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 Cariprazine (Vraylar)

Background

A procedural review 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. The procedural review mechanism is an important part of maintaining fair and accountable reimbursement reviews.

Request for Procedural Review

We received a procedural review request for cariprazine, which was accepted by CADTH in October 2022. A Procedural Review Panel (the "panel") was convened to adjudicate the procedural review regarding the final recommendation that was 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 review and issuing a final recommendation made by an expert committee for a pharmaceutical review.

Panel Decision

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

CADTH Response

CADTH accepts the assessment of the panel and is committed to enhancing transparency in our reviews to ensure our stakeholders understand how decisions are made. In response to previous recommendations from the panel in June 2022, CADTH undertook a comprehensive review of how we write our reports, to identify areas where additional clarity could be provided. In doing so, we identified improvements around how to report committee considerations of the issues and input received from stakeholders in the final recommendation document.

As a result of this work, we implemented changes to improve transparency in our final reports. These changes affect all submissions received after September 1, 2022, and include:

- incorporating a greater level of detail with respect to committee deliberations during reconsideration meetings, to include what information was considered by the committee and key discussion factors that contributed to the decision
- adding a new section to list the sources of information used by the committee at reconsideration meetings, in addition to the sources of information used at the initial meeting
- adding a new section to the recommendation report to include a high-level summary of the issues identified by the sponsor or drug plan for reconsideration.

The recommendation documents are highly trusted by decision-makers and stakeholders and are subject to critical review due to potential significant implications. Changes made to these documents are likely to have a large and widespread impact; therefore, CADTH must take care to ensure any alterations are thoughtful and meaningful. The submission that is the subject of the procedural review in question was completed before the full implementation of the transparency-oriented changes introduced earlier this year; however, in the spirit of transparency and to address the recommendations brought forward by the panel, we will update the final recommendation report for cariprazine, as outlined in the following.

Next Steps

In response to the panel's request, CADTH will facilitate a review of the cariprazine final reimbursement recommendation document by the CDEC Chair and staff. The review will focus on identifying updates to the content to:

- ensure stakeholder feedback is transparently acknowledged within the document
- add a summary of the issues identified by the sponsor
- improve clarity around how the additional information provided to the committee was considered during the reconsideration
- provide additional transparency around key discussion points and decision factors in the reconsideration.

CADTH expects that the final recommendation document will be updated by February 2, 2023.

The *Stakeholder Feedback on Draft Recommendations* document will also be updated by February 2, 2023, to ensure that it reflects all the feedback that was shared with the CDEC presenters.

Acknowledgements

CADTH extends its thanks to the panel members for adjudicating this procedural review. Their time and effort in appraising the issues raised is an integral component of this important process.

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