CADTH

CADTH Consultation: Proposal for Non-Sponsored Reimbursement Review

1. About Non-Sponsored Reimbursement Reviews

The current CADTH reimbursement review process requires an eligible sponsor (e.g., pharmaceutical manufacturer or provincially recognized tumour group) to file an application to initiate the review of a drug. The dependence on an external sponsor to file an application can create gaps in the review and reimbursement landscape when eligible sponsors are unwilling to file an application for review by CADTH. In these situations, the public drug programs typically receive requests for reimbursement from the patient and clinical communities; however, they are unable to leverage a reimbursement recommendation from a pan-Canadian process to support their decision-making. This can result in duplication of effort for the public drug programs, inconsistency in access for patients, and the potential failure to realize the clinical and economic benefits of repurposing drugs for use in patient populations where there are unmet medical needs.

To address these gaps in the existing system, CADTH has drafted a new fit-for-purpose review process to provide the drug programs with a reimbursement recommendation for selected drugs that are not filed by eligible sponsors. This new **non-sponsored reimbursement review** process will largely adhere to the existing CADTH reimbursement review procedures and timelines, with targeted modifications to accommodate the lack of formal participation from an eligible sponsor.

This document provides a summary of the non-sponsored reimbursement review process for the purpose of stakeholder consultation.

2. Eligibility for the Process

Public drug programs may request a reimbursement review in situations where an eligible sponsor does not submit through CADTH's sponsored reimbursement review process. To warrant a non-sponsored review and recommendation from CADTH, sufficient interest across individual jurisdictions would be required from CADTH's advisory committees (the Formulary Working Group [FWG] and the Provincial Advisory Group [PAG]). CADTH may prioritize non-sponsored reimbursement reviews based on advisory committee interest and the availability of evidence.

Before initiating a non-sponsored reimbursement review, CADTH will confirm with the Drug Identification Number (DIN) holder of the branded product that they are declining to file a submission with CADTH (in accordance with section 2.6 of the *Procedures for CADTH Reimbursement Reviews*). However, if the drug is already generic, DIN holders will not be contacted.

CADTH will consider reviewing a drug through the non-sponsored reimbursement review process in the following situations:

- when sponsors of a branded drug have declined to file a submission with CADTH on the basis that competition from generic and/or biosimilar products is imminent
- when genericized or biosimilar drugs are available, and the reference drug did not have a previous CADTH reimbursement review for the indication of interest.

For clinical indications for which a pharmaceutical manufacturer has not applied for a Health Canada Notice of Compliance (i.e., off-label use), drugs will be eligible when:

- there is evidence of use of the drug for the condition of interest in Canadian clinical practice (e.g., integration of the drug into clinical practice guidelines, consultations with clinical specialists)
- clinical data are available for the indication of interest to permit CADTH and the expert committees to evaluate the effectiveness of the drug
- approval for use of the drug for the indication of interest has been issued by other regulatory authorities (e.g., US FDA or the European Medicines Agency)
- there are existing international health technology assessment recommendations in favour of reimbursement.

3. Stakeholder Engagement

Once a non-sponsored reimbursement review is initiated, CADTH will publicly post notice for stakeholder feedback. The posting will contain a description of the drug under review, the indication(s), and the research protocol to be conducted by CADTH.

3.1 Patient Engagement

Open calls for patient input will be solicited, utilized, and posted in accordance with section 6.2 of the sponsored reimbursement review procedures. Patient groups will have 35 business days from the posting date to provide feedback on the submission under review. Patient groups and other stakeholders will have 10 business days to review the draft recommendation and provide feedback in accordance with section 9.4.2 of the *Procedures for CADTH Reimbursement Reviews*.

3.2 Clinician Engagement

Groups or associations of health care professionals will have 35 business days (from the posting date) for preparing and submitting their input. Clinician group input will be solicited, utilized, and posted in accordance with section 6.3 of the sponsored reimbursement review procedures. Groups or associations of health care professionals and other stakeholders will have 10 business days to review the draft recommendation and provide feedback in accordance with section 9.4.2 of the *Procedures for CADTH Reimbursement Reviews*.

