Canada's Drug and
Health Technology Agency

CADTH THERAPEUTIC REVIEW

Therapeutic Review Framework and Process

SEPTEMBER 2023

VERSION 5.0

Revision History

From time to time, CADTH may amend the therapeutic review process. The public drug programs are consulted as required. CADTH will typically request stakeholder feedback for therapeutic review procedural changes. Amendments to, and clarifications of, the procedure and all related documents may be effected by means of directives (called CADTH Pharmaceutical Reviews Updates) issued by CADTH on an as-needed basis, between revisions of these documents. Generally, changes that are corrections or clarifications become effective immediately.

The following version control table, as well as the version number and date on the cover page, are to be updated when any updates or revisions are made.

Table 1: Revision History

Version	Date	Summary of revisions
1.0	January 2012	Original framework posted
2.0	June 2015	The new version of the Therapeutic Review Framework was updated to include: • changes to the definition and scope • addition of detailed processes • clarification of the type of evidence included in a therapeutic review.
2.5	November 2015	As a result of stakeholder feedback received in June 2015, the following changes to the Therapeutic Review Framework were implemented: • The patient group input process was revised to allow for more patient group response time (based on experiences with pilot process and stakeholder feedback). • CADTH will typically request stakeholder feedback for therapeutic review procedural changes. In consideration of the 2015 stakeholder feedback, additional context has been added to ensure clarity with regard to: • when and how CADTH will handle the inclusion of evidence-based expanded use of drugs (off-label) within therapeutic review reports • stakeholder feedback within the therapeutic review process • when observational data are considered for review within therapeutic review projects.
3.0	June 2018	The document was restructured and simplified, and the subsequent procedural changes were added following posting for feedback in 2017 (CDR Update, issues 124 and 125):

Version	Date	Summary of revisions
		• CDEC will consider whether or not the results of a therapeutic review suggest that any existing recommendations from the CDR process should be revised. • Existing CDEC or CEDAC recommendations that could be revised will be identified and communicated to stakeholders. • Patient groups and manufacturers affected by revisions to existing CDEC or CEDAC recommendations have the opportunity to provide feedback on draft revisions.
3.5	November 2019	The following revision was made (Pharmaceutical Reviews Update, issue 11): • The document was restructured to account for the expansion of the therapeutic review process to support new single drug review processes and expert committees.
4.0	October 2020	The document was revised to reflect the alignment and consolidation of CADTH's Drug Reimbursement Review processes.
5.0	September 2023	The document was revised to reflect a change in expert committee deliberations by FMEC. The process was also simplified to improve efficiency and transparency.

CDEC = CADTH Canadian Drug Expert Committee; CDR = CADTH Common Drug Review; CEDAC = Canadian Expert Drug Advisory Committee; FMEC = Formulary Management Advisory Committee.

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1. Introduction

The purpose of this document is to outline a framework and standardized process for therapeutic reviews that meets the needs of CADTH customers. If possible, CADTH may adapt or supplement an existing therapeutic review to shorten timelines.

This process calls for a systematic review of the efficacy, safety, and cost-effectiveness assessments (if data permit), as well as the integration of stakeholder input, ultimately providing evidence-informed implementation guidance for decision-making in a therapeutic area.

1.1 About Therapeutic Reviews

A therapeutic review is an evidence-based review of publicly available sources regarding a therapeutic category of drugs (e.g., antihypertensive drugs) or a class of drugs (e.g., angiotensin-converting enzyme inhibitors) in order to support drug reimbursement decisions and drug policy decisions, and to encourage the optimization of drug therapy. The optimal use of drug therapy involves ensuring that the right drugs are prescribed and used appropriately to improve or maintain optimal health. This requires balancing maximized benefits with minimized risks to people's health based on best-quality evidence, taking into account the options, costs, available resources, patient preferences, and societal context.

