



CDA-AMC Consultation on Improvements to the Drug Reimbursement Reviews Process

Joint Patient Group Submission

We appreciate the opportunity to comment on CDA-AMC’s proposed improvements to the Reimbursement Review Process, as outlined in the consultation document dated January 29, 2026. The drug reimbursement review pathway plays a critical role in equitable and timely patient access to therapies across Canada. While there are some improvements in this proposal, we are concerned that several aspects of the proposed changes will be a detriment to achieving these aims by reducing transparency, limiting timely and relevant input of patient and clinician expertise in the decision-making process and ultimately will be inconsistent with the patient-centred mandate of CDA-AMC.

New Expedited Review Timelines

We strongly support the proposal to open the input period earlier. This will make clinicians and patient organizations, particularly those that are newer to the HTA experience, more comfortable and confident in the development of their submissions.

We do, however, have serious concerns with a number of the new expedited review proposals that we describe below.

While we appreciate the proposed target of ensuring a final recommendation is published within 180 calendar days of initiating the review, should more time be required to do a thorough, effective job of reviewing input at the draft stage because of feedback at the draft stage, this is surely better than providing an expedited review that leads to a negative recommendation without due consideration of patient and clinician input.

Removal of the Publication of Draft Recommendation for Patient and Clinician Input

Currently, draft recommendations are publicly posted for broad multi-sectoral input. Patient groups and clinicians can provide their input at this early stage, a process which is in keeping with one of the cornerstones of the publicly proclaimed process of patient engagement that CDA-AMC espouses.

Under the proposed streamlined process, CDA aims to issue a final recommendation within 180 days without publicly posting the initial (draft) recommendation or allowing public party input at this stage.

Instead, draft recommendations will be embargoed and only shared with drug plans and sponsors, not with patient groups or clinicians. Public feedback is redirected only to the final recommendation stage, where changes cannot be made to that final recommendation.

The exclusion of patients and frontline clinicians, those who receive and deliver care, at the draft stage, creates a structural inequity that contradicts CDA's stated aim to "strengthen patient and clinician input" and increase transparency through process modernization.

Patients and clinicians provide valuable relevant evidence including real-world context, understanding of unmet needs, nuanced insight into treatment appropriateness and experience with side effects, access barriers, and quality of life impacts.

Excluding them from input at the draft recommendation stage may well lead to producing criteria that are out of step with current clinical practice, misaligned with lived experience and less equitable for diverse patient populations.

To be clear, patients make a significant distinction between providing input and providing feedback. We understand from what we have heard that CDA-AMC intentionally defines these terms differently for different process stages. What we wish to continue to be able to provide is input at the early stage of the process not merely "feedback" after the final decision is made.

Patient and clinician submissions are not "feedback" in the casual sense — they are **expert evidence** that has repeatedly influenced CDA-AMC decisions. It is not feedback patients wish to provide post hoc but input that is taken into consideration in the decision-making process.

Moreover, patient groups and clinicians are more than interested parties. We are experts who have direct experience with diseases and treatments under review and whose communities and patients will face the most direct impacts on outcomes from these processes. As such, we are concerned that removing the opportunity for input on a draft recommendation and excluding these groups from the embargo period, undermines other recent efforts by CDA-AMC to improve patient group and clinician input into committee deliberations, and the principles of transparency and patient engagement throughout this process.

Patient/clinician feedback comments will only be allowed after the final recommendation. This shifts patient and clinician contributions from meaningful impact to post-hoc commentary, significantly diminishing the opportunity to correct clinical misinterpretation or refine eligibility criteria.

When asked during the consultation webinar presenting these proposed amendments the purpose of the present process of permitting input at the draft recommendation stage, we were shocked to hear that it is solely to record patient perspectives and is not taken into consideration in the final decision-making. Surely this is entirely at odds with our understanding of the purpose of this input and in fact makes it irrelevant to the entire process. It is also contrary to CDA-AMC's stated aim of engaging patients meaningfully in its decision-making processes.

We know from experience that there have been instances where draft recommendations have been changed or amended after the publication of the draft recommendations and the final decision. For example:

- In July 2019, pERC issued a draft recommendation not to reimburse pembrolizumab for patients with metastatic urothelial carcinoma who were ineligible for cisplatin-containing chemo. The committee cited “considerable uncertainty” in the clinical benefit due to the non-comparative nature of key trials and lack of OS data. After a reconsideration request, the final recommendation shifted to conditional reimbursement. The committee acknowledged the unmet need. Patient group input on the draft was provided.
- In 2019, draft recommendation expressed concerns regarding maturity of survival data and high incremental cost-effectiveness ratio. Following feedback that emphasized the importance of prevention of recurrence in a high-risk population, pERC issued a final conditional positive recommendation. Patient input on the draft was provided.

We understand that 20% of recommendations receive feedback at the draft stage. This is not an inconsequential number and can, in some cases, lead to a change that positively impacts patients. It likely reflects a higher engagement in negative or conditional recommendations as well as the significant resources required to develop such input that many smaller organizations do not have rather than a lack of interest in this process.

We appreciate the indication that CDA-AMC intends to expand the FMEC process, and we welcome any opportunity that enhances patient and clinician engagement. However, we want to be clear that an expansion of FMEC cannot and must not be considered a substitute for the ability of patients, patient organizations, and clinicians to provide meaningful input at the initial recommendation stage of the reimbursement review. FMEC plays an important and distinct role, but it is not designed to address draft recommendation content, clinical nuance, or real-world impacts in the same way that early-stage input does. Ensuring patients and clinicians can review and respond to draft recommendations remains essential to maintaining a transparent, equitable, and evidence-informed process.

