

CADTH PAN-CANADIAN ONCOLOGY DRUG REVIEW EXPERT REVIEW COMMITTEE TERMS OF REFERENCE

1.0 MANDATE

The mandate of the CADTH pan-Canadian Oncology Drug Review (pCODR) Expert Review Committee (pERC) is to provide cancer drug funding recommendations, including conditions and/or criteria for coverage, where appropriate, to the participating provincial and territorial ministries of health, provincial cancer agencies, and federal drug programs, based on Submissions or Resubmissions. The pERC recommendations consider the evidence-based reviews of the clinical effectiveness and cost-effectiveness of cancer drug products conducted by CADTH and the input provided by patient groups, clinicians, and participating jurisdictions.

Upon request, pERC also provides advice to jurisdictions on cancer drug products, which may or may not result in a change to a previously issued pERC recommendation. A Request for Advice may be made by the CADTH pharmaceutical advisory committees and working groups.

2.0 ROLES AND RESPONSIBILITIES

The responsibilities of pERC include:

- to establish, maintain, and apply standards and methodologies to evaluate the therapeutic value and cost-effectiveness of cancer drug products for active disease management (excluding supportive treatments that may be used in the care of patients with cancer)
- to consider submissions and resubmissions made by sponsors, provincially recognized clinician-based tumour groups and/or the Provincial Advisory Group (PAG), and drug class reviews, and all related clinical reviews and economic reviews prepared and provided in accordance with CADTH standards
- to evaluate submissions, resubmissions, therapeutic or class reviews, and requests for advice regarding therapeutic advantages and disadvantages, cost-effectiveness, patient perspectives and the PAG perspective on the impact of the cancer drug product under review, compared to accepted or existing therapies
- to review the provisional algorithm — an algorithm developed for each new cancer drug or indication to indicate how the new therapy could be used compared to existing funded therapies, and the impact on the sequence of use for other existing funded therapies, and provide comments to PAG to better support jurisdictional decision-making for drug reimbursement
- to recommend and provide reasoning — after consideration of a submission, resubmission, or drug class review — of new cancer drug products for active disease management to be considered for funding and advise the provincial and territorial ministries of health, provincial cancer agencies, and federal drug programs of the conditions and/or criteria under which such products should be funded
- to provide advice and, if appropriate, a change to a previously issued recommendation in response to every Request for Advice
- to consider feedback provided by sponsors, manufacturers (if not the sponsor), the PAG, and patient groups on an Initial Recommendation before issuing a Final Recommendation, unless there are instances where pERC determines an Initial Recommendation meets the criteria for early conversion to a Final Recommendation
- to deliberate on a submission or resubmission again and, if appropriate, to change a Final Recommendation, in response to a Procedural Review submitted to CADTH and decided upon by the President and CEO of CADTH, on the advice of the CADTH pharmaceutical advisory committee Chair and Vice-Chair, who will determine if the grounds for a procedural review exist.

3.0 AUTHORITY

The Committee shall report to the President and CEO through its Chair.

4.0 MEMBERSHIP

The committee is composed of 18 members, as follows:

- seven cancer specialists (oncologists)
- one non-oncologic physician
- three health economists
- two pharmacists
- two blood disease specialists (hematologists)
- three patient representatives.

At least one of these members should also have expertise in health ethics.

4.1 Appointment Process

The members shall be identified through a public call for nominations. Members shall be appointed by the CADTH President and CEO.

4.2 Removal

Notwithstanding anything set out in these terms of reference, the President and CEO of CADTH shall have the right to remove and/or replace a pERC member at or before the expiry date of his/her term.

4.3 Resignation

A member may resign from office by giving a written resignation to the Chair and CADTH President and CEO; such resignation becomes effective when received by CADTH or at the time specified in the resignation, whichever is later.

5.0 TERM OF OFFICE

Members of pERC shall normally be appointed for a three-year term, but the term may be renewed once at the discretion of the President and CEO.

Any member who has served two (2) consecutive terms of office shall not normally be eligible for reappointment to the committee until a period of at least one (1) year has elapsed since the end of that member's second consecutive term in office.

The President and CEO may appoint a member who has served two consecutive terms of office for an additional term for the purpose of that member serving as an officer or if a third term is in the best interests of CADTH.

6.0 OFFICERS

The officers of the Committee are the Chair and Vice-Chair.

6.1 Appointment Process

One member shall be appointed by the President and CEO to serve as Chair of the Committee. One member shall be appointed by the President and CEO to serve as Vice-Chair of the Committee.

6.2 Term

Officers shall ordinarily hold office for a term of three (3) years from the date of their appointment as Chair or Vice-Chair, irrespective of years served as a member. The term may be renewed once at the discretion of the President and CEO.

In the event that the Vice-Chair is appointed as Chair, the new appointment term and renewal of this term is not affected by the years previously served as Vice-Chair.

Any officer who has served two (2) consecutive terms of office shall not be eligible for appointment to the committee as a member until a period of at least one (1) year has elapsed since the end of that officer's second consecutive term in office.

6.3 Powers and Duties

The Chair shall, when present, preside at all meetings of the Committee. The Chair shall act as the Committee spokesperson when directed to do so by the President and CEO. Per sections 7.3 and 13.0, the Chair shall participate in the development of meeting agendas and report on Committee activities to the CADTH Board of Directors.