Publicly funded drug programs evaluate and consider the addition of new drugs to their formularies. They do this based on favourable efficacy, safety, and cost-effectiveness analyses as reviewed by CADTH's pharmaceutical review programs. Therapeutic reviews may be useful in any scenario where there is uncertainty regarding the comparative clinical effectiveness and cost-effectiveness of drugs in a particular therapeutic category or drug class.

The primary outputs from a therapeutic review will typically include the Therapeutic Review Summary Reports and Therapeutic Review Recommendations Report. In addition, the therapeutic review process may involve an update and revision to the recommendations that were issued through CADTH's Drug Reimbursement Review processes.

Drug-related recommendations and/or advice from CADTH's Drug Reimbursement Review processes and the therapeutic review program are provided by appointed expert advisory committees to CADTH. The expert committee specifically tasked with conducting therapeutic reviews is the Formulary Management Expert Committee (FMEC).

FMEC is composed of individuals with expertise in drug therapy, drug evaluation, and drug utilization, as well as public and patient members who bring an individual perspective. The current terms of reference and membership are listed on the CADTH website.

1.2 Target Audience and Application for Decision-Making

Therapeutic review reports are produced for federal, provincial, and territorial government drug programs, including provincial cancer agencies, administrators, and health policy-makers working at regional health authorities and hospitals in Canada who make decisions about the optimal use of, access to, or reimbursement of pharmaceuticals. Therapeutic review projects are not meant to replace professional medical advice. Readers are also cautioned that a lack of good-quality evidence does not necessarily mean a lack of effectiveness, particularly in the case of new health technologies for which little evidence is available but may prove to be effective in the future.

2. Transparency and Stakeholder Engagement

CADTH makes every attempt to be as transparent as reasonably possible in the therapeutic review process. The 3 principles of transparency, as defined by CADTH, are to:

- solicit feedback from those affected by CADTH reports (e.g., patient groups, health care providers, and pharmaceutical companies), whenever possible
- facilitate the ability to reproduce or update CADTH reports by reporting:
    - methods used to create reports
    - sources searched and/or provided
- publish CADTH reports in the public domain.

At the start of each project, a protocol that documents the methodology that will be used in the therapeutic review is drafted, posted, and may be registered with PROSPERO. In each Therapeutic Review Summary Report, the policy questions, research questions, selection criteria, included studies, methodology, and search strategy are reported.

Therapeutic reviews are conducted in an open and transparent fashion with input from all interested stakeholders (i.e., public, patients, health care providers, and pharmaceutical companies) solicited in order to facilitate a rigorous review (refer to Table 2 for details). CADTH notifies interested parties of stakeholder feedback opportunities by posting a notice to the Calls for Feedback webpage and issuing an email to subscribers through the CADTH Weekly Summary. Instructions on providing feedback are included with every notification. In the therapeutic review process, stakeholder feedback is solicited at the following stages:

- proposed project scope (including the list of studies and existing CADTH Drug Reimbursement Recommendations for drugs to be included for review, if applicable)
- draft Therapeutic Review Summary Reports
    - Clinical Summary and Economic Summary reports may be posted separately

- draft Therapeutic Review Recommendations Report
- proposed revisions to existing CADTH Drug Reimbursement Recommendations (if applicable).

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

Table 2: Stakeholders in CADTH Therapeutic Reviews

Stakeholder	Consultation activity

All stakeholders[a]	• Provide feedback on:
	  ○ proposed project scope
	  ○ draft Therapeutic Review Summary Reports
	  ○ draft Therapeutic Review Recommendations Report
	  ○ proposed revisions to existing CADTH Drug Reimbursement Recommendations

