CADTH

CADTH Consultation: Proposal for Streamlined Drug Class Reviews

1. About Streamlined Drug Class Reviews

Through consultation with public drug programs, CADTH identified an interest in a streamlined approach to therapeutic reviews that was fit for purpose, leveraging existing published evidence and analyses. A Streamlined Drug Class Review is a form of CADTH Therapeutic Review that leverages published clinical information to provide decision-makers with timely evidence to support drug policy decisions and formulary management. The focus of each review will be on a therapeutic category of drugs (e.g., antihyperglycemic drugs) or a class of drugs (e.g., sodium-glucose cotransporter-2 inhibitors). Table 1 provides a comparison of current therapeutic review process and proposed streamlined drug class review.

The primary outputs from a Streamlined Drug Class Review will be a summary report (which includes a clinical and economic assessment of the class), recommendations report, and knowledge mobilization tools. The Streamlined Drug Class Review will include a recommendation from one of CADTH's drug expert committees (i.e., the Canadian Drug Expert Committee [CDEC] or the pan-Canadian Oncology Drug Review Expert Review Committee [pERC]).

Table 1: Comparison of Current Therapeutic Review Process and Proposed Streamlined Drug Class Review

	Current Therapeutic Review Process	Proposed Streamlined Drug Class Review
Requester(s)	Public drug programs, cancer agencies, or pCPA	
Prioritization	Priority established by CADTH jurisdictional working groups	
Topic Selection	See key factors concerning relevance, timeliness, and potential impact within the Therapeutic Review Framework	The key factors concerning relevance, timeliness, and potential impact within the Therapeutic Review Framework will be applied in addition to the following: • **Existing review:** High quality existing review of the relevant clinical evidence (e.g., from another HTA agency). • **Utilization analyses:** Demonstration that there may be an opportunity to improve appropriate use. • **Budget impact:** National spending (private and public) of at least $50 million per year or when a change in formulary management has a projected combined savings of at least $10 million per year for 3 years when compared with appropriate comparators. • **Loss of exclusivity**: At least one of the drugs of interest has lost exclusivity.
Target timelines	9 to 12 months	4 to 6 months
Clinical Review	Systematic literature review with meta-analysis (if appropriate)	CADTH summary and appraisal of existing published literature review(s)

Economic Evidence	Typically includes a novel pharmacoeconomic evaluation conducted as part of the CADTH review	Will not include a novel pharmacoeconomic evaluation conducted as part of the CADTH review, but may include the following: • a cost comparison • a pan-Canadian budget impact analysis • an economic review leveraging existing published models
Stakeholder feedback	Both reviews engage stakeholders in a similar manner.	
Recommendation Procedure	Both reviews follow the same expert committee recommendation procedures.	

2. Target Audience and Application for Decision-Making

Streamlined Drug Class Reviews are undertaken to inform federal, provincial, and territorial government drug programs, including those from provincial cancer agencies, administrators and health policy-makers working at regional health authorities, and staff at hospitals in Canada who make decisions about the appropriate use of, access to, or reimbursement of pharmaceuticals. Streamlined Drug Class Reviews are not meant to replace professional medical advice.

3. Eligibility and Topic Refinement

The purpose of the Streamlined Drug Class Review is not to replace the CADTH Therapeutic Review, but to leverage existing published evidence where de novo meta-analyses or economic analyses are not required.

The following criteria will be assessed during the scoping phase to determine eligibility for a Streamlined Drug Class Review:

- robust published clinical evidence, which could include existing head-to-head data or high quality existing reviews of the relevant clinical evidence (e.g., from another HTA agency).
- utilization analyses demonstrating that there may be an opportunity to improve appropriate use
- national spending (private and public) of at least $50 million per year or when a change in formulary management has a projected combined savings of at least $10 million per year for 3 years when compared with appropriate comparators
- loss of exclusivity for 1 or several drugs in a class.

