**Reimbursement Review**

**Drug Program Input on Implementation Issues**

**Instructions**

This form provides Canada’s Drug Agency (CDA-AMC) 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 Reimbursement Reviews*, a lead jurisdiction (discussant) prepares a draft of the potential implementation issues for discussion and finalization by the 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 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 the recommendation. 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.

**Drug Program Input on Implementation Issues**

**Section 1: General Information**

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| **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

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| **2.1 RELEVANT COMPARATORS**  Check whether you have identified potential or real **issues** and provide brief details | |
|  | 1. **Issues with the choice of comparator in the submitted trial(s)**   Example text: Comparator drug is not funded in most provinces. |
|  | 1. **Other implementation issues regarding relevant comparators (e.g., access/funding, covered population)**   Example text: CAR-T could be considered a comparator in this population. However, its access is restricted to patients who have experienced three prior lines of therapy. |

Table 2: Policy Considerations for Reimbursing the Drug

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| **2.2 CONSIDERATIONS FOR INITIATION OF THERAPY**  Check any category where you have identified potential or real **issues** and provide brief details | | |
|  | | 1. **Disease diagnosis, scoring or staging for eligibility**   Example: The disease scoring system used in the trial is not used in Canadian clinical practice; it would be challenging to include it in eligibility criteria. |
|  | | 1. **Other patient characteristics for eligibility (e.g., age restrictions, comorbidities)**   Example: Should patients having experienced a drug of the same class be eligible for the drug under review? |
|  | | 1. **Prior therapies required for eligibility**   Example: Should patients having experienced a drug of the same class be eligible for the drug under review? |
|  | | 1. **Eligibility to re-treatment**   Example: Can the drug be given again to patients who relapsed while off therapy? If so, what would be the appropriate timing of re-treatment? |
|  | | 1. **Special subtypes (not explicitly mentioned in the indication) to consider separately for eligibility**   Example: Would patients with CNS metastases equally benefit from this oncology drug and would they be considered eligible? |
|  | | 1. **Consistency with initiation criteria associated with other drugs reviewed in the same therapeutic space**   Example: Consider alignment with reimbursement criteria for drug B. |
| **2.3 CONSIDERATIONS FOR CONTINUATION OR RENEWAL OF THERAPY**  Check any category where you have identified potential or real **issues** and provide brief details | | |
|  | 1. **Challenges related to assessment and monitoring of therapeutic response**   Example: Need for regular brain MRI scans to monitor response to drug. There is limited access in some provinces. | |
|  | 1. **Consistency with renewal criteria associated with other drugs reviewed in the same therapeutic space**   Example: Consider alignment with renewal criteria for drug B. | |
| **2.4 CONSIDERATIONS FOR DISCONTINUATION OF THERAPY**  Check any category where you have identified potential or real **issues** and provide brief details | | |
|  | 1. **Definition of loss of response, absence of clinical benefit, or disease progression**   Example: Need definition of refractory disease (based on what parameters? | |
|  | 1. **Treatment interruptions**   Example: If there is progression during a “drug holiday”, can treatment be resumed? According to what timeframe? | |
|  | 1. **Definition of time-limited therapy**   Example: Should therapy end after x number of doses or after two years, whichever comes first? | |
|  | 1. **Consistency with discontinuation criteria associated with other drugs in the same therapeutic space**   Example: Consider alignment with stopping criteria for drug B. | |
| **2.5 CONSIDERATIONS FOR PRESCRIBING OF THERAPY**  Check any category where you have identified potential or real **issues** and provide brief details | | |
|  | 1. **Dosing, schedule/frequency, dose intensity**   Example: To reduce clinic visits, can the dose of 10 mg/kg Q4W be considered instead of 5 mg/kg Q2W? | |
|  | 1. **Drug administration**   Example: Intrathecal administration requires special training and facilities. | |
|  | 1. **Concerns related to accessing clinical specialists and/or special settings**   Example: There is limited access to specialists within some regions. | |
|  | 1. **Concerns related to combination usage**   Example: The combination includes an oral and an IV drug that would be reimbursed through different programs. | |
|  | 1. **Consistency with prescribing criteria associated with other drugs reviewed in the same therapeutic space**   Example: Consider alignment with prescribing criteria for drug B. | |

Table 3: Special Implementation Issues

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| **2.6 GENERALIZABILITY**  Check any category where you have identified potential or real **issues** and provide brief details | |
|  | 1. **Populations of interest matching the indication but with insufficient data**   Example: Patients with ECOG performance status >1 were excluded from the trial. Can they be considered eligible? |
|  | 1. **Populations outside the indication or reimbursement request but of interest to jurisdictions**   Example: Can this RA drug also be given to patients with giant cell arteritis? |
|  | 1. **Patient on active treatment with a time-limited opportunity to switch to the drug(s) under review**   Example: Potential need to allow switching patients currently receiving a comparator, if the drug under review is recommended and deemed superior. |
| **2.7 FUNDING ALGORITHM (ONCOLOGY ONLY)**  Check any aspect that may require the development of a provisional funding algorithm | |
|  | 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 real **issues** and provide brief details | |
|  | 1. **Administration/dispensing mechanisms**   Example: Drug needs to be initiated in the hospital setting while maintenance therapy would be provided in the community setting. |
|  | 1. **Management of adverse effects**   Example: Tumour lysis syndrome needs to be monitored and managed in the hospital. |
|  | 1. **Additional supportive medication or other health interventions**   Example: Immunosuppressive drug requires co-administration of prophylactic antimicrobials. |
|  | 1. **Companion diagnostics (e.g., access issues, timing of testing)**   Example: Need advice on optimal timing of biomarker testing (e.g., at time of diagnosis, as part of eligibility assessment prior to initiation). |
|  | 1. **Other care provision issues**   Example: To manage toxicity, can one drug of the pair be stopped and the other continued until loss of clinical benefit? |
| **2.9 SYSTEM AND ECONOMIC ISSUES**  Check any category where you have identified potential or real **issues** and provide brief details | |
|  | 1. **Concerns regarding the anticipated budget impact and sustainability**   Example: Provision of this drug in the first line setting may translate into substantial budget impact. A prioritization scheme may be required. |
|  | 1. **Additional costs to be considered (other than related to care provision as detailed above)**   Example: This therapy requires facilities that are not available in all provinces. Drug plans may need to cover travel expenses for eligible patients. |
|  | 1. **Involvement of additional payers**   Example: The implantable device component of this therapy will need to be funded by medical services departments within jurisdictional health care systems. |
|  | 1. **Presence of confidential negotiated prices for comparators**   Example: Comparators A and B have successfully gone through price negotiations for the same indication. |
|  | 1. **Special programs or initiatives for the introduction and management of the drug(s) under review**   Example: Due to their abuse potential, drugs of this class are usually subjected to a controlled distribution program. |
|  | 1. **Other system or economic issues**   Example: High upfront cost of this gene therapy may require special payment arrangements. |

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

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