Pan-Canadian customers	• Identify policy, reimbursement, and practice issues, as well as implementation support activities for Canadian jurisdictions
Patient groups	• Provide patient perspectives on disease and impact on quality of life • Provide first-hand experiences with treatments included in the review • Identify therapeutic issues and controversies from a patient perspective • Comment on existing CADTH Drug Reimbursement Recommendations • Provide stakeholder feedback at designated stages of the process
Expert committee	• Provide input into the development of research questions and guidance for evidence threshold, as well as populations identification and outcomes • Identify information needed to make a recommendation • Identify any practice issues • Make recommendations
Clinical experts	• Provide context for developing research questions: ○ understanding of current clinical approach and therapeutics, natural history of disease, comparators, outcomes, interpretation of evidence, populations, and upcoming therapeutic or diagnostic trends • Identify therapeutic issues and controversies • Identify clinical practice issues that are not captured by clinical evidence review
Manufacturers	• Confirm available evidence • Provide stakeholder feedback at designated stages of the process

[a] Includes the public and all other stakeholders mentioned in the table.

3. Target Timelines

After the project protocol and the list of included studies are finalized, timelines are determined by CADTH in consultation with the jurisdictions. Throughout the therapeutic review project, CADTH

provides multiple opportunities for stakeholder engagement, allowing 10 business days for stakeholder feedback.

4. CADTH Therapeutic Review Process

4.1 Topic Identification and Screening Phase

4.1.1 Topic Identification

Topic identification includes both reactive projects (i.e., those for which a specific request was received from a CADTH customer) and proactive projects (i.e., projects identified by CADTH in anticipation that targeted technologies may have a significant impact on the Canadian publicly funded health system). Factors related to policy issues used to identify potential therapeutic review topics include, but are not limited to the following:

- when there is a request to assess the optimal sequence of drugs in a therapeutic area with increasing treatment options, particularly those that are at or beyond exclusivity
- when a CADTH Drug Reimbursement Recommendation triggers a coverage policy review of existing drugs (i.e., reimbursement policies)
- if a CADTH Drug Reimbursement Recommendation suggests that a therapeutic review should be conducted to evaluate the comparative clinical effectiveness and cost-effectiveness of drugs in a particular therapeutic area.

4.1.2 Topic Screening and Refinement

The aim of the therapeutic review topic submission and selection processes is to ensure that appropriate topics are identified and selected so that outputs are timely and relevant in addressing priority issues for public drug programs. CADTH refines topics through discussions with jurisdictional advisory committees on an annual basis. The initiation of a therapeutic review will require a formal request signed by the Chair of the appropriate jurisdictional committee.

4.1.3 Initial Project Proposal

CADTH develops a project proposal that contains the results of an initial scoping search and the discussions with the jurisdictional advisory committees. The proposal takes into account factors such as relevance, timeliness, and potential impact (Table 3). The public drug programs review the proposals and establish the priority of the therapeutic review projects to be addressed by CADTH.

Table 3: Key Factors Considered in Scoping Potential Therapeutic Review Projects

Factor	Questions for consideration
Relevance	• What are the policy and/or decision problems under consideration? • What are the reimbursement policies for the drug class targeted for assessment? • How are the drugs of interest currently being used in Canadian practice? • Is there evidence of suboptimal health policy or variation in clinical practice? • Are there significant changes anticipated in the therapeutic area (e.g., robust pipeline of new treatments, drugs at or beyond exclusivity)?
Timeliness	• When are the reports and recommendations required by the jurisdictions? • Are resources available to undertake the proposed therapeutic review? • Who are the knowledge partners that may assist with the development and dissemination of the report and recommendations?
Impact	• How could recommendations change clinical practice? • Who is the target population? • What is the Canadian prevalence of the condition(s)? • How could people living in Canada be affected by reimbursement, policy, or behavioural changes that may result from the therapeutic review? • What are the health care costs (e.g., direct, indirect, governmental, or societal costs) associated with the drugs of interest? • How could the recommendations from the therapeutic review impact health care costs (e.g., change in purchasing decisions, change in drug formulary policy)? • Is there similar work that has been recently published or undertaken by another organization (e.g., other HTA organizations)? If so, are there opportunities for partnerships in research activities and/or the dissemination of the information? • Who are the target audiences for the therapeutic review (e.g., patients, policy-makers, clinicians, and/or health care practitioners)? • What is the possibility of changing policy and/or clinical practice?

