DELIBERATIVE FRAMEWORK

Background:
The Canadian Drug Expert Committee (CDEC) is an advisory body that makes drug-related recommendations and provides drug-related advice to the Canadian Agency for Drugs and Technologies in Health (CADTH). CDEC’s recommendations and advice are provided to CADTH to inform key clients and a range of stakeholders. CDEC considers the following while making recommendations:

- input from patient groups
- clinical studies demonstrating the safety, efficacy, and effectiveness of the drug compared with alternatives
- therapeutic advantages and disadvantages relative to current accepted therapy
- cost and cost-effectiveness relative to current accepted therapy.

CDEC Membership and Conflict of Interest:
CDEC comprises 11 to 14 members, including the Chair. Two of the members are public members, tasked with bringing a lay perspective to the Committee and ensuring that patient concerns are accorded important consideration in CDEC discussions and deliberations.

CDEC members declare all conflicts of interest before deliberations on each submission in accordance with the Conflict of Interest Guidelines for CADTH Expert Committee and Panel Members. All CDEC members at a CDEC meeting (either in-person or by teleconference) must vote, unless precluded by conflict of interest.

Before a CDEC Meeting:
- For each drug submission, a CDEC brief is made available to all members of the Committee two weeks before the CDEC meeting. CDEC members are responsible for reviewing the CDEC briefs for all drugs under consideration. Materials contained in a CDEC brief include, but are not limited to:
  - patient group input
  - submission history table of similar drugs reviewed by the Canadian Expert Drug Advisory Committee/CDEC
  - Common Drug Review Clinical Reviewers’ Report
  - manufacturer’s comments on the clinical report and the clinical reviewers’ responses
  - Pharmacoeconomic Reviewers’ Report

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1 Therapeutic Review and Optimal Use reports prepared by CADTH are included in CDEC briefing materials when relevant.
• manufacturer’s comments on the pharmacoeconomic report and the pharmacoeconomic reviewers’ responses
• drug plan listing status for comparators
• additional information
  o reference material (for clinical and economic review reports)
  o manufacturer’s disclosure of ongoing trials
  o manufacturer’s executive summary.

• Three CDEC members, including one public member, are assigned as “discussants” for each drug on the CDEC agenda early in the review process. The discussants prepare brief written overview reports based on patient group input, clinical and economic reports, and the materials contained in the CDEC brief. No new clinical or economic information — i.e., information that was not submitted or included in the review of the submission or resubmission — is included in the overview reports.
• CADTH staff review the discussant reports to ensure the data are accurate and no new information is introduced that was not included in the CDR Clinical and Pharmacoeconomic Review Reports. The final discussant reports are subsequently provided to all CDEC members in advance of the meeting.

CDEC Meetings:

Attendees
In addition to CDEC members, the following persons may attend a CDEC meeting:
• health ministry officials, appointed by participating jurisdictions, who attend as observers, but do not participate in deliberations or voting
• CADTH staff and contractors employed in the review who may present information relevant to the submission and/or provide administrative and secretariat support, but do not participate in deliberations or voting
• invited experts, such as clinical specialists, methodologists, or economists, who provide clarification as required, but do not participate in deliberations or voting.

CDEC Deliberative Process:

• Consideration of each submission begins with presentations by the assigned discussants.
• The public member makes the first presentation, focusing on the issues of patients and/or their caregivers related to the condition for which the drug is indicated and its treatment.
• The other two CDEC discussants present their overviews of the clinical and economic evidence.
• Following the discussant presentations, all CDEC members provide input; and CDR staff, including clinical and economic reviewers, and invited experts provide input as required.
• CDEC members deliberate the patient group input, and clinical and economic evidence.
• Based on the deliberation of the available evidence, CDEC members choose one of four recommendation options: List, List with clinical criteria and/or conditions, Do not list at the submitted price, or Do not list.
• CDEC members then vote on the recommendation.
• Draft reasons for the recommendation are provided by CDEC members.

