

Reflections on the Enhanced CDA-AMC Reimbursement Review Process

The Canadian HTA and payer landscape is constantly evolving. The past year was no exception: after embarking on a public consultation process, CDA-AMC announced major enhancements to its Procedure for Reimbursement Reviews in February 2025.

Key changes were:

- ✓ Changes to checkpoints with Sponsors throughout the process, including the addition of an Evidence Presentation Meeting held after receiving submission.
- ✓ New deliberative framework for expert committees, which includes a 5th new domain of “social and ethical considerations.”
- ✓ Proportionate review processes including the PACES tailored reviews and a modular approach for Complex Reviews.
- ✓ Enhancements to the review and recommendation report formats.
- ✓ Streamlining of certain application requirements (e.g., templates and letters)
- ✓ Accelerated access pathways including rolling submissions and expansion of time limited recommendations.

These changes applied to oncology applications received on or after April 28, 2025, and non-oncology applications received on or after May 12, 2025. The first draft recommendations for reviews conducted under the enhanced review process started arriving in the last quarter of 2025.

EVERSANA has been partnering with Canadian pharmaceutical clients for over twenty (20) years to develop submissions to CDA-AMC, INESSS, and provincial and private payers and typically prepares approximately one-third of all Sponsor submissions each year. In addition to preparing the key submission components, we support our clients in a full-service manner and, if needed, take responsibility for all touchpoints with the HTA organizations, and jurisdictional and private payers, while providing strategic advice to optimize our clients’ market access success.

As we start the new year, we thought it would be timely to share reflections on the changes and experiences to date with the new CDA-AMC reimbursement review processes. In this article we focus on the implications of the changes to checkpoints with Sponsors, the new “social and ethical considerations” domain of the deliberative framework, and the opportunity for Sponsors to propose recommendation criteria and clinician expert advisors.

Evidence Presentation Meetings: A Catalyst for Gaining Insight

Under the new process, the purpose and timing of checkpoint meetings with CDA-AMC have changed. Pre-submission meetings are now reserved only for procedural questions; in our experience to date, CDA-AMC prefers to handle administrative questions via email (not meetings) to resolve them as efficiently as possible. It is therefore more important than ever for Sponsors to work with a partner who, based on a depth of experience, can advise on an appropriate approach to the submission strategy and the Evidence Meeting. The CDA-AMC Scientific Advice Process is another avenue for questions on methods or approach to the submission.



The new Evidence Presentation Meetings occur 5-20 days post-submission. These meetings serve as an orientation for the CDA-AMC review team to the submission package and allow the team to ask questions regarding the submitted evidence. We have found the meetings to be constructive; the number and types of questions have been robust and can provide important insights into the preliminary considerations of the review team. Expert clinician involvement in Evidence Presentation Meetings is also key to providing insights to the review team regarding unmet need, place in therapy, and clinical meaningfulness of endpoints. CDAAMC does not limit attendance at Evidence Presentation Meetings; therefore, it may also be helpful to have participation by representatives that can address more detailed questions on key components of the submission, such as indirect treatment comparisons (ITCs) or the economic model.

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The timing of the Evidence Meeting can be a challenge. We are recommending to our clients to request these meetings (in the Advance Notification Form) as early as possible to secure timeslots that suit all attendees (particularly the clinician) within the required window post submission (i.e., 5-20 business days, exceptions are not granted). An additional consequence of the timing of the new Evidence Presentation Meeting is the challenge of preparing for the meeting and concurrently developing submissions for INESSS and private payers, as well as provincial copies. This has inadvertently created a tremendous burden on Sponsors to mobilize internal resources, including global teams to review documents.

EVERSANA works diligently with our clients to map out these HTA submission requirements and touchpoints (using our proprietary Canadian HTA Milestone and Date Calculator) thereby proactively managing project workflow and supporting a smooth HTA process.

Leveraging the Opportunity to Propose Clinical Experts and Recommendation Criteria

One of the most significant changes in the review process is the opportunity for the Sponsor to propose recommendation criteria/conditions and rationale within the Clinical Evidence Template. The reimbursement conditions proposed by the Sponsor are included in the Supplemental Materials for the Review Reports without modification by CDA-AMC. Our clients have been very positive about this new development and are taking care to develop realistic and balanced recommendation criteria and conditions. Great efforts are being made by Sponsors to propose reasonable eligibility criteria (e.g., aligned with trial eligibility criteria) and optimal requirements for assessment and monitoring of therapy (e.g., duration of initial authorization, continuation and renewal criteria) in the context of real-world Canadian clinical practice. Feedback from expert Canadian clinicians to validate the proposed reimbursement conditions is key, although it should be recognized that expert opinion is rarely unanimous and may differ significantly both by region and specialty.

