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

Procedures for Therapeutic Reviews

November 2024

Version 6.0

Revision History

From time to time, Canada's Drug Agency (CDA-AMC) may amend the Therapeutic Review process. The public drug programs are consulted as required. We will typically request partner 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 Pharmaceutical Reviews Updates) issued by CDA-AMC 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): • 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.

Version	Date	Summary of 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.
6.0	November 2024	The document was revised to reflect the following changes: • CDA-AMC branding • "stakeholders" changed to "partners" or specific group • wording revised for purposes of clarity and transparency of process • Procedures section moved for readability.

CDA-AMC = Canada's Drug Agency; CDEC = Canadian Drug Expert Committee; CDR = Common Drug Review; CEDAC = Canadian Expert Drug Advisory Committee; FMEC = Formulary Management Advisory Committee.

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1.0 Introduction

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. 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 our 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 Report(s) and Therapeutic Review recommendations report. In addition, the Therapeutic Review process may involve an update to the recommendations that were issued through our drug Reimbursement Review processes by 1 of our expert committees (i.e., the pan-Canadian Oncology Drug Review Expert Review Committee (pERC), Canadian Drug Expert Committee [CDEC], Formulary Management Expert Committee [FMEC], and Canadian Plasma Protein Product Expert Committee [CPEC]).

Drug-related recommendations and/or advice from our drug Reimbursement Review processes are provided by appointed expert committees to our organization. The expert committee specifically tasked with reviewing and issuing reimbursement recommendations for Therapeutic Reviews is 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 CDA-AMC 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.

2.0 Therapeutic Review Process

2.1 Topic Identification and Refinement Phase

2.1.1 Topic Identification

Topic identification includes both reactive projects (i.e., those for which a specific request was received from a CDA-AMC customer) and proactive projects (i.e., projects identified by our organization in anticipation of evolution within a therapeutic space or drug class that 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, including those that are at or beyond exclusivity
- when a CDA-AMC drug reimbursement recommendation triggers a review of coverage of existing drugs used within the treatment paradigm (i.e., reimbursement policies)
- if a CDA-AMC 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.

2.1.2 Topic Scoping 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. We refine topics considering factors outlined in Table 2 and through discussions with jurisdictional advisory committees (i.e., the Pharmaceutical Advisory Committee [PAC], PAC Formulary Working Group [FWG], and Provincial Advisory Group [PAG]) on a regular basis. The initiation of a Therapeutic Review will require a formal request signed by the Chair of the appropriate jurisdictional advisory committee.

Table 2: 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?

Factor	Questions for consideration
	• 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.

Following detailed scoping, refinement, and request from a jurisdictional advisory committee, we create a Proposed Project Scope document. The scope is determined by the needs of our jurisdictional customers and includes assisting in the development of policy questions, research questions, and elements that will inform the literature search once the research protocol is finalized. 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 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 Proposed Project Scope document is posted on the CDA-AMC website for partner input (typically for a period of 10 business days). Any interested partners may comment on the Proposed Project Scope. Our organization especially welcomes input on the population, comparators, and outcomes described in the scope, as this is used to inform the research protocol development. All input is reviewed by the CDA-AMC and is used to finalize the scope and research protocol of the Therapeutic Review project. Based on partner input, our organization refines the project scope. In the case of any substantive changes, we obtain final advice from the public drug programs on how to proceed.

Our partners 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 CDA-AMC website, affected manufacturers and

partners, including patient groups, may be notified directly by our organization. To support and encourage patient groups to participate, groups may be invited to a teleconference with CDA-AMC staff in the process. During the teleconference, the project is described, expectations are identified, and possibilities for involvement in the project are discussed.

2.2 Research Protocol

Once the project scope is finalized, we create the project research protocol. The research protocol addresses the scope of the project and the methodologies to be used. Input on the draft research protocol is obtained from representatives of the jurisdictional advisory committee and clinical experts. Input includes, but is not limited to, further identifying relevant outcomes and identifying subgroups of potential interest. Once finalized, the research protocol is posted on the CDA-AMC website for information purposes only, and may be registered in the PROSPERO international database.

2.3 List of Included Studies

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 partners. Following this, they come to a consensus on which studies meet the inclusion criteria for the project (as documented in the research 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.