The Vice-Chair shall, in the absence or disability of the Chair, perform the duties and exercise the powers of the Chair.

7.0 MEETINGS

pERC will meet in person on a monthly basis, on a pre-specified day of each month. Under exceptional circumstances, additional meetings may be called.

7.1 Attendance

Members shall make best efforts to attend all meetings of the Committee. A member who is unable to attend an in-person meeting may request permission from the Chair to participate in the meeting via teleconference or other means. Permissions will be granted provided all members are in agreement. Alternates are not permitted to attend in place of a member.

7.2 Quorum

A majority (50% + 1) of voting members of the Committee shall constitute quorum.

7.3 Agenda

Meeting agendas are prepared by CADTH, in consultation with the Committee Chair.

7.4 Decision-Making

Decisions of pERC shall ordinarily be decided by a consensus of the members present at the meeting. Should consensus not be reached, the Chair shall refer the question to be decided by a majority vote of the members. The Chair of the meeting shall not normally vote except in the event of a tie, in which case the Chair of the meeting may exercise a casting vote. All committee members will support a committee decision once it is made.

7.4.1 Abstaining

Although full participation of members is in the best interest of the work undertaken by the committee and CADTH, in some cases members may abstain from voting. If a member is not present for the majority of the discussion on the motion being passed, or if the member feels unable to vote for moral reasons, the member may abstain from voting.

When a member abstains, their vote is not counted and the decision is made by a majority of remaining voting members.

7.5 Minutes

CADTH staff keeps a written record of meetings of the Committee. A copy of the minutes will be provided to each member of the Committee.

7.6 Attendees

In addition to pERC members, and observers invited in accordance with section 7.7, only the following persons shall be entitled to attend pERC meetings:

- members of CADTH pharmaceutical advisory committee(s) and PAG members
- Clinical and Economic Guidance Panel members and experts by invitation only (see below)
- CADTH staff (see below).

CADTH pharmaceutical advisory committee members and PAG members appointed by provincial and territorial ministries of health and provincial cancer agencies shall be entitled to attend. At each meeting, the PAG Chair (or his or her delegate from among the PAG members) will be given the opportunity to provide the perspective of PAG on submission(s) for consideration by pERC. These attendees shall not have the right to participate in pERC deliberations or to vote (i.e., beyond the steps of information gathering and clarification).

Clinical and Economic Guidance Panel members and/or experts may attend the pERC meetings by invitation from the pERC Chair, only, in circumstances where pERC has questions or requires clarifications regarding a submission, a resubmission, a Reconsideration of an Initial Recommendation, a Request for Advice, or a pCODR guidance report. Panel members and experts, however, shall not participate in, or be present during, any pERC deliberations or vote.

CADTH staff attending the meeting shall serve as a resource to pERC. The staff provides administrative and secretariat support and may actively participate in the presentation of information, Requests for Advice, submissions, resubmissions, and Reconsiderations of an Initial Recommendation at the request of the pERC Chair. The staff shall also assist in obtaining additional information and/or expert advice at pERC's request.

7.7 Observers

CADTH, in consultation with the Chair, may invite observer(s) to attend committee meetings from time to time.

The committee shall have the right to exclude observers from any meeting held in camera, either in whole or in part.

8.0 CODE OF CONDUCT

All members of the Committee shall comply with the CADTH code of conduct.

9.0 CONFLICT OF INTEREST

All members of the committee shall comply with the CADTH conflict of interest policy. Conflicts of interest shall be declared at the start of each meeting.

10.0 INDEMNIFICATION

Every pERC member shall be indemnified and saved harmless by CADTH from and against:

- All costs, charges, and expenses which such pERC Member sustains or incurs in or about any action, suit of proceedings, which is brought, commenced or prosecuted against him or her, or in respect of any act, deed, matter or thing whatsoever, made, done or permitted by him or her, in or about the execution of the duties of such committee members or in respect of any such liability.
- All such costs, charges, and expenses which he or she sustains or incurs in or about in relation to the affairs thereof, except such costs, charges, or expenses as are occasioned by his or her own wilful neglect or default.

11.0 CONFIDENTIALITY

It is the responsibility of pERC members to know what information is confidential and to obtain clarification from CADTH when in doubt. Except as compelled by the applicable legal process, a pERC member must, both while having and after ceasing to have that status, treat as confidential all information regarding the policies, internal operations, systems, business, or affairs of the committee and of CADTH obtained by reason of his or her status as a committee member and not generally available to the public. A pERC member shall not use information obtained as a result of his or her involvement on the committee for personal benefit. Each pERC member shall avoid activities which may create appearances that he or she has benefited from confidential information received during the course of his or her duties as a committee member.

More details on confidentiality are set out in the CADTH code of conduct (available on the CADTH website).

12.0 REMUNERATION

Members may be eligible to receive remuneration in accordance with the CADTH policy on remuneration. Expenses incurred in the course of performing duties as a committee member are eligible for reimbursement in accordance with the CADTH travel policy.

13.0 REPORTING

pERC shall make a report to the CADTH Board of Directors at least annually through its Chair, by verbal and/or written means.

14.0 SECRETARIAT SUPPORT

Secretariat support for pERC shall be provided by CADTH staff.

15.0 AMENDMENTS TO THE TERMS OF REFERENCE

These terms of reference may be amended at any time at the discretion of the CADTH President and CEO.