Canada's Drug and
Health Technology Agency

Procedures for CADTH Streamlined Drug Class Reviews

June 2023

Table of Contents

Record of Updates

Version	Date	Summary of revisions
2	June 22, 2023	• Revisions to note that recommendations will be issued by the CADTH Formulary Management Expert Committee • Additional details regarding issuing revised reimbursement recommendations through the streamlined drug class review process
1	January 26, 2023	• Original version posted

1. Introduction

1.1 About Streamlined Drug Class Reviews

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., antihyperglycemia drugs) or a class of drugs (e.g., sodium-glucose cotransporter-2 inhibitors). The purpose of the streamlined drug class review is not to replace the CADTH therapeutic review, but to leverage existing published evidence when de novo meta-analyses or economic analyses are not required to support more timely decision making. Table 1 contrasts both the therapeutic review and the streamlined drug class review.

Table 1: Comparison of CADTH Therapeutic Review and Streamlined Drug Class Review

	Therapeutic Review	Streamlined Drug Class Review
Requester(s)	Public drug programs, cancer agencies, or pCPA	
Prioritization	Priority established by one of CADTH's advisory committees (Formulary Working Group [FWG], Provincial Advisory Group [PAG], Pharmaceutical Advisory Committee [PAC])	
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: • **Published meta-analyses:** Existing evidence assessing the effectiveness of the drug class (e.g., from another HTA agency). • **Utilization analyses:** Demonstration that there may be an opportunity to improve optimal use. • **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	Similar stakeholder engagement.	
Recommendation Procedure	Both reviews follow the same expert committee recommendation procedures.	

The primary outputs from a streamlined drug class review will be a summary report (which includes a clinical and economic assessment of the class) and a recommendations report. The recommendation report will include a recommendation from the CADTH Formulary Management Expert Committee (FMEC).

1.2 Target Audience

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 optimal use of, access to, or reimbursement of pharmaceuticals. Streamlined drug class reviews are not meant to replace professional medical advice.

2. Eligibility, Scoping and Topic Refinement

2.1 Drug Eligibility and Identification

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

- Robust published evidence of the clinical effectiveness of the drug class, which could include existing head-to-head data or high-quality existing systematic review(s) and meta-analyses of relevant clinical outcomes (e.g., from another HTA agency). Published evidence that is recent and includes the necessary comparators to inform the policy question will be considered.
- Utilization analyses demonstrating that there may be an opportunity to improve optimal use.
- One or more of the drugs in the class are later in their lifecycle, based on publicly available Health Canada resources (patent register and/or register of innovative drugs).

- In alignment with the CADTH Therapeutic Review process, topics are also selected and prioritized based on the result of a CADTH drug reimbursement recommendation.

Topics under consideration can be found on the CADTH website.

2.2 Scoping and Topic Refinement

CADTH refines topics through jurisdictional working groups comprised of representatives from public 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 the Therapeutic Review procedures). In circumstances when recent CADTH Health Technology Reviews have been completed and demonstrate opportunities for formulary management (i.e., Integrated Technology Review), these reports may be leveraged as the project proposal. Public drug programs review the proposals and establish the priority of the streamlined drug class review topics. Topics under consideration will be posted quarterly on the CADTH website.

3. 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 the clinical and economic evidence (described below).

3.1 Research Protocol

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). Input on the included publications is also 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.

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.

3.2 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 may include:

- health technology assessments
- systematic reviews
- network meta-analyses
- clinical guidelines
- comments, newspaper articles, editorials, and letters are excluded.

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.

3.3 Review of Clinical Evidence

A streamlined drug class review leverages published meta-analyses rather than a de novo CADTH 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 may also be discussed in the summary report.

3.4 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/Technology Reviews. If appropriate, the review may include a cost comparison and a pan-Canadian budget impact analysis completed in accordance with the CADTH's existing *Procedures for CADTH Reimbursement Reviews*.

3.5 Summary Report

The Summary Report will include a combined clinical and pharmacoeconomic report. In addition to the clinical and economic evidence described above, the summary report may also include a CADTH

Integrated Technology Review that has been 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 specific 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).

4. Recommendation Phase

4.1 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)

A recommendations report will summarize 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.

4.2 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.

4.3 Revised CADTH Reimbursement Recommendations

One of the outputs from a CADTH streamlined drug class review may be revised recommendations for drugs that have previously been reviewed through the CADTH reimbursement review processes.

a) Identification of Existing CADTH Reimbursement Recommendations

Existing CADTH reimbursement recommendations that could be revised as a result of the streamlined drug class review will be identified and communicated to stakeholders during the scoping phase of the review process.

b) Expert Committee Recommendation Process

As part of the deliberative process for a streamlined drug class review, FMEC will consider whether or not the results of the review suggest that any existing recommendations that were issued through the reimbursement review process should be revised.

c) Stakeholder Feedback on Revised Recommendations

Proposed revisions to existing reimbursement review recommendations will be posted for stakeholder feedback at the time the draft streamlined drug class review recommendations are posted. The following information will be included:

- the recommendation that may be revised as a result of the streamlined drug class review
- the revised reimbursement conditions being proposed (if applicable)
- the rationale for the proposed revision(s).

Stakeholders will have the opportunity to provide feedback on the proposed revisions to the draft recommendations. There will be no opportunities to request reconsideration of revised reimbursement recommendations through the streamlined drug class review.

d) Consideration of Stakeholder Feedback

Similar to feedback on the draft streamlined drug class review recommendations, CADTH staff will collate stakeholder feedback on any revisions to existing reimbursement review recommendations. The stakeholder feedback is presented and discussed by the committee.

The committee will consider the stakeholder feedback, the evidence from the streamlined drug class review, and the final streamlined drug class review recommendations and determine if any existing reimbursement review recommendations should be revised.

Depending on stakeholder feedback and the final streamlined drug class review recommendations, this could result in revisions that were not initially identified at the time of stakeholder feedback. CADTH will only issue a second call for stakeholder feedback for revised reimbursement recommendations when the committee's recommendation has been substantially revised following the initial round of stakeholder feedback. Specifically, this process will apply in the following circumstances:

- the recommendation category has been changed (e.g., from a recommendation that a drug should be reimbursed with or without conditions to a recommendation that the drug should not be reimbursed)
- the reimbursement conditions have been revised to reflect a different place in therapy relative to alternative therapies (e.g., a change to the recommended sequence of therapies)
- the patient population identified in the reimbursement conditions has been substantially altered relative to the initially proposed recommendation (e.g., the population has been narrowed or expanded); in these cases, the expert committee will determine if an additional call for stakeholder feedback is warranted as part of the deliberations.

e) Finalizing Revised Reimbursement Recommendations

When the committee has determined that a previous recommendation should be revised as a result of a streamlined drug class review, CADTH will issue a new final recommendation. The revised recommendation will be an abbreviated document containing the following key information:

- the drug and indication of interest
- the recommendation, including any conditions (if applicable)
- a statement indicating that the revised recommendation has been issued as a result of a CADTH streamlined drug class review
- a disclaimer indicating that the revised recommendation supersedes the previous reimbursement review recommendation for the drug and indication of interest.

A disclaimer will be added to the previous final recommendation stating that it has been superseded by the revised recommendation.

f) Posting Revised Reimbursement Recommendations

The revised final recommendation will contain no confidential information; therefore, sponsors will not be asked to complete a redaction request form. Posting of the revised final recommendation may occur before posting of the final streamlined drug class review recommendations.

5. Transparency and Stakeholder Engagement

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, CADTH provides 10 business days for stakeholders to provide feedback 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.