The list of studies that have been selected as relevant for the Clinical Summary Report, based on the final research protocol, are posted for partner feedback (typically for a period of 10 business days). 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 CDA-AMC Grey Matters Checklist, and by consulting internet search engines, web-based materials, CDA-AMC web-based resources, and additional web-based materials.
- Clinical experts are engaged and given the opportunity to suggest evidence to be reviewed.
- CDA-AMC 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. We inform the recipient in writing about an upcoming Therapeutic Review.

Interested partners 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 and will not have the opportunity to request redactions.

2.4 Research Phase

Our 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 CDA-AMC processes are incorporated. Therapeutic Reviews are based on the best available evidence for addressing the relevant policy question(s).

2.4.1 Review of Clinical Evidence

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 draft Clinical Summary Report is internally reviewed.

2.4.2 Review of Economic Evidence

Once the results of the focused economic literature search and unique information from partners (if sent) have been received, we determine whether a new economic model is required to provide information on cost-effectiveness. We 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, we will explore other options to assess the economic or financial implications.

2.4.3 Drafting the Summary Reports

The review team prepares a draft Clinical and Economic Summary Report. The draft Therapeutic Review Summary Report(s) are posted for feedback and interested partners are invited to provide feedback. The draft reports are posted for feedback on the CDA-AMC website. The time allotted for feedback is 10 business days. Partner feedback is subsequently reviewed, and the report is revised based on the feedback (as required). The final Summary Report(s) are shared with the expert committee as part of their meeting package to help inform deliberations and decisions.

2.5 Recommendations Phase

2.5.1 Draft Therapeutic Review Recommendations

The expert committee deliberates based on presentations of the input from patients and caregivers, clinical and economic evidence (Summary Report[s]), 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 updates and revisions to existing CDA-AMC 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 updates and revisions to any existing CDA-AMC drug 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 draft Therapeutic Review Summary Report(s) are also posted for informational purposes.

2.5.2 Final Therapeutic Review Recommendations

Our organization and the Chair of FMEC meet to discuss partner feedback. CDA-AMC prepares a report that includes responses to partner feedback on the recommendations and/or advice statement(s), and revisions to the proposed final statement(s) (if applicable). Once discussed and agreed upon with the Chair, the report summarizing partner feedback, responses, and proposed final statements (if applicable) are presented to the expert committee. If deemed necessary by the committee Chair, a further discussion will be held at the next scheduled expert committee meeting. The expert committee then finalizes the recommendations and/or advice statements. A summary statement of the feedback considered will be included within the final Therapeutic Review recommendations report.

2.5.3 Revised Drug Reimbursement Recommendations

One of the outputs from a Therapeutic Review may be updated and revised reimbursement recommendations for drugs that have previously been reviewed through the CDA-AMC 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 1 of our Reimbursement Reviews should be revised.

Partner Feedback on Revised Recommendations

Proposed updates and revisions to existing reimbursement recommendations will be posted for partner feedback at the time the draft Therapeutic Review recommendations are posted.

The following information will be included:

- the drug (generic and brand name where appliable) and CDA-AMC project number of the reimbursement recommendation
- the indication and date of the reimbursement recommendation
- the recommendation that may be revised as a result of the Therapeutic Review
- the updated or revised reimbursement conditions being proposed by FMEC (if applicable).

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 Therapeutic Review procedure. Only public drug programs, through the jurisdictional advisory committees, may request a reconsideration.

Consideration of Partner Feedback

Similar to feedback on the draft Therapeutic Review recommendations report, our staff will collate partner feedback on any revisions to existing reimbursement recommendations. The partner feedback will be presented to the Chair of the expert committee for consideration of revisions based on partner feedback, and if deemed necessary, discussed by the committee at the next scheduled expert committee meeting for any further revisions based on feedback received.

Depending on partner feedback, 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 updated and revised reimbursement recommendations when the committee's recommendation has been substantially revised following the initial round of partner 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 committee will determine if an additional call for partner feedback is warranted as part of the deliberations.

