



## Response to the Procedural Review Panel's Memorandum Report on the Procedural Review of Inclisiran (Leqvio)

CADTH introduced a revised procedural review process in April 2021 that provides our stakeholders with an opportunity to engage with us if they perceive that CADTH failed to act in accordance with the *Procedures for CADTH Reimbursement Reviews* (the *Procedures*) in conducting a drug reimbursement review and issuing a final recommendation. This mechanism was put in place to help us maintain a fair and accountable process.

We received and accepted our first procedural review request under the revised process in March 2022. A Procedural Review Panel (the "panel") was convened to adjudicate the procedural review for Leqvio to determine whether the *Procedures* were followed in the development of the final recommendation issued by the CADTH Canadian Drug Expert Committee (CDEC). It is important to note that the panel's mandate and responsibility relates only to determining whether the process was followed, and not to the content(s) or scientific issue(s) that may or may not be included in the final recommendation.

The panel concluded that the reimbursement review of Leqvio did not deviate from the established *Procedures*. You can read about the panel's findings and decision in the [memorandum report](#) provided to CADTH.

A key theme that emerged in this process is the value of additional clarity in the final recommendation report, particularly around how and what information the CADTH expert committees consider in their deliberations and decisions. In its report, the panel recommended that CADTH review what it communicates through its decision documents for clarity and comprehensiveness, to enhance transparency about expert committee deliberations and outcomes, and to provide insight into how stakeholder input is considered throughout the review process.

CADTH acknowledges and agrees with the recommendations made by the panel. Increasing transparency is an important component of our strategic plan. As an organization, we are committed to reviewing our processes and working with our expert committees to increase the transparency in our reviews, to ensure our stakeholders understand how decisions are made.

To do this, we are actively reviewing how we write our reports, to identify areas where we can provide additional clarity. This work includes examining the current process, where a document is prepared that summarizes each of the issues raised in a review and includes input from each of the key participants in the process, which may include:

- CADTH review team (focus is primarily on relevant evidence identified within the review reports)
- sponsor (if the reconsideration request is filed by the drug programs)



- drug programs (if the request is filed by the industry sponsor)
- clinical experts consulted by CADTH
- feedback from clinician groups
- feedback from patient groups (a summary of relevant issues is identified and summarized by the patient member[s] of the expert committee).

This information is collated, and the issues and input received from the key participants are provided to the expert committee for review and discussion. At present, these responses and how this information was considered are not fully reported in the final recommendation document.

It is clear that providing greater transparency on expert committee discussions is important for external stakeholders. We are reviewing all materials to understand how they can be improved to provide greater transparency in our final reports, and will be moving forward with changes to submissions received after September 1, 2022, given the importance of building this work into our processes.

The procedural review mechanism is an important part of maintaining fair and accountable reimbursement reviews. We have a responsibility to ensure that rigour is applied to this important process and will use the insights gained through this procedural review to continue identifying opportunities to improve our reimbursement review processes going forward.

CADTH extends its thanks to the panel members for their time and effort in adjudicating this procedural review, as we navigated this new process for the first time. The panel's commitment to the critical, independent appraisal of the issues raised was integral to ensuring a robust and comprehensive procedural review.

Questions about this procedural review should be directed to Jocelyn Chisamore, Director, Governance, Policy & Performance Measurement, via [requests@cadth.ca](mailto:requests@cadth.ca).