Revising CADTH Common Drug Review Recommendations in the CADTH Therapeutic Review Process

CADTH is seeking stakeholder feedback on a revised therapeutic review process that would incorporate revisions to existing Canadian Drug Expert Committee (CDEC) recommendations issued through the CADTH Common Drug Review (CDR) process.

BACKGROUND
Under the current Procedure for the CADTH Common Drug Review (August 2014) and the Therapeutic Review Framework and Process (August 2016), existing recommendations that have been issued through the CDR process can only be updated following the initiation of the request for advice process. To enhance the efficiency of CADTH’s drug portfolio and to reduce the burden on manufacturers and patient groups, CADTH is proposing an update to the Procedure for the CADTH Common Drug Review and the Therapeutic Review Framework and Process to permit CDEC to revise existing recommendations from the CDR process as part of the therapeutic review process. This revision will eliminate the need to initiate the request for advice process and result in a more efficient process for all stakeholders. In developing the proposed process, CADTH has consulted with the CDR-participating drug plans.

PROPOSED PROCEDURE FOR THE REVISION OF EXISTING CDEC RECOMMENDATIONS

1. Existing CDEC recommendations\(^1\) that could be revised as a result of the therapeutic review will be identified and communicated to stakeholders during the scoping phase of the therapeutic review process.

2. As part of the deliberative process for therapeutic reviews, CDEC will consider whether or not the results of a therapeutic review suggest that any existing recommendations from the CDR process should be revised. When considering revisions to existing recommendations, CDEC will continue to use the recommendation framework described in the Recommendation Framework for CADTH Common Drug Review and pan-Canadian Oncology Drug Review Programs: Guidance for CADTH’s Drug Expert Committees.

3. CADTH will notify affected manufacturers at the time the initial therapeutic review recommendations are posted and identify the following information:
   - the CDEC recommendation that is being revised as a result of the therapeutic review
   - the revised reimbursement criteria and/or conditions
   - the rationale for the revision.

4. There will be no embargo period for the revised CDEC recommendations.

5. Manufacturers whose products are affected would be given the opportunity to provide stakeholder feedback in accordance with the therapeutic review framework but will not be given the opportunity to file a request for reconsideration.

\(^1\) This also includes existing recommendations from the Canadian Expert Drug Advisory Committee (CEDAC) which was replaced by CDEC in September 2011.
6. In lieu of a formal request for reconsideration, CDEC will consider the manufacturer’s input regarding the revised CDEC recommendation(s) prior to finalizing the therapeutic review recommendations.

7. At the meeting held to finalize the therapeutic review recommendations, CDEC will also finalize any revisions to the existing recommendations from the CDR process.

8. Manufacturers will be notified by CADTH within ten business days that a revised recommendation will be issued for one or more of their products.

9. The revised recommendation will be an abbreviated document noting the following key information:
   - the drug and indication of interest
   - the recommendation, including any clinical criteria and conditions (if applicable)
   - a statement indicating that the revised recommendation has been issued as a result of a CADTH therapeutic review.
   - a disclaimer indicated that the revised recommendation supersedes the previous CDEC recommendation for the drug and indication of interest.

10. The revised CDEC Final Recommendation will contain no confidential information; therefore, manufacturers will not be asked to complete a redaction request form.

11. Posting of the revised CDEC Final Recommendation on the CADTH website will typically coincide with posting of the final therapeutic review recommendations.

12. A disclaimer will be added to the previous CDEC Final Recommendation stating that it has been superseded by the revised CDEC Final Recommendation.

HOW TO SUBMIT YOUR FEEDBACK

Please email your feedback by 5:00 p.m. EDT on September 15, 2017 to feedback@cadth.ca.

- To provide feedback, you must identify yourself — feedback provided by individuals who do not identify themselves and the organization they represent will not be considered.
- Only one response per organization will be considered. If more than one response is received, only the first response received will be considered.
- Feedback must be provided in 11-point font using this template and saved in one of the following formats:
  - Microsoft Word document (.doc or .docx)
  - Unlocked PDF document that permits copying and pasting of text.
- Feedback should be presented clearly and succinctly.

If you have any questions about the feedback process, please email us at feedback@cadth.ca. We thank you in advance for your interest.

NEXT STEPS:

The final decision regarding the proposed revision to the CDR procedure and therapeutic review framework will be made after careful assessment of stakeholder feedback generated from this consultation and communicated in a future CDR Update.