Finalizing Revised Reimbursement Recommendations

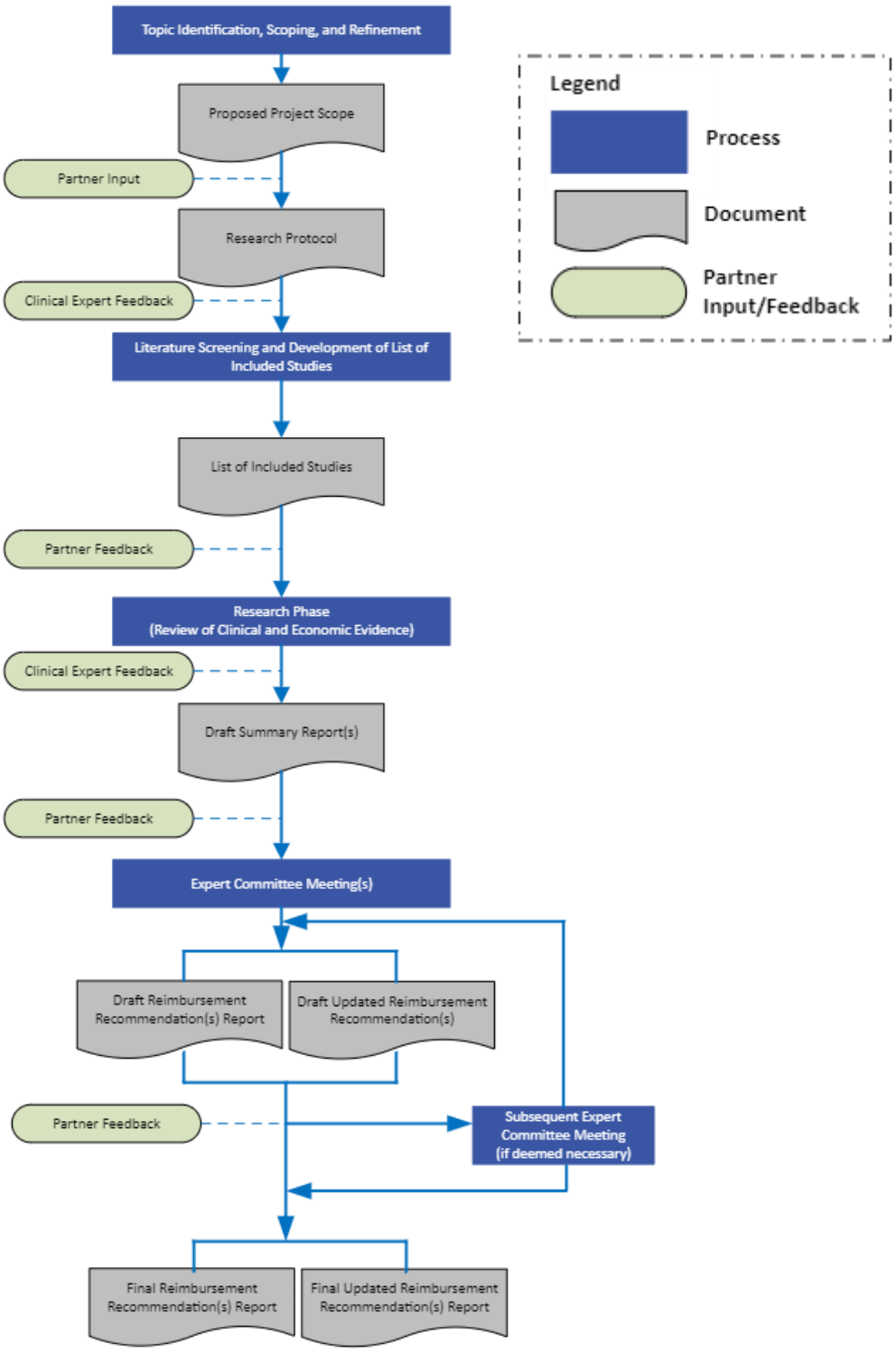
When the committee has determined that a previous recommendation should be updated or revised because of a Therapeutic Review, we will issue an updated recommendation and reasons. The updated and revised recommendation will be an abbreviated document containing the following key information:

- rationale for updates to the reimbursement recommendation(s)
- the recommendation(s), including any conditions (if applicable)
- a statement indicating that the revised recommendation has been issued as a result of a CDA-AMC Therapeutic Review
- a disclaimer indicating that the revised recommendation supersedes the previous Reimbursement Review recommendation(s) for the drug and indication of interest
- a table outlining the drug(s) and the updates or revisions to the reimbursement recommendation(s) by FMEC.