HTA = health technology assessment.

4.1.4 Detailed Scoping

Following prioritization and approval, CADTH conducts detailed scoping on the therapeutic review topics and creates a proposed project scope document. The scope is determined by the needs of CADTH's jurisdictional customers. In exceptional circumstances, the project scope may include drugs with evidence-based expanded use (i.e., for a clinical indication for which a pharmaceutical manufacturer has not applied to Health Canada and that is not included in an approved Health Canada product monograph, sometimes referred to by stakeholders as off-label use). Key considerations used when determining whether to include a comparator that does not have regulatory approval from Health Canada for that indication are:

- evidence of use of the drug for the condition of interest in Canadian clinical practice (e.g., integration of the drug into clinical practice guidelines, consultations with clinical specialists)
- availability of data evaluating the efficacy and safety of the drug in an indication for which the manufacturer has not applied or received approval from Health Canada
- evidence of health technology assessment organizations and/or payers having made recommendations or decisions to fund the drug, despite lack of regulatory approval
- approval for use of the drug for the indication of interest has been issued by other regulatory authorities (e.g., FDA or the European Medicines Agency).

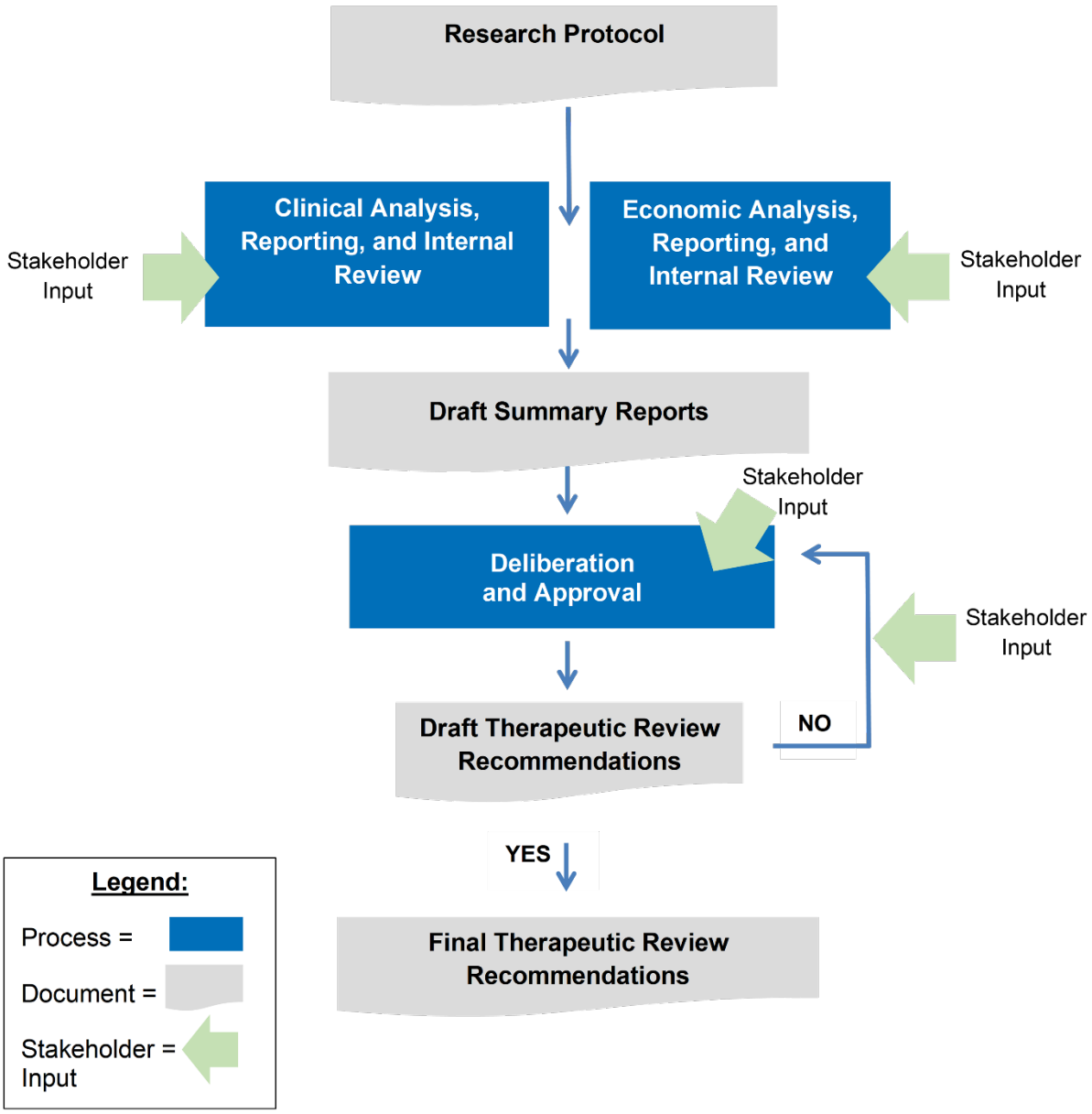
The project scoping document is posted on the CADTH website for stakeholder feedback (typically for a period of 10 business days). Any stakeholders may comment on the proposed project scope. CADTH especially welcomes feedback on the population, comparators, list of included studies, and outcomes described in the scope, as this is used to inform protocol development. All feedback is reviewed by CADTH and is used to finalize the scope of the therapeutic review project. Based on stakeholder feedback, CADTH refines the proposed project scope document and obtains final advice from the public drug programs on whether or not to proceed.