Sponsors also appreciate the opportunity to suggest clinical experts and clinical specialties to advise CDA-AMC on its appraisal in the new Advance Notification Form. EVERSANA assists our clients with thoughtful planning to ensure clinicians recommended to CDA-AMC are not those who are expected to support the Sponsor on submission development and/or participate in the Evidence Meeting with CDA-AMC.

While CDA-AMC continues to maintain the anonymity of clinical experts consulted during the review process, we hope that high level information will eventually be reported by the organization on the extent to which sponsor-suggested experts are engaged by review teams.

Overall, both initiatives have been welcome enhancements which we anticipate will improve the relevance and breadth of the clinical input that CDA-AMC receives to guide its appraisals.



Broadening Value Assessment to Include Social and Ethical Perspective

The enhanced CDA-AMC review process describes five types of Complex Reviews. Only Scenario 1 Complex Review (i.e., first treatment for the submitted indication) allows the Sponsor to include a societal perspective base case in the submitted pharmacoeconomic analysis.

In our view, a societal perspective may be beneficial to consider in numerous scenarios beyond Scenario 1, such as when a treatment provides greater clinical benefits than existing alternatives for a condition that poses considerable burden on caregivers or is associated with substantial productivity losses in working age adults. In instances where the societal perspective is thought to be important in their product's value story, we advise our clients to include an alternative societal scenario in the economic model and to emphasize these arguments throughout the other submission documents. It may also be worthwhile to submit a Pharmacoeconomic Deviation request to obtain permission to submit a societal co-base case analysis even if the product falls outside Scenario 1.

The new deliberative framework more clearly outlines the CDA-AMC recommendation pathway and the new Recommendation reports summarize the deliberations of the expert committee and how the deliberative framework factored into the decision (including the number of votes in favour and against the recommendation). The new Social and Ethical Considerations domain of the deliberative framework provides an opportunity for considerations of value that may not be captured in the economic components of the submission.

For example, a new formulation could provide broader societal benefits by allowing patients to receive home-based care versus travel to a clinic, providing better access for patients in remote or non-urban areas, or reducing strain on caregivers. We are advising our clients to weave these important aspects into the Clinical Evidence Template even if not formally incorporated into the economic model to ensure they are considered in the new domain of the deliberative framework. As more recommendations are issued over time using the new deliberative framework, we look forward to gaining insights regarding the practical impact of CDA-AMC's renewed focus on societal and ethical considerations, in particular, the circumstances under which such considerations "move the needle" by overriding limitations or uncertainties regarding clinical effectiveness.

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Strategic Touchpoint Management is Essential for Maximizing the Value of CDA-AMC Process Enhancements

The CDA-AMC process enhancements have provided opportunities to more efficiently review drugs and achieve Target Zero (reducing the time from NOC to issuance of a draft recommendation). Nevertheless, it is crucial for Sponsors to have expert support to navigate the HTA process in Canada and to avoid pitfalls that could result in unnecessary delays or unfavourable outcomes. EVERSANA is recommending use of the updated Eligibility Form as a valuable tool that should be used early in submission development to exchange information with CDA-AMC and to align acceptability of the planned submission strategy.

Early communication with CDA-AMC on critical submission development decision points, such as exclusion of non-relevant or non-feasible comparators, allows the Sponsor to pivot accordingly. For example, a formal indirect treatment comparison (ITC) feasibility assessment may be required for CDA-AMC to agree that a comparator can be excluded due to lack of sufficient comparative evidence; finding this out early in the submission development process allows time for the sponsor to tailor the ITC strategy accordingly. EVERSANA uses our extensive expertise and tools, such as our proprietary HTA Milestone and Date Calculator and Canadian HTA Recommendations Database, to provide strategic insight and advice to guide our client's overall reimbursement strategy and to ensure a smooth, well-planned submission process.



In summary, there were significant enhancements and adjustments made to the CDA-AMC reimbursement review process in 2025. As we start a new year, we would like to thank our clients for entrusting the EVERSANA team to expertly navigate the HTA process on their behalf to ensure timely access for Canadian patients to new drugs. We look forward to embracing more change in the Canadian HTA environment in 2026. We would welcome early discussion with current and new clients on the opportunities and challenges for your products in the Canadian HTA landscape, and how we can help maximize Canadian market potential through our outstanding full-service market access offerings.

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