3.3 Drug Program Engagement

When a non-sponsored reimbursement review is initiated, a lead jurisdiction will be tasked with detailing potential implementation issues to be discussed and finalized with other members of the advisory committee (FWG and PAG). The summary of implementation issues will be presented by the lead jurisdiction (or designate) to the expert review committee. The draft recommendation will be discussed with FWG and PAG to collate and finalize their feedback.

3.4 Industry Engagement

As the review is initiated by public drug programs, no documentation will be required from a sponsor, although additional information provided from sponsors may be considered. For the non-sponsored reimbursement

review process, industry refers to all current and future DIN holders (including manufacturers of generic or biosimilar drugs). Industry will have 35 business days from the posting date to provide feedback on the non-sponsored submission under review. Industry will also have 10 business days to review the draft recommendation and provide feedback in accordance with section 9.4.2 of the *Procedures for CADTH Reimbursement Reviews*. As the reimbursement reviews are not sponsored, input from industry manufacturers is not required.

3.5 Clinician Expert

CADTH review teams will include at least 1 clinical specialist with expertise in the diagnosis and management of the condition for which the drug is indicated. The expert(s) will be involved in all phases of the review process in accordance with section 6.3.2 of the *Procedures for CADTH Reimbursement Reviews*.

4. Review Procedure

The review procedure will primarily follow the sponsored reimbursement review procedure (in accordance with section 8), with some minor amendments as outlined in in the following.

4.1 Clinical Review

The clinical review process will be completed in accordance with CADTH's standard review process with the following revisions to accommodate the absence of a sponsor:

- DIN holders will not have the opportunity to review and comment on the draft CADTH clinical review report before the expert review committee.
- DIN holders will not have the opportunity to review and request the redaction of any information in the clinical report before it is posted on the CADTH website.

4.2 Economic Review

In the absence of an application filed by a sponsor, CADTH will not have access to an economic model for the drug under review. As such, the following revised approaches will be considered:

- a comparison of the costs of the drug under review and appropriate comparators
- a pan-Canadian budget impact analysis developed by CADTH.

In the absence of a sponsor, DIN holders will not have the opportunity to review and comment on the draft CADTH economic report before the expert review committee. If additional information from outside the public domain is provided by a sponsor, CADTH will not provide an opportunity to review and request redactions before posting on the CADTH website.

5. Recommendation Procedure

The output from the non-sponsored reimbursement review process will be a recommendation from one of CADTH's drug expert committees (i.e., the Canadian Drug Expert Committee [CDEC] or the pan-Canadian Oncology Drug Review Expert Review Committee [pERC]). CADTH recommendations from the non-

sponsored reimbursement review process may be issued based on the active substance to accommodate scenarios where there are or will be multiple DIN holders.

5.1 Deliberative Processes and Recommendation Framework

The expert committees will apply the deliberative processes and recommendation framework described in the *Procedures for CADTH Reimbursement Reviews* (in accordance with section 9).

