Cancer Care Ontario
Action Cancer Ontario

EVIDENCE BUILDING PROGRAM

SUMMARY AND RESPONSE TO STAKEHOLDER CONSULTATION

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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 seeks 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 New Drug Funding Program (NDFP) for cancer drugs, and the process for making drug funding decisions in the province.

Ontario's process for evaluating new – and often expensive - cancer drugs is based on the best scientific evidence. The Evidence Building Program is intended to bring additional rigour and consistency to funding decisions for eligible drugs, while meeting the responsibility to deliver high-quality care and to spend Ontario's healthcare dollars wisely to produce the greatest value for patients and society.

Between March and July, 2011 Cancer Care Ontario (CCO) and Ministry staff worked collaboratively to develop the parameters of the new EBP. Since the initiation of this work, it was intended that CCO and the MOHLTC would seek stakeholder input into the policy and program framework, as part of an overall commitment to transparency and ongoing program improvements envisioned for the program.

CCO and MOHLTC undertook numerous consultations in July and August 2011. This document summarizes those consultations, outlines the EBP policy, and describes the next steps in establishing a permanent Evidence Building Program.

How We Consulted

The consultations were a joint initiative between the MOHLTC and CCO, which sought input from clinicians, researchers, pharmacists, industry, associations, members of the public and academics.

The draft policy was published on the CCO website on June 17, 2011. Invitations to comment and participate in facilitated discussions on the policy were distributed thereafter. Comments were invited in writing and via web survey.

Breakdown of Consultation Sessions and Responses

Over 140 organizations and individuals contributed feedback during the consultation period. Eight live consultation sessions were held

Feedback was provided by a diverse group of stakeholders, including individual health professionals, large partner associations and pharmaceutical manufacturers.

The following table summarizes the sources of feedback on the policy:

EBP Consultation Participation

Date	Group	# of Participants
June 17-19	Citizen's Council	21
June 29	Industry Oncology Working Group	13
July 6	Associations & Partners	9
July 12	Pharmacists	13
July 14	Disease Site Groups	8
July 15	Researchers	5
July 20	Oncologists	6
	Other Written Input	5
	Survey Respondents	60
	TOTAL	140

The draft policy was also presented by CCO and MOHLTC staff to other groups, including the pan-Canadian Oncology Drug Review Steering Committee.

Key Learnings

Extensive comments were provided on the policy. Overall, the Evidence Building Program was viewed positively by the respondents. Many emphasized the importance of this type of program for Ontario cancer patients.

The consultations were focused on 28 specific questions that sought input on principles, inclusion criteria, evaluation and prioritization criteria, drug consideration pathways, analytic frameworks, data collection, and governance/stakeholder input.

Those consulted generally supported the overall program intent, and the central role of CCO's DSGs as the initiators of project funding requests. Some suggested there was a need for a larger role for other stakeholders in priority setting. This has been addressed in the revised policy.

We modified the prioritization criteria based on the feedback received. We have decided to defer any consideration of formally weighing criteria, until we have more experience applying the policy.

Two issues repeatedly surfaced as program limitations. First, the decision to restrict the program only to injectable therapies, accessed through CCO's New Drug Funding Program. We acknowledge this limitation, and commit to continuing to explore opportunities to consider oral therapies in future.

The second limitation identified was the decision to restrict consideration to drugs already funded. We feel that if the drug is not already publicly covered for a specific indication, then the onus remains on the manufacturer (or Disease Site Group) to work within the existing funding

review processes to secure traditional funding, before the drug should be considered for funding through the EBP program.

There were considerable differences of opinion on the role of the manufacturers in the priority setting and the funding process.

An important question was raised regarding the need for research ethics board approval as part of the EBP process. We have clarified in the policy that any proposal that would require REB approval would not be eligible for funding through the program.

Summary of Feedback Received

Principles

1. **Do these principles include the relevant program considerations?**
2. **What other principles for the EBP are recommended?**

Summary of Feedback Received during Consultation:
There was broad support for the principles as proposed. It was recognized that the program could not, and should not, act as an alternative to, or a replacement for, clinical trials. Many emphasized the importance of partnerships and the need for a proper ethical framework in the program.

There were multiple requests for further clarification with suggestions that a more detailed explanation of the policy would be helpful. Questions included:

- Would evidence from other jurisdictions be considered? If so, how?
- How does this program fit with other drug-evaluation and funding programs for cancer drugs in Ontario?
- Is the program intended to make population-level funding policies, or would it be a program that would consider individual circumstances?

