

OVERVIEW OF SUBMISSION PROCESS FOR CANCER-RELATED DRUGS

The Ontario Public Drug Programs (OPDP) and Cancer Care Ontario (CCO) have developed a joint initiative concerning a common submission and evaluation process for all cancer-related drugs for consideration under the New Drug Funding Program (NDFP) and/or the Ontario Drug Benefit (ODB) program.

This common submission and evaluation process ensures that all cancer-related drugs in Ontario are considered through a consistent review mechanism by an expert advisory subcommittee that makes recommendations to the OPDP for ODB products and for NDFP products administered by CCO. This initiative provides an opportunity to share information and expertise about cancer drugs between the Ministry's expert advisory committee, the Committee to Evaluate Drugs (CED) and CCO. This streamlining of processes and consistency in evaluation and recommendations has helped to contribute to continuity of care for cancer patients in Ontario.

The current mandate of the Committee to Evaluate Drugs/Cancer Care Ontario (CED/CCO) subcommittee is:

1. To review, assess, and provide a recommendation to the CED regarding which cancer drug products should be considered for public funding; and to advise the CED and Ministry of the conditions under which such products should be funded;
2. To establish, refine and apply criteria to evaluate the therapeutic value and cost-effectiveness of cancer drug products;
3. To monitor and evaluate, on a continuous basis, the list of cancer drugs available through NDFP and/or OPDP in light of drug use patterns, experience and current scientific knowledge;
4. When requested, to contribute and support CCO / CED / Ministry efforts on education regarding the prescribing of cancer drugs according to best practices;
5. To provide advice on relevant drug, policy, and therapeutic questions and issues solicited or requested by CCO / Ministry, from time to time;

The subcommittee has membership from the CED and CCO. The subcommittee reviews, evaluates, and provides advice to the CED on which products should be reimbursed through either the NDFP or the OPDP.

The subcommittee aligns the review processes for both organizations to allow for consistency in approach as noted above.

On June 20, 2006, Bill 102, "The Transparent Drug System for Patients Act", received Royal Assent. Recommendations made by the CED are submitted to the Executive Officer for the OPDP and are subject to his/her review and decisions made by the Ministry and the government.

Communication during the Submission Process:

All documentation for new drug submissions, correspondence regarding listed drug products or any other drug-related matters must be directed to the OPDP and/or CCO, and not to the CED/CCO subcommittee, its chair, or any members or consultants to the committee.

Direct approaches (in any form) to the CED/CCO subcommittee members and/or consultants, in their capacity as members of the subcommittee, may be viewed as introducing a conflict of interest and might create an appearance of bias or unfairness on the part of the subcommittee members and/or consultants.

Written Communication to Manufacturer:

Once a submission is screened, a Notice of Drug Submission Status (NDSS) is issued. The NDSS will indicate the status of the submission (Complete or Incomplete) as well as the assigned file numbers. Each submission is assigned a unique master file number, and each individual drug product within the same submission is assigned a unique drug product number. The NDSS for an incomplete submission will state the reasons why the submission was deemed incomplete. When additional information is received, a subsequent NDSS letter indicating whether the submission is complete or incomplete will be issued.

After the CED has made a recommendation and the minutes have been finalized, the manufacturer is notified of the CED recommendation (both positive and negative) in a further NDSS. The Ministry will inform the manufacturer in writing should it, the CED-CCO subcommittee, or the CED have any questions or concerns, or should additional data be required to complete the evaluation of a submission.

Once the Executive Officer has reviewed the CED's recommendation, the manufacturer will be notified, in writing, of the Executive Officer's final decision.

For more information please contact:

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