Posting Revised Reimbursement Recommendations

The revised final recommendation will contain no confidential information; therefore, manufacturers will not be asked to complete a redaction request form. Any unique information provided to CDA-AMC by impacted manufacturers, including unpublished information, is subject to being included in CDA-AMC Therapeutic Review Summary Report(s) and/or recommendation report(s) with no opportunity for redactions.

Figure 1: Therapeutic Review Process Flow Chart



3.0 Target Timelines

After the project scope, followed by the list of included studies, is finalized, timelines are determined by our organization in consultation with the jurisdictions. Throughout the Therapeutic Review project, we provide multiple opportunities for partner engagement, allowing 10 business days for input and feedback (as outlined in sections 2 and 4).

4.0 Transparency and Partner Engagement

Our organization makes every attempt to be as transparent as reasonably possible in the Therapeutic Review process. The 3 principles of transparency, as defined by the CDA-AMC, are to:

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

Therapeutic Reviews are conducted in an open and transparent fashion with input from all interested partners (i.e., public, patients, health care providers, and pharmaceutical companies) solicited to facilitate a rigorous review (refer to Table 3 for details). Our organization notifies interested parties of partner feedback opportunities by posting a notice to the Calls for Feedback web page and issuing an email to subscribers through the CDA-AMC Weekly Summary. Instructions on providing feedback are included with every notification. In the Therapeutic Review process, partner input or feedback is solicited at the following stages:

- proposed project scope
- list of included studies selected for the Clinical Review
- draft Therapeutic Review Summary Report(s)
  - Clinical Summary and Economic Summary Reports may be posted separately, if required
- draft Therapeutic Review recommendations report
- proposed updates and revisions to existing CDA-AMC drug reimbursement recommendations (if applicable).

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

4.1 Patient Group Input

Interested patient groups are asked to complete a patient group template, available on the CDA-AMC website. Groups can contact CDA-AMC's Engagement team (requests@cda-amc.ca) with questions.

To encourage diversity of voices and experiences, we accept patient group input from organized patient groups, but not from individual patients or caregivers. Interested individuals should either contact a relevant patient group, contact the CDA-AMC to be connected with a relevant patient group, or consider alternative input and feedback opportunities (refer to Table 3).

Once patient group input has been received, it may be summarized by our organization 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 CDA-AMC, is posted publicly on our website as appropriate. It is the responsibility of the patient group submitting their input and feedback to ensure no confidential patient information is included within.

Table 3: Partners in CDA-AMC Therapeutic Reviews

Partner	Consultation activity

All partners[a]	• Provide input or feedback on:
	  ○ proposed project scope
	  ○ list of included studies selected for the clinical review
	  ○ draft Therapeutic Review Summary Report(s)
	  ○ draft Therapeutic Review recommendations report
	  ○ proposed revisions to existing CDA-AMC drug reimbursement recommendations

Pan-Canadian customers (e.g., jurisdictional advisory committees)	• Inform development of policy and research question(s) • Identify policy, reimbursement, and practice issues, as well as implementation considerations and 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 CDA-AMC drug reimbursement recommendations • Provide feedback at designated stages of the process
Expert committee	• Use the CDA-AMC's Summary Report(s) and input from partners to deliberate and then develop reimbursement recommendations • Provide guidance on other issues related to reimbursement and optimal use of pharmaceutical products (e.g., identify and/or provide guidance on practice or implementation issues)
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 input and feedback at designated stages of the process

CDA-AMC = Canada's Drug Agency.

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

Appendix 1: Definitions

Advice: Advice consists of a statement provided by CDA-AMC'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 CDA-AMC office is open for business during normal business hours.

CDA-AMC: CDA-AMC is an independent, not-for-profit agency funded by Canada's federal, provincial, and territorial governments. CDA-AMC'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 CDA-AMC customer is an entity or organization that requests CDA-AMC's products or engages CDA-AMC's services. (The customer is most often the first point of contact and requests knowledge from CDA-AMC. 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 CDA-AMC produces.)

Expert committee: A CDA-AMC 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 CDA-AMC 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.

Partners: Partners 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. Partners 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.

Patient group: For the purpose of CDA-AMC 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 CDA-AMC 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.

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.