5.2 Draft Recommendations

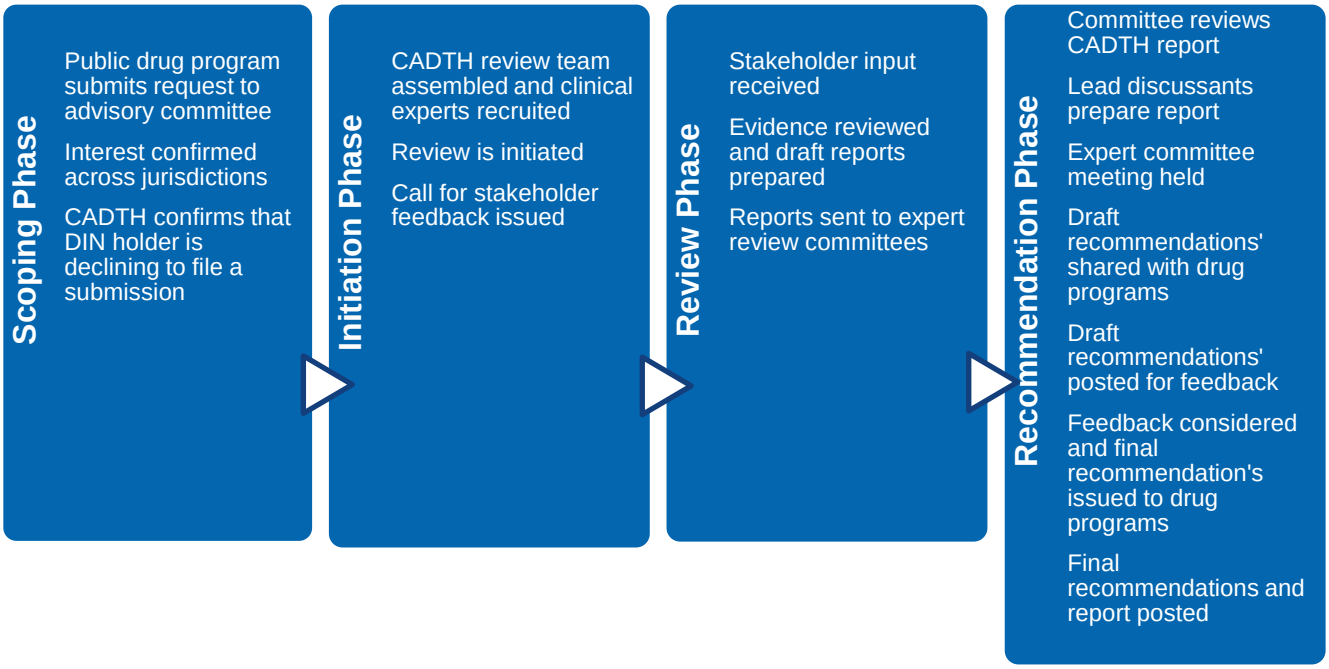
In accordance with the process described in the *Procedures for CADTH Reimbursement Reviews*, draft recommendations will be posted for stakeholder feedback for 10 business days. The drug programs, patient groups, clinician group(s), and DIN holders for the drug under review may provide feedback on the draft recommendation using the applicable CADTH template.

5.3 Reconsideration

The participating drug programs may file a request for reconsideration of the draft recommendation. In the absence of a sponsor, DIN holders will not have the opportunity to request reconsideration of the draft recommendation; however, their feedback on the draft recommendation may be considered if a reconsideration has been requested by the drug programs.

Figure 1: Overview of CADTH's Non-Sponsored Reimbursement Review Process

The figure depicts the overall process of a non-sponsored reimbursement review from start to completion. Each sequential phase of the review and recommendation procedure is described from left to right.



DIN = Drug Identification Number.

CADTH

6. Transparency

In accordance with CADTH's existing reimbursement processes, the following information will be posted on the CADTH website for non-sponsored reimbursement reviews:

- calls for patient and clinician group input
- key dates of the non-sponsored reimbursement reviews
- CADTH reports and recommendations
- stakeholder feedback on the draft recommendation.

As previously stated, DIN holders will not have the opportunity to review and request redactions of CADTH reports or recommendations before they are posted on the CADTH website.

7. Submitting Feedback

To provide comments on the proposal, please use the Survey Monkey feedback template. Feedback must be received by **5:00 p.m. EDT on April 14, 2022**. If you have any questions about the feedback process, please email CADTH. We thank you in advance for your interest in CADTH's non-sponsored drug reimbursement review process.

8. Next Steps

Following the consultation period, CADTH will carefully assess all stakeholder feedback before announcing any decisions regarding changes to proposed process. We thank you in advance for your interest. If you have any questions about the feedback process, please email CADTH.