CADTH

Consultation on Recommendation Framework for CADTH Common Drug Review and pan-Canadian Oncology Drug Review Programs

October 9, 2015

Call for Feedback Deadline:
November 9, 2015 at 5:00 p.m. ET via email to **feedback@cadth.ca**

Purpose

CADTH is inviting stakeholder comments and feedback on the proposed framework to align drug expert committee recommendations to be used in both the CADTH Common Drug Review (CDR) and pan-Canadian Oncology Drug Review (pCODR) programs.

Background and Current Status

At the Stakeholder Engagement Session held on February 5, 2015, CADTH announced its intent to create a single recommendation framework that is applied by its drug expert committees (the CADTH Canadian Drug Expert Committee [CDEC] and the CADTH pCODR Expert Review Committee [pERC]).

Table 1 summarizes the current CDR and pCODR categories of recommendation options.

TABLE 1: CURRENT RECOMMENDATION CATEGORIES

CDR Recommendation Categories	pCODR Recommendation Categories
There are four recommendation categories: • List • List with clinical criteria and/or conditions • Do not list at the submitted price • Do not list	There are three recommendation categories: • Recommend to fund • Recommend to fund with conditions • Do not recommend funding

Proposed Revisions to the Recommendation Framework for the CDR and pCODR Programs

As part of the ongoing process to align the two programs, CADTH and the participating jurisdictions have agreed that the following three recommendation categories and terminology will be adopted for use in both CDR and pCODR:

- Reimburse
- Reimburse with clinical criteria and/or conditions
- Do not reimburse

In view of these changes, CADTH is drafting a revised recommendation framework for CDR and pCODR based on the three new categories. This proposed framework is intended to be incorporated into the existing deliberative frameworks and processes to support the CADTH drug expert committees in making recommendations to the participating jurisdictions to guide their reimbursement decisions.

The key elements supporting the CADTH drug expert committees' recommendations would include:

- clinical and economic evidence available at the time of the review
- patient input provided by patient advocacy groups and individual patients and caregivers
- existing treatment options
- existing programs and policies (i.e., what is/is not reimbursed and who is covered for reimbursement)
- submitted price of the drug under review and publicly available prices of the comparators
- implementation considerations at the jurisdictional level

Final reimbursement decisions remain the responsibility of each participating jurisdiction.

Table 2 describes the new proposed recommendation categories along with guidance on how it could be applied. Additional context is also provided to clarify the "Reimburse with clinical criteria and/or conditions" category.

TABLE 2: NEW RECOMMENDATION CATEGORIES

Reimburse
A drug[a] demonstrates clinical benefit and acceptable cost/cost-effectiveness relative to one or more appropriate comparators[b] to recommend reimbursement in accordance with the defined patient population under review, which is typically the patient population defined in the Health Canada–approved indication (as applicable).
Reimburse with clinical criteria and/or conditions
Scenarios that typically fit this category include: **Comparable or added clinical benefit** • A drug[a] demonstrates comparable or added clinical benefit and acceptable cost/cost-effectiveness relative to one or more appropriate comparators in a subgroup of patients within the approved indication. In such cases, the subgroup is specified through "clinical criteria." • A drug[a] demonstrates comparable clinical benefit and acceptable cost/cost-effectiveness relative to one or more appropriate comparators.[b] In such cases, a condition may include that the drug[a] be listed in a similar manner to one or more appropriate comparators.[b] • A drug[a] demonstrates comparable or added clinical benefit, but the cost/cost-effectiveness relative to one or more appropriate comparators[b] is unacceptable. In such cases, a condition may include a reduced price. **Uncertain clinical benefit, but significant unmet clinical need** • A drug[a] demonstrates uncertain clinical benefit, but significant unmet clinical need exists. In such cases, if cost/cost-effectiveness is unacceptable, then a condition of a reduced price will be included.
Do not reimburse
Insufficient evidence identified to recommend reimbursement. Scenarios that typically fit this recommendation category include: • A drug[a] does not demonstrate comparable clinical benefit relative to one or more appropriate comparators.[b] • A drug[a] demonstrates inferior clinical outcomes or significant clinical harm relative to one or more appropriate comparators.[b]

[a] Refers to a drug under review.

