclusion in the CADTH review report(s).

**CADTH Reimbursement Review**

**Drug Program Input on Implementation Issues**

**Section 1: General Information**

|  |  |
| --- | --- |
| **1.1 Drug Product Information:** | |
| **Drug name (generic):** | **Sponsor:** |
| **Indication:** | |
| **Reimbursement Request:** | |

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| --- |
| **1.2 Lead Jurisdiction** |
| **Jurisdiction:** |

**Section 2: Jurisdictional Implementation Issues**

Table 1: Jurisdictional Context

|  |  |
| --- | --- |
| **2.1 RELEVANT COMPARATORS**  Check whether you have identified potential or current **issues** and provide brief details | |
|  | 1. **Issues with the choice of comparator in the submitted trial(s)**   Enter text here. |
|  | 1. **Other implementation issues regarding relevant comparators (e.g., access/funding, covered population)**   Enter text here. |

Table 2: Policy Considerations for Reimbursing the Drug

|  |  |  |
| --- | --- | --- |
| **2.2 CONSIDERATIONS FOR INITIATION OF THERAPY**  Check any category where you have identified potential or current **issues** and provide brief details | | |
|  | | 1. **Disease diagnosis, scoring or staging for eligibility**   Enter text here. |
|  | | 1. **Other patient characteristics for eligibility (e.g., age restrictions, comorbidities)**   Enter text here. |
|  | | 1. **Prior therapies required for eligibility**   Enter text here. |
|  | | 1. **Eligibility to re-treatment**   Enter text here. |
|  | | 1. **Special subtypes (not explicitly mentioned in the indication) to consider separately for eligibility**   Enter text here. |
|  | | 1. **Consistency with initiation criteria associated with other drugs reviewed by CADTH in the same therapeutic space**   Enter text here. |
| **2.3 CONSIDERATIONS FOR CONTINUATION OR RENEWAL OF THERAPY**  Check any category where you have identified potential or current **issues** and provide brief details | | |
|  | 1. **Challenges related to assessment and monitoring of therapeutic response**   Enter text here. | |
|  | 1. **Consistency with renewal criteria associated with other drugs reviewed by CADTH in the same therapeutic space**   Enter text here. | |
| **2.4 CONSIDERATIONS FOR DISCONTINUATION OF THERAPY**  Check any category where you have identified potential or current **issues** and provide brief details | | |
|  | 1. **Definition of loss of response, absence of clinical benefit, or disease progression**   Enter text here. | |
|  | 1. **Treatment interruptions due to toxicity**   Enter text here. | |
|  | 1. **Definition of time-limited therapy**   Enter text here. | |
|  | 1. **Consistency with discontinuation criteria associated with other drugs reviewed by CADTH in the same therapeutic space**   Enter text here. | |
| **2.5 CONSIDERATIONS FOR PRESCRIBING OF THERAPY**  Check any category where you have identified potential or current **issues** and provide brief details | | |
|  | 1. **Dosing, schedule/frequency, dose intensity**   Enter text here. | |
|  | 1. **Drug administration**   Enter text here. | |
|  | 1. **Concerns related to accessing clinical specialists and/or special settings**   Enter text here. | |
|  | 1. **Concerns related to combination usage**   Enter text here. | |
|  | 1. **Consistency with prescribing criteria associated with other drugs reviewed by CADTH in the same therapeutic space**   Enter text here. | |

Table 3: Special Implementation Issues

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| --- | --- |
| **2.6 GENERALIZABILITY**  Check any category where you have identified potential or current **issues** and provide brief details | |
|  | 1. **Populations of interest matching the indication but with insufficient data**   Enter text here. |
|  | 1. **Populations outside the indication or reimbursement request but of interest to jurisdictions**   Enter text here. |
|  | 1. **Patient on active treatment with a time-limited opportunity to switch to the drug(s) under review**   Enter text here. |
| **2.7 FUNDING ALGORITHM (ONCOLOGY ONLY)**  Check any aspect that may require the development of a provisional funding algorithm by CADTH | |
|  | Drug may change place in therapy of comparator drugs |
|  | Drug may change place in therapy of drugs reimbursed in previous lines |
|  | Drug may change place in therapy of drugs reimbursed in subsequent lines |
|  | Complex therapeutic space with multiple lines of therapy, subpopulations, or competing products |
|  | Other aspects: Enter text here. |
| **2.8 CARE PROVISION ISSUES**  Check any category where you have identified potential or current **issues** and provide brief details | |
|  | 1. **Drug preparation, storage, administration or dispensing**   Enter text here. |
|  | 1. **Management of adverse effects**   Enter text here. |
|  | 1. **Additional supportive medication or other health interventions**   Enter text here. |
|  | 1. **Companion diagnostics (e.g., access issues, timing of testing)**   Enter text here. |
|  | 1. **Other care provision issues**   Enter text here. |
| **2.9 SYSTEM AND ECONOMIC ISSUES**  Check any category where you have identified potential or current **issues** and provide brief details | |
|  | 1. **Concerns regarding the anticipated budget impact and sustainability**   Enter text here. |
|  | 1. **Additional costs to be considered (other than related to care provision as detailed above)**   Enter text here. |
|  | 1. **Involvement of additional payers**   Enter text here. |
|  | 1. **Presence of confidential negotiated prices for comparators**   Enter text here. |
|  | 1. **Special programs or initiatives for the introduction and management of the drug(s) under review**   Enter text here. |
|  | 1. **Other system or economic issues**   Enter text here. |

Table 4: Drug Program Questions for Clinical Experts and/or Expert Committee

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| --- |
| 1. Enter text here. |
| 1. Enter text here. |
| 1. Enter text here. |
| 1. Enter text here. |