Stakeholders are apprised of the proposed therapeutic review and the target dates for providing input. While notice of the proposed therapeutic review is posted on the CADTH website, affected manufacturers and stakeholders, including patient groups, may be notified directly by CADTH. To support and encourage patient groups to participate, groups may be invited to a teleconference with CADTH staff in the process. During the teleconference, the project is described, expectations are identified, and possibilities for involvement in the project are discussed.

4.2 Research Phase

CADTH's therapeutic review processes reflect nationally and internationally recognized standards and methodologies. New methodologies for assessing drugs are continuously monitored and evaluated, and those that are found to enhance current CADTH processes are incorporated. Therapeutic reviews are based on the best available evidence for addressing the relevant policy questions.

Figure 1: Research and Recommendation Phases Flow Chart



4.2.1 Research Protocol

CADTH drafts the project protocol using the scoping documents and scoping search. The project protocol addresses the scope of the project and the methodologies to be used. Input on the draft project protocol is obtained from expert committee members and clinical experts. Input includes, but is not limited to, assisting in the development of research questions, identifying relevant outcomes, and identifying subgroups of potential interest. Once finalized, the project protocol is posted on the CADTH website for information purposes only, and may be registered in the PROSPERO international database.

The list of studies that have been selected as relevant for the clinical report are posted for stakeholder feedback. The list of included studies may be revised depending on the feedback received. The primary evidence evaluated for possible inclusion in a therapeutic review is from the public domain. Sources of evidence are described as follows:

- Published literature is identified by searching major biomedical bibliographic databases using an internally peer-reviewed search strategy. Biweekly search updates are run for the duration of the review.
- Grey literature (literature that is not commercially published) is identified by searching relevant sections of the CADTH Grey Matters Checklist, and by consulting internet search engines, web-based materials, CADTH web-based resources, and additional web-based materials.
- Clinical experts are engaged and given the opportunity to suggest evidence to be reviewed.
- CADTH will make an effort to contact the manufacturers affected by the review to expand on the existing evidence, unless the drug is already generic or biosimilars have been approved. CADTH informs the recipient in writing about an upcoming therapeutic review process, requesting that the recipient provide information (including the drug's pricing, existing or published research on its clinical effectiveness, adverse effects, and economic evaluations) by a specified deadline. These materials should be submitted to CADTH at requests@cadth.car, and a copy sent to projects@cadth.ca. Authors may handsearch the references of included studies.

