Canada's Drug and Health Technology Agency | L'Agence des médicaments et des technologies de la santé au Canada

Response to the Procedural Review Panel's Memorandum Report on the Procedural Review of Pegvaliase (Palynziq)

Background

The Procedures for CADTH Reimbursement Reviews (the Procedures) define the steps CADTH will take in the development of a final recommendation issued by a CADTH expert committee for a pharmaceutical reimbursement review (reimbursement review).

A procedural review provides our stakeholders with an opportunity to engage with us if they perceive CADTH failed to act in accordance with the Procedures in conducting a reimbursement review and issuing a final recommendation. This mechanism is an important part of maintaining fair and accountable reimbursement reviews.

Request for Procedural Review

CADTH received and accepted a procedural review request for pegvaliase in December 2022. A Procedural Review Panel (the Panel) was convened to adjudicate the procedural review regarding the final recommendation issued by the CADTH Canadian Drug Expert Committee (CDEC).

The Panel's mandate relates only to determining whether CADTH deviated from the Procedures in conducting a reimbursement review and issuing a final recommendation made by an expert committee.

Panel Decision

The Panel concluded that the reimbursement review of pegvaliase did not deviate from the established Procedures. The Panel provided its findings and decision in a memorandum report to CADTH.

CADTH Response

CADTH extends its thanks to the members of the Panel for adjudicating this procedural review. The Panel's contributions are an integral component of this important process, and we greatly appreciate their time and effort in appraising the issues raised.

CADTH recognizes that its recommendation documents are highly trusted by decision-makers and stakeholders. Feedback from the Panel is used to inform CADTH's continuous improvement approach to the reimbursement review process. Since September 1, 2022, CADTH has made changes to its reports to enhance the transparency in its work including providing a greater level of detail with respect to committee deliberations during reconsideration meetings, a high-level summary of the issues identified by the sponsor or drug plan for reconsideration, and a new section that lists the sources of information used by the committee at reconsideration meetings.

In the coming weeks, CADTH will be working on updates to the Procedures document to enhance clarity in the specific areas that the Panel has raised. We will also be updating Appendix 2 in the Procedures to clearly identify those issues that have previously been adjudicated by the Panel. We anticipate that this information will be helpful in guiding the content of any future procedural review applications.

Questions

Questions about this procedural review should be directed to Jocelyn Chisamore, Director, Strategy and Governance, through requests@cadth.ca.