Finally, considerable feedback was received from multiple stakeholders emphasizing the importance of accommodating oral therapies within the EBP.

CCO/MOHLTC Response
This program is designed to develop and collect real-world data for cancer drugs for a defined patient population, where there is evolving evidence demonstrating benefit. This is a population-based approach. It is not meant to deal with unique patient circumstances, nor is the program's *primary* goal one of increasing public drug access.

We recognize that clear communication about the details of the final process and for reimbursement programs for cancer drugs in general, is essential. Both CCO and the MOHLTC will work to enhance the program information on its websites, with a particular focus on identifying and differentiating among the various processes and corresponding programs.

We agree with a recommendation to clarify that the program will be routinely evaluated rather than continuously evaluated and have modified the policy wording accordingly.

We acknowledge the importance of incorporating oral cancer therapies into the program and agree in principle. This issue is discussed in more detail under Question 17.

We accept the recommendations to clarify the patient participation parameters (ethics consent) for the program's participants. We expect this to vary based on the variety of evaluation approaches that exist. In all cases, clear information is required by clinicians to support informed discussions with patients.

Inclusion Criteria

3. Do the inclusion criteria clearly define which drugs are eligible for consideration? What ambiguity exists?

Summary of Feedback Received during Consultation:
The consultation identified several areas of ambiguous inclusion criteria:

- Whether a drug had to have been reviewed by the CED (or any other public drug funding evaluation body, such as CCO's former advisory group, the Policy Advisory Committee);
- Whether there was enough information available (publicly, or to DSGs) from prior funding reviews to guide or prompt the consideration of drugs/indication as possible candidates for EBP consideration;
- How the terms "extension", "expansion" and "modification" would be interpreted, and how the program would define a "new indication" for a drug;
- How the terms above would shape the interpretation of whether a drug was already "publicly funded."

Some respondents commented that restricting eligibility to only those drugs already publicly funded could lead to excluding potentially good drug funding candidates for the program. (Also discussed in Question #5.)

Some commented that the existence of ongoing clinical trials should not automatically exclude consideration of drug funding candidates. In general, this criterion was felt to excessively and unnecessarily limit the number of drugs that would be considered through the program.

Several said the role of DSGs and the inclusion criterion related to the requirement for DSG support required greater transparency on composition and participation to reduce the perception of potential conflicts of interest.

There were some questions about what was meant by "utilization data" and what this term describes.

CCO/MOHLTC Response
As described above, the primary objective of the program is to build evidence – it is not a separate funding mechanism that circumvents established review pathways. New indications will continue to be reviewed through the regular drug review process.

Regarding clinical trials: The EBP is not intended to provide answers to questions more properly addressed by clinical trials. Ongoing clinical trials, with endpoints relevant to the uncertainty in question, will exclude drugs from EBP. In addition, when there are cases where there is sufficient uncertainty that research ethics board approval would be necessary, the drug would not be considered an EBP candidate.

Any drug considered for the EBP must have been formally reviewed for public funding. We agree the term Committee to Evaluate Drugs (CED) is unnecessarily restrictive and have modified the policy wording accordingly.

Any drug considered for EBP funding must already be funded in some capacity. If the general indication in question is not already funded, then the most appropriate action would be for the manufacturer (or DSG, depending on who initiated the submission) to continue to submit the drug for review through the regular funding pathways. Like other policy elements, the impact of this criterion will be routinely evaluated.

Clinical trials being run to answer questions surrounding a candidate drug do not have to be conducted in Canada. A randomized clinical trial would be expected to provide better quality data than any real-world observation. We agree that the term “clinical trials” would be better termed “studies” to reflect the kinds of evaluations that could potentially be underway and might be relevant to drugs under consideration. The policy wording has been modified accordingly.

We also agree that the role and responsibilities of the DSG within the EBP needs to be clearly outlined when the full program is implemented. Transparency around membership and potential conflicts of interest will be considered in the context of the EBP program principles.

4. Are further criteria required to clearly identify drugs appropriate for funding through the EBP?

5. Do the criteria, as proposed, exclude drugs that should be appropriate for this process? Provide an example.

Summary of Feedback Received during Consultation (for Questions 4 & 5):
The omission of oral therapies was the most frequently identified program limitation, although the challenge of evaluating oral therapies was acknowledged during the consultation. Some felt the restriction solely to cancer drugs was also a concern.

