CADTH

CADTH Process for Drugs with Expanded Health System Implications

1. Background

As previously announced in November 2019, CADTH had undertaken an internal review of our drugs and devices processes for the purposes of optimizing how cell and gene therapies are reviewed by CADTH. This work led to the establishment of the following:

- revisions to the drug reimbursement review processes (i.e., CADTH Common Drug Review, CADTH pan-Canadian Oncology Drug Review, and CADTH Interim Plasma Protein Product Review Process) that will accommodate the majority of cell and gene therapies (announced in January 2020)
- revisions to the CADTH Optimal Use process to accommodate a subset of pharmaceuticals that are perceived to pose significant implementation challenges for multiple components of the public health care system and, therefore, require an expanded review process.

CADTH will apply the expanded process to products that are not necessarily well-suited to CADTH's drug reimbursement review processes. For example, novel products that could require complex and broad changes throughout the health care system for adoption to occur in a timely manner. This document provides an overview of CADTH's new process for drugs with broad health system implications.

2. Eligibility for the Process

Interventions eligible for consideration under this new process will include novel products that are likely to pose substantial system-wide implementation challenges (e.g., complex administration process, significant pre- and post-treatment requirements, and the need for coordination across the broader health care system). Eligibility will be determined by CADTH based on the information in the standardized eligibility request form, which must be completed and sent to CADTH (requests@cadth.ca). CADTH will review the form and provide confirmation to the sponsor, typically within 10 business days of receiving the form.

Interventions will be selected for evaluation through the expanded drug review process on a case-by-case basis in consultation with CADTH's advisory committees.

3. Pre-submission Procedure

Pre-submission activities for the expanded review process will be aligned with those currently used in CADTH's drug review processes. This includes the opportunity for a pre-submission meeting with CADTH and the participating drug programs anytime within 12 months of the anticipated submission filing date. In accordance with CADTH's advance notification processes, sponsors of these interventions are required to provide CADTH with a minimum of 30 business days or 120 calendar days advance notice for anticipated submissions for non-oncology and oncology products, respectively.

4. External Engagement

4.1. Patient Engagement

Patient input includes patients' experiences and perspectives of living with a medical condition for which an intervention under review is indicated, their experiences with currently available treatments, and their expectations for the intervention under review. The call for patient input regarding a submission for a technology will be posted 20 business days in advance of the anticipated filing date (as provided in the advance notification form).

As with CADTH's existing drug reimbursement review processes, CADTH will accept patient input from individual patients and caregivers only when there is no patient advocacy group representing patients with a condition for which the technology under review is indicated.

For complete details regarding the processes for patient engagement, please consult CADTH's procedures for non-oncology and oncology products.

4.2. Clinician Engagement

To best support recommendation development, clinical experts will be incorporated into the review team and expert committee for an intervention under review.

4.3. Stakeholder Engagement

Participating drug programs and other stakeholders in the health system will provide input on each intervention being reviewed through the expanded process by identifying issues that may impact CADTH's ability to implement a recommendation.

As part of the review for these interventions, the drug plans or other health system stakeholders will be asked to review and comment on a completed implementation plan template filed by the sponsor. Their feedback on the implementation plan could help provide early identification of potential access issues within the different jurisdictions, potential issues with administration or distribution mechanisms (e.g., need for specialty clinics), and/or challenges with diagnostic testing requirements.

For complete details regarding the processes for drug program engagement, consult CADTH's procedures for non-oncology and oncology products.

4.4. Industry Engagement

Sponsors will continue to be engaged in the same manner as in CADTH's current drug review processes. This includes the following opportunities:

- a pre-submission meeting with CADTH and the participating drug programs anytime within 12 months of the anticipated submission filing date
- an opportunity to review and provide commentary on the draft review reports before the expert review committee meeting
- an optional reconsideration teleconference with CADTH staff.

5. Submission Requirements

The clinical, economic, and administrative submission requirements for the expanded process will be the same as those currently used in CADTH's drug reimbursement review process for cell and gene therapies.

6. Application and Screening Procedure

6.1. Application

Sponsors must have completed the CADTH Collaborative Workspaces Registration before filing a submission or resubmission for the expanded process. The application filing and screening procedures for the expanded process will be identical to those currently used in the CADTH's drug reimbursement review processes.

6.2. Application Fees

All submissions filed by manufacturers for drugs reviewed through the expanded process will be subject to a schedule F application fee (see the *Fee Schedule for CADTH Pharmaceutical Reviews* for complete details).

7. Review Procedure

The expanded review process is closely aligned with CADTH's existing drug reimbursement review processes. CADTH will conduct the clinical and economic portions of the review in accordance with the standard review procedures applied in the drug reimbursement review processes. The review of ethical aspects may include an analysis. Additional components of the expanded review process will include organizational aspects and a review of patients' and caregivers' perspectives and experiences. The targeted timelines for drugs reviewed through the expanded process are provided in Table 1.

7.1. Organizational Aspects

Sponsors will be required to complete a template with key details about their plans for implementing the intervention in the Canadian system. This approach will allow CADTH and the participating jurisdictions to reflect on potential organizational aspects and corresponding mitigation strategies in an efficient manner. In addition, an analysis will be conducted to identify other relevant health system considerations, including health care resources, infrastructure, and capacity that may be required to optimize use of the intervention. The review of organizational aspects takes into consideration the conclusions of CADTH's review of the economic evidence, ethical aspects, and patients' perspectives.

7.2. Patient, Caregiver, and Clinician Perspectives and Experiences

CADTH will provide an analysis of published qualitative literature with the goal to describe and interpret perspectives on, experiences with, and expectations related to the use of the clinical intervention. Input gathered through the patient engagement process (as described in Section 4.1) will be also incorporated.

8. Recommendation Procedure

The output from the process will be a recommendation from the CADTH Health Technology Expert Review Panel (HTERP), in accordance with the deliberative framework used for the medical devices and clinical interventions process. HTERP is the most appropriate committee for these products as there may be aspects of the recommendation that extend beyond the mandate and framework of the expert review committees used in the drug reimbursement review processes.

9. Transparency

In accordance with CADTH's processes, the status and key dates for the expanded review will be posted on the CADTH website. CADTH will post the review report(s) for all interventions reviewed through the expanded process. The sponsor will be responsible for identifying any confidential information included in the reports.

Table 1: Targeted Timelines for the Expanded Process

Phase	Milestones	Business days
Screening phase	• Receipt, screening, and acceptance for review	10
Review phase	• Reviews initiated • Review protocols drafted	24 to 38
	• First draft of CADTH reports: ▪ clinical report ▪ economic report ▪ organizational aspects report ▪ ethics report ▪ patient perspectives and experiences report	50 to 85
	• Formatting and preparation for distribution • Distribution to sponsor and targeted stakeholders	5 to 10
	• Sponsor and targeted stakeholder comment period	15 to 20
Recommendation phase	• Committee preparation • Committee meeting	18
	• Committee meeting to recommendation	10
	• Finalize recommendation	5
	• Redactions • Posting recommendation	2
Totals	**From receipt to posting recommendation document**	**164 to 228**
	From initiation to posting recommendation document	**154 to 218**