Canadian Journal of Health Technologies

CADTH

July 2022 Volume 2 Issue 7

Response to "Outdated Criteria for Drug Plan Reimbursement Obstruct Evidence-Based Care" Editorial in *CMAJ*

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Background

CADTH read with great interest an editorial published by Bayoumi and Laupacis (2021) late last year that highlighted the challenges associated with conducting health technology assessments (HTAs) shortly after the regulatory approval stage and the limited opportunities for updating decisions based on new or longer-term evidence.[1] CADTH, a federally, provincially, and territorially funded not-for-profit agency, provides Canada's public drug programs (with the exception of Quebec) with HTAs to help inform their decisions about the life-cycle management of drugs, devices, and services used to prevent, diagnose, and treat medical conditions. The authors highlighted that the processes for HTAs are focused on the initial evidence package for drugs, thus the practice is lagging in Canada because new evidence does not get regularly incorporated into HTAs. The authors argued that this may impact patients. The authors provided recommendations for HTAs to address these gaps:

1. incorporate automatic times for review or regular reviews of evidence
2. accept non-sponsor submissions
3. audit prescribing for nonadherence to restricted drugs.

We would like to respond to their recommendations by outlining some existing and new evolving initiatives here at CADTH.

Recommendation 1: Incorporate Automatic Times for Review or Regular Reviews of Evidence

The first recommendation asked to establish criteria for ongoing regular reassessments of evidence. Currently, a reassessment is triggered by a resubmission from the sponsor, usually the manufacturer, based on new evidence or by public drug plans if there are questions regarding existing reimbursement criteria. However, a reassessment is not done automatically with the emergence of new evidence. In addition, a pharmaceutical manufacturer can request a broader indication for a drug if new evidence emerges, and public drug plans can ask for a review of reimbursement criteria. On September 1, 2022, CADTH will launch its new Post-Marketing Drug Evaluation (PMDE) program which will examine and validate longer-term effectiveness and safety outcomes for drugs in the system. The program will bring together an external network of Canada's expert applied researchers, methodologists, and data analysts to provide evidence to answer questions posed by federal, provincial, and territorial decision-makers about post-market drug safety and effectiveness. For more detailed information on the PMDE program, refer to the PMDE Program Overview or reach out to the PMDE team at infoPMDE@CADTH.ca.

CADTH is also launching a new process, Streamlined Drug Class Reviews, in which CADTH will use previously published evidence (e.g., meta-analysis) to support expert committee deliberations for drug classes that do not require de novo synthesis. This approach is less complex than the existing CADTH Therapeutic Review. Streamlined Drug Class Reviews will be particularly relevant for drugs at the end of their exclusivity period, when their value can be reassessed with more recent data than what was used for their initial HTA.

CADTH's Therapeutic Reviews are used to examine the appropriate use of drug classes and to incorporate expert committee deliberations based on CADTH-led meta-analyses and cost-utility models. CADTH is currently working on a Therapeutic Review about treatments for transplant-ineligible multiple myeloma. This review, expected to be published in fall 2022, represents several firsts for CADTH: it is our first Therapeutic Review in oncology, our first review to use real-world evidence from a registry, and our first review involving international collaboration. Real-world evidence from the Canadian Myeloma Research Group will inform the meta-analysis and cost-utility model that is being conducted in collaboration with the Erasmus School of Health Policy and Management in the Netherlands.

Recommendation 2: Accept Non-Sponsor Submissions

CADTH's trigger for a Reimbursement Review is a submission from a manufacturer for a drug to be reviewed for a particular indication. However, in specific situations, there are other options for triggering a Reimbursement Review. For example, CADTH accepts clinician-led drug submissions, which are treated as sponsor-submitted reviews. These submissions meet the needs of prescribers who are looking for access to medications that are unavailable to them because there has not been a sponsored submission. CADTH works with the submitting clinician group to identify what is required for a reimbursement submission, which may include approaching the manufacturer for a sharable economic model. Despite the availability of this option, there has been limited uptake to date.

Public drug plans can also request reimbursement reviews in particular situations, namely when manufacturers do not submit a file for review and the drug is at the end of or beyond its loss of exclusivity. This procedure, called the Non-Sponsored Review Process, was formally launched at CADTH in June of this year. In this process, CADTH conducts a literature review of the clinical evidence and a streamlined economic analysis to support deliberations by expert review committees for their recommendation. Many countries are interested in "repurposing" older drugs; for example, Australia's Pharmaceutical Benefits Advisory Committee.

Recommendation 3: Audit Prescribing for Nonadherence to Restricted Drugs

CADTH has invested in a new stream of work dedicated to formulary management, including the study of appropriate use of drugs. The goal of these reviews is to promote the appropriate use of drugs by providing public drug plans with insights to harmonize and modernize their reimbursement criteria for drug classes with the greatest need. This work stream may identify new data that support appropriate use and could trigger a Therapeutic Review as described in the section on recommendation 1. CADTH has partnered with data holders and developed Therapeutic Reviews (i.e., streamlined class reviews) to allow for timely analyses supporting public drug plans.

Two Formulary Management Reviews have been published — the first about the use of conventional medications in rheumatoid arthritis and the second about the use of older-generation biologics in plaque psoriasis. The review on rheumatoid arthritis presented evidence that combination therapies are more effective than monotherapies but there is inconsistency in the implementation criteria across drug plans. The review on plaque psoriasis found that newer-generation biologics were more efficacious and less expensive per patient compared with older-generation biologics. Results from the review show there are significant expenditures on older-generation biologics beyond their loss of exclusivity, and we provide rationale for drug plans to consider promoting the earlier use of newer-generation biologics.

Next Steps

CADTH recently released its 2022–2025 Strategic Plan *Ahead of the Curve: Shaping Future-Ready Health Systems*. As we begin to implement the plan, we will continue to look for innovative ways to adopt a life-cycle approach to our reviews and address the recommendations as highlighted by Bayoumi and Laupacis (2022) and as implemented by other HTA agencies. Integrating new initiatives into our processes will transform the way CADTH reviews drugs and other health technologies and help us shape a future-ready health system.

Reference

1. Bayoumi A, Laupacis A. Outdated criteria for drug plan reimbursement obstruct evidence-based care. *CMAJ*. October 12, 2021;193(40);E1573-E1574; DOI: https://doi.org/10.1503/cmaj.211617