CADTH refines topics through jurisdictional working groups comprised of representatives from drug programs and clinical experts. CADTH develops a project proposal that contains an initial scoping literature search (including existing recommendations from CADTH's single drug review programs for drugs to be included for review, if applicable), discussions with the jurisdictional representatives, and consideration of factors such as relevance, timeliness, and potential impact (Table 2 of Therapeutic Review procedures). Public drug programs review the proposals and establish the priority of the Streamlined Drug Class Review topics.

4. Transparency and Stakeholder Engagement

If a topic is supported across jurisdictions, a project scoping document is posted on the CADTH website for 10 business days for stakeholder feedback (i.e., the public, patients, health care providers, and pharmaceutical companies). The scoping document will outline the policy questions, research questions, selection criteria,

included studies (to be summarized and appraised in the review), methodology, and search strategy. The literature search will be conducted in accordance with the Therapeutic Review framework (section 4.2.2). While notice of the proposed review is posted on the CADTH website, affected manufacturers and stakeholders, including patient groups, may be notified directly by CADTH. Stakeholders may comment on the proposed project scope or share concerns with the list of included studies. All feedback is reviewed by CADTH and is used to finalize the scope of the review. Based on stakeholder feedback, CADTH refines the proposed project scope document and obtains final advice from the public drug programs on whether to proceed.

To support and encourage patient groups to participate, groups are invited to a teleconference with CADTH staff early in the process. During the teleconference, the project is described, expectations are identified, and possibilities for patient group involvement in the project are discussed.

CADTH notifies interested parties that a Streamlined Drug Class Review has been initiated and outlines target dates for providing feedback by posting a notice to the Calls for Feedback webpage and issuing an email to subscribers of the CADTH E-Alert service. Instructions on providing feedback are included with every notification. In the Streamlined Drug Class Review process, stakeholder feedback is solicited at the following stages:

- proposed project scope
- draft summary report
- draft recommendations report
- proposed revisions to existing recommendations from CADTH's single drug review programs (if applicable).

Streamlined Drug Class Review reports are posted on the CADTH website for anyone to access and review, although in exceptional circumstances, embargo periods may be considered.

5. Target Timelines

After the project protocol and the list of included studies are finalized, the typical time frame for development of the expert committee recommendations is 4 to 6 months. Exact timelines are determined by CADTH in consultation with the jurisdictions. Throughout the Streamlined Drug Class Review project, CADTH provides multiple opportunities for stakeholder engagement, allowing 10 business days for stakeholder feedback.

6. Research Phase

CADTH aims to conduct its streamlined reviews in the most efficient manner. CADTH will include equity, diversity, and inclusion considerations in the evidence and input collected as part of the research phase. The largest differentiation between Therapeutic Reviews and Streamlined Drug Class Reviews relates to the review of clinical and economic evidence (described as follows).

6.1 Research Protocol

The list of included publications is incorporated in the initial scoping document posted for stakeholder feedback. Input on the included publications is obtained from expert committee discussants and clinical experts. Input includes, but is not limited to, assisting in the development of research questions, identifying relevant outcomes, identifying subgroups of potential interest, and identifying any methodological weaknesses of the included publications. Once finalized, the project protocol is posted on the CADTH website for informational purposes.

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6.2 Included Studies

The list of included studies incorporated in the final summary report may be revised if additional information is provided following stakeholder feedback. The primary evidence evaluated for possible inclusion in a Streamlined Drug Class Review is retrieved from publicly available scientific research sources, such as peer-reviewed scientific journals and grey literature sources. Sources of evidence include:

- health technology assessments
- systematic reviews
- network meta-analyses
- conference abstracts
- clinical guidelines
- comments, newspaper articles, editorials, and letters are excluded, as are systematic reviews where all applicable studies are captured in a more recent and comprehensive review.

Stakeholders are given the option of identifying and providing unpublished data for consideration in the Streamlined Drug Class Reviews on the condition that, if used, it will be included in publicly available reports and documents related to the review.

6.3 Patient Group Input

Patient group input will occur as described in section 4.2.3 of the *Therapeutic Review Framework*.