2 One or more experts are included in each CDR review. Selection of experts is based on qualifications, expertise and compliance with CADTH’s Conflict of Interest Guidelines.
Voting:

- Only CDEC members vote. All CDEC members must vote unless there is a declared conflict of interest that precludes a member from voting.
- CDEC members vote secretly on the recommendation option and the reasons for the recommendation.
- The CDEC Chair validates the voting results and announces if the motion is carried. Results of the vote are determined based upon a simple majority of the voting members.\(^3\) The CDEC Chair votes only in the case of a split vote.
  - CDEC must make a recommendation or defer if additional clarification is needed.

Post-CDEC Meeting:

Following the meeting, the draft recommendation document is finalized by CADTH staff with input from CDEC members. After approval by the CDEC Chair, the embargoed recommendation is distributed to the CDR participating drug plans and the drug manufacturer, and subsequent steps of the review process are followed in accordance with the current Procedure for Common Drug Review. Final CDEC recommendation documents are posted on the CADTH website and include the final recommendation, reasons for the recommendation, a summary of patient input, key evidence from the clinical and pharmacoeconomic assessments, and other relevant information.

CDR Recommendations Options

CDEC may recommend any of the following options for a drug under review:

- that a drug be listed
- that a drug be listed with clinical criteria and/or conditions
- that a drug not be listed
- that a drug not be listed at the submitted price.

CDEC may also elect to defer a recommendation pending clarification of information.

The CDR recommendations options and framework are described in Table 1.

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\(^3\) A quorum for the meeting is 66% of CDEC members. For details refer to the Canadian Drug Expert Committee Terms of Reference, April 2011 (www.cadth.ca)
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<th>Recommendation Options</th>
<th>Description and Considerations</th>
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<tbody>
<tr>
<td>List</td>
<td>• A drug&lt;sup&gt;a&lt;/sup&gt; demonstrates comparable or added clinical benefit and acceptable cost/cost-effectiveness relative to one or more appropriate comparators.&lt;sup&gt;b&lt;/sup&gt;</td>
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| List with clinical criteria and/or conditions | Examples that typically fit this listing category include:  
• A drug<sup>a</sup> 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<sup>a</sup> demonstrates added clinical benefit, but the cost/cost-effectiveness relative to one or more appropriate comparators<sup>b</sup> is unacceptable. In such cases, a condition may include a reduced price.  
• A drug<sup>a</sup> demonstrates comparable clinical benefit and acceptable cost/cost-effectiveness relative to one or more appropriate comparators<sup>b</sup>. In such cases, a condition may include that the drug<sup>a</sup> be listed in a similar manner to one or more appropriate comparators.  

Examples of clinical criteria include, but are not limited to:  
• characteristics that identify a patient subgroup, for example:  
  • comorbidity status  
  • inadequate response to appropriate comparator(s)  
  • intolerance to appropriate comparator(s)  
  • inability to use appropriate comparator(s).  
• characteristics of the care setting (e.g., prescribed by or under the care of an experienced clinical team)  
• starting and stopping rules (e.g., response to treatment).  

Examples of conditions include, but are not limited to<sup>c</sup>:  
• pricing considerations  
• reimbursement limits (e.g., number of doses supported by clinical and cost-effectiveness evidence)  
• current formulary listing status of one or more appropriate comparators (i.e., if a drug under review is similar to (a) listed appropriate comparator(s), the condition may be to list the drug in a similar manner to the listed comparator(s)).
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| **Do not list at the submitted price** | An example that typically fits this listing category includes:  
- A drug\(^a\) demonstrates comparable clinical benefit, but the cost/cost-effectiveness relative to one or more appropriate comparators\(^b\) is unacceptable.  

**Note:**  
The “Of Note” section in the recommendation may provide additional context around price, comparator(s), patient subgroups to whom the drug might be restricted, and other relevant considerations. |
| **Do not list** | • A drug\(^a\) does not demonstrate comparable clinical benefit relative to one or more appropriate comparators.\(^b\) |

\(^a\) Refers to a drug under review.  
\(^b\) An appropriate comparator is typically a drug listed by one or more CDR participating drug plans for the indication under review.  
\(^c\) Although not listed as conditions, evidence gaps and the need for evidence development may be highlighted in the CDEC Recommendation document as appropriate.