Recommendation 1: Patient and clinician groups that have provided input into the review process be provided the same opportunity to review and respond with input to the draft recommendations as do the sponsors and drug plans.

Recommendation 2: Establish a process to ensure that this input from patient and clinician groups is formally considered and meaningfully incorporated into the draft recommendation and embargo period deliberations, similar to the treatment of input from sponsors and drug plans.

New Reconsideration Process

While we are certainly in favour of a reconsideration process, the proposal to make it a new process will potentially significantly increase the time for the entire review process for those drugs under reconsideration. We consider the present model where reconsideration is part of the review process between draft and final recommendations to be far more efficient, effective and ensures expedited reviews

Recommendation 3: The present reconsideration process remain in place.

A second issue is that the proposed reconsideration process provides an evidence review meeting that explicitly excludes a patient expert and a clinician as part of the process. The present process permits their inclusion.

Recommendation 4: The evidence review meeting to include a patient expert and a clinician.

A third issue is that this new process is that reconsideration now becomes the only mechanism for changing a recommendation. It cannot prevent inaccurate or incomplete criteria from being publicly released.

Our review of the past five years of CDA decisions shows that ~25% of submissions requested reconsideration (43/170) with 7 reconsiderations reversing a negative recommendation to a positive one and many others resulted in expanded or clarified criteria.

These are significant outcomes and they occurred precisely because the opportunity for reconsideration existed before the final recommendation. Removing early feedback risks increasing delays and could lead to preventable misalignments with real-world clinical practice.

Recommendation 5: Retain this feedback opportunity but not as the first and only mechanism to provide patient input and feedback.

A fourth concern is that it will also likely increase the number of reconsideration requests because issues cannot be addressed earlier. This means that it take much longer for urgently needed treatments to reach patients.

New Resubmission Procedures

We appreciate the proposal to create a streamlined resubmission category as an effort to expedite processes where appropriate. Although it is anticipated that most cases will continue to flow through the standard process, we acknowledge that where criteria is met, there is effort to increase efficiency and effectiveness through a more expedited process (≤ 150 calendar days for streamlined resubmissions compared to ≤ 180 calendar days for standard resubmissions).

Enhancement of Testing Procedure Assessments

No opportunity for patient and/or patient group input has been identified within the consultation in respect of the proposed testing procedure assessments. While the new patient group input template poses the question, 'What are patients' and caregivers' experiences with the testing associated with the drug under review?', the absence of discourse of the value, and the impact, of patient group input within the consultation document is disheartening. How will the values, priorities, preferences and perspectives of persons with lived experiences (PWLE) with cancer diagnostics and treatments be considered during testing procedure assessments? The consultation document seems to prioritize costs, capacities, and implications of testing, with little reflection being given to the patients impacted by its recommendations.

We respectfully suggest that consideration be given to the ability to initiate a complementary testing procedure review independently from that of the drug review process. Tests that are applicable to

inform a part of a clinical pathway, (such as diagnosis, monitoring outcomes, disease prognosis, treatment discontinuation), are often broadly relevant across multiple drug indications and their inclusion through this structured evaluation pathway may be beneficial (e.g., ctDNA for minimal residual disease).

In respect of implementation considerations, and in recognition that jurisdictions differ in readiness (Husereau & Servidio-Italiano, 2026), as is rightly identified in the consultation document, it is important to provide technical assistance, capacity-building initiatives, education and training, and transitional funding to ensure equitable and effective implementation across regions. Further, we recommend that the importance of rapid turnaround times is explicitly communicated, including the promotion of reflex biomarker testing, which is an effective way to reduce turnaround times and support faster treatment decisions.

In acknowledgement of the rapidly evolving biomarker landscape, testing procedure assessments must remain adaptive, as flexibility will help to ensure responsiveness to scientific advances. Broadly, we respectfully maintain that evaluating individual biomarkers on a case-by-case basis is flawed. We strongly urge CDA-AMC to consider 'future-proofing' their biomarker testing recommendations to include the broad adoption of comprehensive genomic profiling (CGP) for metastatic cancer patients in Canada as a national standard.

Recommendation 6: Meaningfully integrate patient feedback into the testing procedure assessments and reframe strategic planning to prepare for CGP becoming a standard of care for metastatic cancer patients in Canada.

Summary of Recommendations from the Patient Community

Recommendation 1

Patient and clinician groups that have provided input into the review process be provided the same opportunity to review and respond with input to the draft recommendations as do the sponsors and drug plans.

Recommendation 2

Establish a process to ensure that this input from patient and clinician groups is formally considered and meaningfully incorporated into the draft recommendation and embargo period deliberations, similar to the treatment of input from sponsors and drug plans.

Recommendation 3

The present reconsideration process remain in place.

Recommendation 4

The evidence review meeting to include a patient expert and a clinician.

Recommendations 5

Retain this feedback opportunity but not as the first and only mechanism to provide patient input and feedback.

Recommendation 6

Meaningfully integrate patient feedback into the testing procedure assessments and reframe strategic planning to prepare for CGP becoming a standard of care for metastatic cancer patients in Canada.

Conclusion

We recognize and support CDA-AMC's intention to modernize and streamline the Reimbursement Review Process. As proposed presently, however, patient groups do not support the changes for the reasons listed above including: limiting the potential meaningful input of patient and clinician expertise into the decision process, misalignment with real clinical practice, increasing reliance on reconsideration, which will further delay access, reducing transparency and significantly impairing the credibility of the process.

We strongly urge CDA to ensure that modernization does not come at the cost of equity, patient-centredness, or evidence quality.

We would welcome ongoing dialogue and remain committed to working collaboratively toward a process that is both efficient and meaningfully inclusive.

Sincerely,

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