6.4 Review of Clinical Evidence

A Streamlined Drug Class Review leverages published meta-analyses rather than having CADTH conduct a de novo meta-analysis. Included publications are critically appraised by CADTH based on the best available methods, and a summary of the collective findings are presented in the summary report. Clinical guidelines are also presented in the summary report.

6.5 Review of Economic Evidence

Streamlined Drug Class Reviews will not include de novo cost-utility analyses. When applicable, the economic review may leverage existing published models or economic models from previous CADTH Therapeutic Reviews. If appropriate, the review may include a cost comparison and a pan-Canadian budget impact analysis completed in accordance with CADTH's existing reimbursement review procedures.

6.6 Drafting the Summary Report

The CADTH review team prepares a draft report that combines both the clinical and economic evidence and analyses. As many Streamlined Drug Class Reviews will be conducted when a class of drugs has lost, or will be losing data exclusivity, the summary report may include a CADTH Optimal Use 360 that CADTH has conducted in the therapeutic area to summarize existing products. CADTH products may include a summary of Horizon Scan Bulletins on emerging drugs in the therapeutic area, an Environmental Scan Bulletin to assess the policy and regulatory landscape (e.g., national regulatory, exclusivity, and reimbursement status), or utilization analyses based on public and/or private data.

The draft summary report is posted for feedback on the CADTH website and forwarded to targeted stakeholders (e.g., affected manufacturers and patient groups), and stakeholders are invited to provide

comments. The time allotted for comments is 10 business days. The stakeholder feedback is then reviewed, and the report is revised based on the feedback (as required).

7. Recommendation Phase

7.1 Draft Recommendations

At the first meeting, the expert committee discusses the summary report and whether any changes are necessary. The committee hears presentations of the input from patients and caregivers, clinical and economic evidence, input from clinical experts, and implementation considerations at the jurisdictional level. All committee members can ask questions or make comments. Stakeholder feedback on the draft summary report is shared and discussed. Clinical experts involved in the Streamlined Drug Class Review are available to answer questions and to comment on the evidence presented. There are 2 primary objectives of this meeting:

- to develop draft recommendations or advice to address the policy and research questions that were raised by the public drug programs at the outset of the Streamlined Drug Class Review process
- to propose revisions to existing recommendations from CADTH's reimbursement review process (if applicable, based on the outcome of the Streamlined Drug Class Review)

The recommendations report summarizes the recommendations and/or advice, the reasons for the recommendations, patient perspectives, the clinical and economic evidence that was discussed, and the research gaps that were identified by the committee. The draft recommendations report and a document summarizing the committee's proposed revisions to any existing CADTH reimbursement recommendations (if applicable) are posted on the CADTH website for stakeholder feedback for a period of 10 business days. at this time, the final summary report is also posted for informational purposes.

7.2. Final Recommendations

CADTH and the expert committee discussants meet to review the stakeholder feedback. The discussants prepare a report that includes responses to stakeholder feedback on the recommendations and/or advice statement, and the proposed final statement. The discussants' report and stakeholder feedback are presented to the expert committee along with a revised statement, and a discussion is held on feedback and revisions. the expert committee then finalizes the recommendations and/or advice statements. a summary of the feedback considered is included within the final recommendations report.

7.3 Revised CADTH Reimbursement Recommendations

If required, revised recommendations will be issued in accordance with the procedures for reassessment through the CADTH therapeutic review process.

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8. Submitting Feedback

To provide comments on the proposal, please use the Survey Monkey feedback template. Feedback must be received by **5:00 p.m. EDT on April 14, 2022**. If you have any questions about the feedback process, please email CADTH. We thank you in advance for your interest in CADTH's streamlined optimal use process.

9. Next Steps

Following the consultation period, CADTH will carefully assess all stakeholder feedback before announcing any decisions regarding changes to proposed process. We thank you in advance for your interest. If you have any questions about the feedback process, please email CADTH.

Figure 1: Overview of Streamlined Drug Class Review Process

Alt text: The figure depicts the overall process of a streamlined drug class review from start to completion. Each sequential phase of the review and recommendation process is described from left to right.