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

4.2.2 Patient Group Input

Interested patient groups are asked to complete a patient group template, available on the CADTH website. Groups can contact CADTH's Stakeholder Engagement team (requests@cadth.ca) with questions.

To encourage diversity of voices and experiences, CADTH accepts patient group input from organized patient groups, but not from individual patients or caregivers. Interested individuals should either contact a relevant patient group, contact CADTH to be connected with a relevant patient group, or consider alternative feedback opportunities (refer to Table 2).

Once patient group input has been received, it may be summarized by CADTH and sent back to the patient group(s) for comments on accuracy and completeness. The summary is incorporated into the Therapeutic Review Clinical Summary Report, with perspectives and shared experiences discussed when relevant. The completed patient group input template, as provided to CADTH, is posted on the CADTH website as appropriate.

4.2.3 Review of Clinical Evidence

Once the results of the clinical literature search have been received, the 2 authors independently screen retrieved titles and abstracts and come to a consensus on what literature to order. Both authors independently review the full-text articles selected, as well as any unique information received from stakeholders. Following this, they come to a consensus on which studies meet the inclusion criteria for the project (as documented in the project protocol). If there is disagreement on the findings, a third clinical researcher is engaged in the analysis. Unique studies identified are added to the project's list of included studies for review.

If sufficient studies are found that meet inclusion criteria with similar populations and outcomes, data are extracted from the included studies to conduct a meta-analysis. The meta-analysis is a statistical summary of the selected studies that tests the pooled data for statistical significance. Both authors critically appraise, analyze, and interpret the clinical data to generate a reproducible, transparent, and rigorous review of the available clinical evidence. The clinical draft is internally reviewed.

4.2.4 Review of Economic Evidence

Once the results of the focused economic literature search and unique information from stakeholders (if sent) have been received, CADTH determines whether a new economic model is required to provide information on cost-effectiveness. CADTH then assesses the feasibility of undertaking a full economic analysis. Where a model is developed, it will adhere to the Guidelines for the Economic Evaluation of Health Technologies: Canada and be based on input from the clinical experts and project team. Data inputs for the model are sought from the published literature or based on available data. If a full economic analysis is not feasible, CADTH will explore other options to assess the economic or financial implications.

4.2.5 Drafting the Summary Reports

The review team prepares a draft clinical summary and economic summary reports. The draft Therapeutic Review Summary Reports are posted for feedback and stakeholders are invited to provide

comments. The draft reports are posted on the CADTH website. The time allotted for comments is 10 business days. Stakeholder feedback is subsequently reviewed and the report is revised based on the feedback (as required).

4.3 Recommendations Phase

4.3.1 Draft Therapeutic Review Recommendations

The expert committee deliberates based on presentations of the input from patients and caregivers, clinical and economic evidence, input from clinical experts, and implementation considerations at the jurisdictional level. Clinical experts involved in the therapeutic review are available to answer questions and comment on the evidence presented. There are 2 primary objectives of committee deliberations:

- to develop draft recommendations or advice to address the policy questions that were raised by the public drug programs at the outset of the therapeutic review process
- to propose revisions to existing CADTH Drug Reimbursement Recommendations (if applicable, based on the outcome of the therapeutic review).

The Therapeutic Review Recommendations Report summarizes the recommendations and/or advice, reasons for recommendations, values and preferences of the committee members, patient preferences, clinical and economic evidence that was discussed, and research gaps that were identified by the committee. The draft Therapeutic Review Recommendations Report and a document summarizing the committee's proposed revisions to any existing CADTH Drug Reimbursement Recommendations (if applicable) are posted on the CADTH website for stakeholder feedback for a period of 10 business days. At this time, the draft Therapeutic Review Summary Reports are also posted for informational purposes.

4.3.2 Final Therapeutic Review Recommendations

CADTH and the expert committee members meet to discuss stakeholder feedback. A lead committee member prepares a report that includes responses to stakeholder feedback on the recommendations and/or advice statement, and the proposed final statement. The members' 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 Therapeutic Review Recommendations Report.