[b] An appropriate comparator is typically a drug reimbursed by one or more drug plans for the indication under review. However, the choice of appropriate comparator(s) in the review is made on a case-by-case basis, considering input from jurisdictions and clinical experts.
Note: Existing treatment options may include best supportive care and non-pharmaceutical health technologies or procedures.

Additional Context for the "Reimburse with Clinical Criteria and/or Conditions" Category

Clinical Criteria and Conditions

The CADTH drug expert committees recommend clinical criteria to provide additional characteristics to identify the patient population for whom reimbursement is being recommended. These are typically provided in addition to any clinical characteristics specified in the Health Canada–approved indication. The CADTH drug expert committees recommend conditions to provide guidance to the participating jurisdictions on implementation and operational issues related to the drug under review. Table 3 lists some of the common considerations regarding clinical criteria and conditions.

This is not intended to be an exhaustive list of all possible clinical criteria and conditions.

TABLE 3: EXAMPLES OF COMMONLY USED CLINICAL CRITERIA AND CONDITIONS

Clinical criteria	Examples of clinical criteria include, but are not limited to:
	• Characteristics that identify a patient subgroup, for example:
	  ○ comorbidity status
	  ○ inability to use, intolerance, or inadequate response to appropriate comparator(s)
	  ○ severity of disease or disease progression
	  ○ disease subtype (e.g., specific mutation)
	• Starting and stopping rules, for example:
	  ○ duration of treatment
	  ○ response to treatment
	  ○ patients are receiving appropriate first and/or second line therapies and have had a suboptimal response despite an adequate trial

Conditions	Examples of conditions include, but are not limited to:
	• Cost considerations, for example:
	  ○ not to be reimbursed at the submitted price (i.e., cost-effectiveness must be improved)
	  ○ cost of drug under review not to exceed cost of appropriate comparator
	• Reimbursement limits, for example:
	  ○ number of doses supported by clinical and cost-effectiveness evidence
	• Characteristics of the care setting, for example:
	  ○ prescribed by or under the care of an experienced clinical team
	• Reimbursement of the drug in a manner similar to comparator(s) that are reimbursed by the participating jurisdictions at the time of the review
	• Real-world evidence development considerations for scenarios where there is uncertain clinical benefit, but significant unmet need

Uncertain Clinical Benefit, but Significant Unmet Clinical Need

In some cases where there is uncertain clinical and pharmacoeconomic evidence, the CADTH drug expert committees may issue a recommendation to reimburse with clinical criteria and/or conditions, due to practical challenges in conducting robust clinical trials and pharmacoeconomic evaluations and in the presence of significant unmet medical need. Significant unmet clinical need is identified on a population or subpopulation basis (i.e., not on an individual basis) through the CDR and pCODR processes.

These cases typically involve a combination of two or more of the following characteristics:

- There is significant unmet clinical need, as identified by patient input, clinical expert opinion, CADTH review teams, and participating jurisdictions.
- There is a lack of availability of an effective alternative treatment option.
- The drug is indicated for a relatively small patient population.

In addition, there are some common evidence challenges in these cases, such as:

- There are a limited number of clinical trials and they have small sample sizes.
- Clinical data are either limited to surrogate end points or provide insufficient evidence on meaningful clinical end points.
- There is a lack of robust cost-effectiveness models due to limitations in clinical data.

Next Steps

CADTH will carefully assess all stakeholder feedback from this consultation before implementing the new recommendation framework. Any future changes will be applied to and implemented for both the CDR and pCODR programs simultaneously, unless there are compelling reasons to suggest otherwise.

How to Submit Your Feedback

- To provide feedback, you must identify yourself — feedback provided by individuals who do not identify themselves and the organization they represent will not be considered.
- Only one response per organization will be considered. If more than one response is received, only the first response received will be considered.
- Feedback *must* be provided in 11-point font using this template and saved in one of the following formats:
  - Microsoft Word document (.doc or .docx)
  - Unlocked PDF document that permits copying and pasting of text.
- Feedback should be presented clearly and succinctly.

If you have any questions about the feedback process, please email us at **feedback@cadth.ca**.
We thank you in advance for your interest.