Ontario Public Drug Programs, Ministry of Health and Long-Term Care

Executive Officer Notice
Drug Submission - Information Bulletin

Effective April 1, 2016, all drug products reviewed by the Common Drug Review (CDR) and the pan-Canadian Oncology Drug Review (pCODR) will no longer require a routine review by the Committee to Evaluate Drugs (CED), the ministry's expert drug advisory committee.

This decision was made to better align with national processes, including the pan-Canadian Pharmaceutical Alliance.

On a case-by-case basis, the Ontario Public Drug Programs (OPDP) may seek CED's advice on drug products previously reviewed by the CDR or pCODR.

The CED will continue to review submissions for brand products that are not eligible for the CDR's or pCODR's review process, as well as provide advice to the ministry on important initiatives such as formulary modernization and drug class reviews.

Manufacturers must continue to make submissions to the OPDP to have their products considered by the Executive Officer for listing and funding, in accordance with Regulation 201/96 of the *Ontario Drug Benefit Act* and Regulation 935 of the *Drug Interchangeability and Dispensing Fee Act*.

Ontario

Appendix: Frequently Asked Questions

What changes are being made to Ontario's drug funding review process?

In general, when manufacturers of new medications want their products considered for reimbursement under federal/provincial/territorial public drug plans, they must make a funding request to either the national Common Drug Review (CDR; for non-cancer drugs) or the pan-Canadian Oncology Drug Review (pCODR; for cancer drugs).

As part of Ontario's current drug funding review process, CDR and pCODR recommendations are reviewed by the Committee to Evaluate Drugs (CED), the ministry's expert advisory committee on drug-related issues. After considering all relevant issues, including the Ontario context, the CED recommends whether or not a drug should be publicly funded in Ontario.

Effective April 1, 2016, drug products reviewed by the CDR or pCODR will no longer require a routine CED review. This change applies to drug submissions received by OPDP prior to April 1, 2016 that have not yet been reviewed by the CED.

As a result, CED recommendation letters will no longer be issued for drugs eligible for CDR or pCODR review.

On a case-by-case basis, the ministry may seek CED's advice on drug products previously reviewed by the CDR or pCODR.

Why are the changes being made?

This decision was made to better align with national review processes, including the pan-Canadian Pharmaceutical Alliance.

Since the CED will no longer routinely evaluate CDR- or pCODR-reviewed drug products, do manufacturers still need to make submissions for these products to the OPDP?

Yes. For drug products to be eligible for funding in Ontario, drug manufacturers must continue to provide complete submissions to the OPDP, in accordance with O. Reg. 201/96 under the *Ontario Drug Benefit Act* and/or Regulation 935 under the *Drug Interchangeability and Dispensing Fee Act*.

Do the changes impact the review process for brand products that are not eligible for CDR or pCODR review (e.g., line-extension products)?

No. Funding submissions for these products will continue to be reviewed by the CED, and the ministry will continue to issue a CED recommendation letter upon conclusion of each review.

Do these changes impact the review process for generic product submissions to the OPDP?

No. Non-streamlined generic drug product submissions will continue to be reviewed by the CED, and the ministry will continue to issue a CED recommendation letter upon conclusion of each review.

Should patient advocacy groups continue to make patient evidence submissions to the OPDP for drug products reviewed by the CDR or pCODR?

Patient submissions for CDR- or pCODR-reviewed drug products will still be considered through the respective national reviews.

However, for any products where patient groups feel there is Ontario-specific information that was not incorporated into the CDR or pCODR submissions, they can submit information directly to the OPDP.

Since the CED will continue to review submissions for single source drugs that are not reviewed through the CDR or pCODR processes, patient advocacy groups are encouraged to continue making patient evidence submissions to the OPDP for these products.

I have additional questions. Who should I contact?

General inquiries should be directed to:
Ontario Public Drug Programs
5700 Yonge Street, 3rd Floor
Toronto, Ontario
M2M 4K5
Tel: 416 327-8109 (in Toronto) or 1-866-811-9893 (toll-free)
Fax: 416 327-8912 (in Toronto) or 1-866-598-6530 (toll-free)
Email: PublicDrugPrgrms.moh@ontario.ca