Canada's Drug Agency
L'Agence des médicaments du Canada
Drugs. Health Technologies and Systems. Médicaments, technologies de la santé et systèmes.

Procedures for CDA-AMC Streamlined Reviews

August 2024

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Record of Updates

Version	Date	Summary of revisions
3	August 29, 2024	• Updated with CDA-AMC branding • Updated product name from “Streamlined Drug Class Reviews” to “Streamlined Reviews”, and removed reference to “drug class”. • Expanded network meta-analysis to include other forms of published evidence. • “Stakeholders” changed to “Partners” or specific group
2	June 22, 2023	• Revisions to note that recommendations will be issued by the CDA-AMC’s 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 Reviews

A streamlined review is a form of CDA-AMC 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 review is not to replace the CDA-AMC 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 review.

Table 1: Comparison of CDA-AMC Therapeutic Review and Streamlined Review

	Therapeutic Review	Streamlined Review
Requester(s)	Public drug programs, cancer agencies, or pCPA	
Prioritization	Priority established by one of the CDA-AMC'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 or other published evidence:** Existing evidence assessing the clinical effectiveness (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)	CDA-AMC summary and appraisal of existing published literature review(s)

Economic Evidence	Typically includes a novel pharmacoeconomic evaluation conducted as part of the CDA-AMC review	Will not include a novel pharmacoeconomic evaluation conducted as part of the CDA-AMC review, but may include the following: • a cost comparison • a pan-Canadian budget impact analysis • an economic review leveraging existing published models
Partner feedback	Similar partner engagement.	
Recommendation Procedure	Both reviews follow the same expert committee recommendation procedures.	

The primary outputs from a streamlined review will be a summary report (which includes a clinical and economic assessment) and a recommendation report. The recommendation report will include a recommendation from our organization's Formulary Management Expert Committee (FMEC).

1.2 Target Audience

Streamlined 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 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 Review:

- Robust published evidence of the clinical effectiveness, 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 are later in their lifecycle, based on publicly available Health Canada resources (patent register and/or register of innovative drugs).

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

2.2 Scoping and Topic Refinement

Our organization refines topics through jurisdictional working groups comprised of representatives from public drug programs and clinical experts. We develop a project proposal that contains an initial scoping literature search (including existing recommendations from the CDA-AMC'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 CDA-AMC Health Technology Reviews have been completed and demonstrate opportunities for formulary management (e.g., 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 review topics.

3. Research Phase

Our organization aims to conduct its streamlined reviews in the most efficient manner. We 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 reviews relates to the review of the clinical and economic evidence (described below).

3.1 Research Protocol

If a topic is supported by jurisdictions, a project scoping document is posted on the CDA-AMC website for 10 business days for partner 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) if available, 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 CDA-AMC website, affected manufacturers and partners, including patient groups, may be notified directly by our organization. Our partners may comment on the proposed project scope or share concerns with the list of included studies. All feedback is reviewed by our organization and is used to finalize the scope of the review. Based on

partner feedback, we refine the proposed project scope document and obtain 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 partner feedback. The primary evidence evaluated for possible inclusion in a streamlined 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
- published findings of clinical studies
- clinical guidelines
- comments, newspaper articles, editorials, and letters are excluded.

Partners are given the option of identifying and providing unpublished data for consideration in the streamlined 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 review leverages published meta-analyses or other published evidence rather than de novo CDA-AMC analyses. Included publications are critically appraised by our organization based on the best available methods, and a summary of the collective findings presented in the summary report. Clinical guidelines may also be discussed in the summary report.

3.4 Review of Economic Evidence

Streamlined reviews will not include de novo cost-utility analyses. When applicable, the economic review may leverage existing published models or economic models from previous CDA-AMC Therapeutic/Technology Reviews. If appropriate, the review may include a cost comparison and a pan-Canadian budget impact analysis completed in accordance with the our existing *Procedures for CDA-AMC 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 CDA-AMC Integrated Technology Review that has been conducted in the therapeutic area to summarize existing products, if available. CDA-AMC 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 CDA-AMC website and forwarded to specific partners (e.g., affected manufacturers and patient groups), who are invited to provide comments. The time allotted for comments is 10 business days. The 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. Partner feedback on the draft summary report is shared and discussed. Clinical experts involved in the streamlined 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 review process
- to propose revisions to existing recommendations from our organization's reimbursement review process (if applicable, based on the outcome of the streamlined 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 CDA-AMC reimbursement recommendations (if applicable) are posted on the CDA-AMC website for partner 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

The CDA-AMC and the expert committee discussants meet to review the partner feedback. The discussants prepare a report that includes responses to partner feedback on the recommendations and/or advice statement, and the proposed final statement. The discussants' report and partner 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 CDA-AMC Reimbursement Recommendations

One of the outputs from our streamlined review may be revised recommendations for drugs that have previously been reviewed through the CDA-AMC reimbursement review processes.

a) Identification of Existing CDA-AMC Reimbursement Recommendations

Existing CDA-AMC reimbursement recommendations that could be revised as a result of the streamlined review will be identified and communicated to our partners during the scoping phase of the review process.

b) Expert Committee Recommendation Process

As part of the deliberative process for a streamlined 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) Partner Feedback on Revised Recommendations

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

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

Our partners 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 review.

d) Consideration of Partner Feedback

Similar to feedback on the draft streamlined review recommendations, CDA-AMC staff will collate partner feedback on any revisions to existing reimbursement review recommendations. The feedback is presented and discussed by the committee.

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

Depending on feedback and the final streamlined review recommendations, this could result in revisions that were not initially identified at the time of partner feedback. We will only issue a second call for partner feedback for revised reimbursement recommendations when the committee's recommendation has been substantially revised following the initial round of 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 partner 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 review, we 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 CDA-AMC streamlined 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 review recommendations.

5. Transparency and Partner Engagement

To support and encourage patient groups to participate, groups are invited to a teleconference with CDA-AMC 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.

We notify interested parties that a streamlined 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 CDA-AMC E-Alert service. Instructions on providing feedback are included with every notification. In the streamlined review process, our organization provides 10 business days for partners to provide feedback at the following stages:

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

Streamlined review reports are posted on the CDA-AMC website for anyone to access and review, although in exceptional circumstances, embargo periods may be considered.