

Cancer Care Ontario

Action Cancer Ontario

EVIDENCE BUILDING PROGRAM

POLICY

Version: 1.0 version 20111021

Date Created: October 2011

Policy Owner: Provincial Drug Reimbursement Programs

LIST OF AMENDMENTS

Version	Section Amended	Date Amended

A. INTRODUCTION

In March 2011, the Ministry of Health and Long-Term Care (MOHLTC) announced a new Evidence Building Program (EBP) for cancer drugs. The EBP, a joint initiative between Ontario Public Drug Programs (OPDP) and Cancer Care Ontario (CCO), is designed to resolve uncertainty around clinical and cost-effectiveness data related to the expansion of cancer-drug coverage in Ontario. The EBP complements and strengthens Ontario's process for making drug-funding decisions.

The EBP brings additional rigour and consistency to funding decisions for eligible drugs, while meeting the responsibility to deliver high-quality care and to spend Ontario's health-care dollars wisely to produce the greatest value for patients and society.

B. OBJECTIVES

The objective of the EBP is to develop and collect real-world data on cancer drugs where evolving evidence demonstrates clinical benefit beyond the current reimbursement criteria.

This data will be given to the Executive Officer of Ontario Public Drug Program, who will use the information to make a final funding decision.

C. PRINCIPLES

The EBP will:

- Enhance the integrity of the existing evidence-based review and decision-making information process for cancer drugs. The program will collect data on real-world outcomes during periods of conditional reimbursement to provide meaningful results to inform future funding decisions
- Have transparent, equitable, defensible, and timely policies and processes
- Measure and report on its efficiency and cost-effectiveness on an ongoing basis
- Be routinely evaluated and informed by each drug-funding request considered through the EBP process

Note: Initially only injectable cancer drugs will be considered under the EBP. Over time, there will be ongoing evaluation and gradual expansion of the program to consider oral cancer drug therapies.

D. INCLUSION CRITERIA

The inclusion criteria will determine which drugs/indications will be considered under the EBP. Drugs that do not meet **all of the inclusion criteria** will not be considered for EBP funding.

- The drug must have been reviewed by the Committee to Evaluate Drugs, or its equivalent.
- The drug currently must be funded publicly and the indication for which funding is being sought is an extension/expansion/modification of the current funding criteria.
- There must be questions about a drug’s clinical- or cost-effectiveness in a specific patient population (beyond the current reimbursement criteria) that can be resolved through the collection of real-world utilization data over the proposed study period.
 - *For example, if the issue is one of cost-effectiveness or budget impact that can be resolved through other mechanisms, such as a product listing agreement, the drug would not be considered under the EBP.*
- The collection and analysis of the real-world data are expected to be sufficient to inform a future funding decision.
- There are no studies underway that are expected to address the issue within the EBP funding period.
- The Disease Site Group (DSG) supports inclusion of the drug in the EBP.
- Research ethics board approval is not required.

E. EVALUATION AND PRIORITIZATION CRITERIA

These factors will be considered in the evaluation process. They are not weighted or ranked.

Consideration	Criteria
Burden of Disease and Expected Clinical Impact	<ul style="list-style-type: none"> • What are the impacts of this disease on individuals and the Ontario population? • How many Ontarians are expected to be eligible for the indication in question? • Is there another option for this patient population? • What type of impact does this drug have? (e.g., progression-free survival vs. disease-free survival vs. overall survival vs. quality of life) • How many people might this drug harm? • How serious are the consequences of adverse events? • Is the drug expected to be supplanted/made obsolete during the study period?
Supportive Evidence	<ul style="list-style-type: none"> • How compelling is the existing evidence that there would be a meaningful benefit to treatment? • Is evidence expected to emerge that will make EBP evaluation unnecessary?
Economic Evaluation	<ul style="list-style-type: none"> • Is there some preliminary evidence to suggest that the treatment could be cost-effective? • How will EBP funding resolve questions of cost-effectiveness?
Budget Impact	<ul style="list-style-type: none"> • What is the cost of providing the drug? • What is the expected cost of the evaluation?
Current Standards of	<ul style="list-style-type: none"> • How is this treatment used in other jurisdictions? • Do significant differences exist between the clinical guidance from

Practice	the DSG/Program in Evidence Based Care and the current reimbursement status?
Stakeholder Support	<ul style="list-style-type: none"> • Is this a priority for stakeholders, the DSG, and patient groups? • Is this a project for which financial support (via manufacturer) exists to mitigate evaluation expenses?

F. EBP DRUG EVALUATION PATHWAY

- The EBP consideration process must be initiated by a DSG. Stakeholders may provide input into the EBP prioritization and consideration process by providing candidate drug recommendations to the EBP directly – not to the DSG
- A preliminary proposal will be prepared by the DSG (with support from EBP staff). This report will outline the rationale for including a drug in the EBP, document congruence with the inclusion criteria, and provide a preliminary proposal for data collection, analysis, and endpoints
- Proposals that satisfy the inclusion criteria will be reviewed with OPDP, and expert advisory committees*, as required
- Proposals that are thought to meet the inclusion criteria, and are of high priority based on the review by OPDP, CCO, and relevant advisory and/or steering bodies, will be presented to the Executive Officer (EO) for review. Proposals without support will be returned to the DSG, outlining the project limitations
- Following EO project approval, a full project plan will be developed by the DSG and the EBP. An external analytic group may be engaged to support the development and validation of the analytic framework
- The full project plan will be presented by the DSG and EBP to relevant provincial advisory/steering bodies. (This may be an iterative process, if significant modifications to the project plan are requested.)
- The proposal will be reviewed by an appointed Steering Committee (final structure to be determined) for consideration
- The final project will go to the EO for a final decision on inclusion in the EBP
- If the EO decides to include the drug/indication in the EBP, CCO or OPDP will implement the time-limited funding of the drug with the necessary supporting documentation
- A reconsideration process will be developed for those drugs/indications the EO decides not to include in the EBP

*Note: Given the evolution of Ontario’s cancer drug funding evaluation to the pan-Canadian Oncology Drug Review, the EBP evaluation pathway will need to be aligned with the future design of provincial advisory and evaluation mechanisms.

G. ANALYTIC FRAMEWORK

International experience suggests that EBP-type programs benefit from partnership with external analytic expertise to inform design and data collection, and to independently evaluate this data. Consequently, the EBP will engage with external analytic groups to get their input on

the design of the data-collection protocol and the evaluation of drugs funded. The EBP will partner with research and academic organizations with the relevant expertise, infrastructure, and capacity to complete this analytic work in a timely and rigorous manner, and provide external validation of the results to make them useful for subsequent funding decision-making. The EBP will implement an engagement process that is transparent, cost-effective, and timely.

H. DATA COLLECTION

Where possible, EBP analyses will rely on data from administrative databases, if they have the relevant information to inform an evaluation of the desired endpoint(s). In some situations, it may be necessary to collect additional data to inform an analysis. Data could be requested from physicians or pharmacists, and may be requested at the time of enrolment, during the duration of treatment, upon treatment discontinuation, and, possibly, at specific intervals in the future. Further details on data collection will be determined by the program, on a drug-by-drug basis.