4.3.3 Revised Drug Reimbursement Recommendations

One of the outputs from a therapeutic review may be revised Reimbursement Recommendations for drugs that have previously been reviewed through the CADTH Reimbursement Review processes.

Expert Committee Recommendation Process

As part of the deliberative process for a therapeutic review, the expert committee 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.

Stakeholder Feedback on Revised Recommendations

Proposed revisions to existing Reimbursement Review Recommendations will be posted for stakeholder feedback at the time the draft Therapeutic Review Recommendations are posted.

The following information will be included:

- the recommendation that may be revised as a result of the therapeutic 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 therapeutic review framework.

Consideration of Stakeholder Feedback

Similar to feedback on the draft Therapeutic Review Recommendations Report, CADTH staff will collate stakeholder feedback on any revisions to existing Reimbursement Review Recommendations. The stakeholder feedback will be 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, 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.

Finalizing Revised Reimbursement Recommendations

When the committee has determined that a previous recommendation should be revised as a result of a therapeutic 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.

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.

Appendix 1: Definitions

Advice: Advice consists of a statement provided by CADTH's expert committees that provides direction regarding a policy decision or course of action related to the optimal use of a health technology, but does not make a recommendation. Advice is issued based on an assessment of supporting evidence.

Business day: Any day (other than a Saturday, Sunday, statutory holiday, or company holiday) on which the CADTH office is open for business during normal business hours.

CADTH: CADTH is an independent, not-for-profit agency funded by Canada's federal, provincial, and territorial governments. CADTH's role is to deliver reliable, timely, and credible evidence-based information and impartial advice to Canada's health care leaders and decision-makers through a variety of customized products and services.

Customer: A CADTH customer is an entity or organization that requests CADTH's products or engages CADTH's services. (The customer is most often the first point of contact and requests knowledge from CADTH. Customer needs may vary with specific topics, and they may request or choose between different products, services, and suppliers. By expressing their needs, customers drive the knowledge that CADTH produces.)

Expert Committee: A CADTH advisory body composed of individuals with expertise in therapy and evaluation, and public members. For drugs reviewed through the Therapeutic Review or Drug Reimbursement Review process, an expert committee makes formulary Reimbursement Recommendations for use by the participating federal, provincial, and territorial publicly funded drug programs. Expert committees also provide other drug-related recommendations or advice based on CADTH reviews, to inform decisions and strategies including optimal drug use in Canada.

Jurisdictions: These include the federal, provincial, and territorial health ministries from across Canada.

Meta-analysis: A quantitative statistical analysis that is applied to separate but similar experiments of different and usually independent researchers, and that involves pooling the data and using these pooled data to test the effectiveness of the results.

Optimal use: Use of a drug or health technology that balances maximized benefits with minimized risks for people's health based on quality evidence, taking into account the options, costs, available resources, and societal context.

Patient group: For the purpose of CADTH therapeutic reviews, a patient group is defined as an organized group that represents patients with a specific disease or condition, or collection of diseases or conditions. A group will typically have members who are patients, and/or patients' family members, and have a public face, such as a website or Facebook page.

Recommendations: Statements issued by CADTH on behalf of an expert committee that provide specific counsel to support the optimal use of a drug or health technology on the basis of the assessment of the supporting evidence.

Stakeholders: Stakeholders for the therapeutic review process are organizations, institutions, or individuals who have a strong and vested interest in specific optimal use projects and their outcomes. Stakeholders may include (but are not limited to):

- federal, provincial, and territorial ministries of health
- hospitals and health institutions
- health regions
- individual patients, consumers, and caregivers
- patient groups
- health professionals
- industry.

Summary reports: The systematic evaluation of the properties and effects of a health technology that addresses a technology's direct and intended effects, as well as its indirect and unintended consequences. Health technology assessments are primarily aimed at informing decision-making regarding health technologies.