There were some suggestions that the inclusion criteria should extend to new indications and new drugs already funded in other Canadian and even international jurisdictions. It was suggested that data obtained from other jurisdictions could be evaluated by the EBP, especially in situations where there may be a lack of Ontario-specific data.

There was a request that CCO/MOHLTC clarify the duration of the data collection component of the EBP. It was unclear if the two- to three-year timeframe proposed encompassed data collection only, or the entire period between funding initiation and the final publication of results.

There was suggestion that other groups, beside DSGs, such as patient advocacy groups and manufacturers should be permitted to make funding requests. Some questioned whether the DSG model, based on the 10 most common cancer disease sites, would unfairly penalize more uncommon/rare cancers, which have no affiliated DSG.

Some also suggested that a value of information analysis be conducted for each potential drug to ensure the proposed evaluation will actually reduce the degree of uncertainty and justify the cost of research.

CCO/MOHLTC Response

Oral therapies are not included in the criteria at this time due to the difficulties in implementation. We agree that oral cancer therapies should be included in the EBP once feasibility questions have been addressed.

The EBP is open to accepting data from other jurisdictions as part of the data collection process. An understanding of ongoing evaluations and any other existing data sources should be developed during the project consideration process. Following a decision to fund a drug through the EBP, an ongoing process of horizon-scanning should identify any appearance of new data. Such cases will be assessed for appropriateness as they come forward.

The program will only consider drugs already approved for funding, as outlined in the response to Question #3.

To date, all drugs already reviewed and approved for funding have included the input of a DSG. Consequently, we don't expect many instances in which there will be lack of a DSG for any drug being considered. If this becomes an issue for truly rare cancers that do not fall within an existing DSG, EBP will give this further consideration.

The timeframe for data collection discussed during the consultation (2-3 years on average) was provided for general intent, based on international best practices. Any decision to extend an evaluation beyond this target would need to be explicitly made possible through a value-of-information analysis.

Evaluation and Prioritization Criteria

6. Which factors should be included in the prioritization process?
In addition to the factors already proposed, these factors were specifically recommended:

- Consider quality-of-life data, ethical considerations and a value of Information analysis.
- For the term "expected clinical impact", include additional safety benefits and the potential for reduced adverse effect. An examination of risk trade-offs was proposed.
- Consider a reduction in other healthcare resources under economic considerations.
- That the term "level of evidence" would be better termed "supportive evidence" to be more consistent with the intent of the program.
- Accommodate changing priorities over time.

Questions were raised regarding:

- How the program would equally weight prevalent vs. rare cancers
- Whether weighting criteria were appropriate
- If disease stage would factor into consideration
- How conflicts would be resolved

It was repeatedly suggested that the EBP should not become an appeal process for all 'No' recommendations from the CED.

CCO/MOHLTC Response
Modifications to the criteria have been made to include quality-of-life considerations and to further clarify our intent to address suggestions raised during the consultation.

This program is not intended to be a catch-all for every "No" decision. Any drug considered can only enter the process after CED has completed an initial review of the drug, and if the drug is currently being funded in some way for the indication under consideration. Thus, it will only be a small number of drugs that fit into this process, which is the intent. For new drugs and indications, it should be the manufacturer who conducts the clinical trial. It is not anticipated that groups such as CED would make an initial recommendation to fund through the EBP.

7. How should the prioritization factors be weighed to rank competing projects?
Multiple rankings were suggested, though most respondents had difficulty assigning weights and cautioned against weighting one factor against another. Overall, respondents agree that clinical factors should be weighted more heavily than economic factors. It was suggested that a value of information analysis may remove the need for prioritization.

Concerns were also raised on the impact of low stakeholder support in the prioritization process, particularly for rare cancers.

CCO/MOHLTC Response
There was a lack of consensus on weighting. Some assigned weights: others cautioned against prematurely assigning weights. Consequently, we have elected not to assign weights. This will be re-evaluated after several drugs have been worked through the consideration process.

To reflect the lack of weighting or ranking, the numerical assignments have been removed from the policy document.

8. Who should be involved in the prioritization process?
Feedback suggested all stakeholders should have some form of involvement in the process. Many responses concurred that the DSGs should prioritize proposals within their own tumour site, and that the prioritization process and the rationale for decisions should be made transparent. In the case where there are multiple drug/indication candidates across different tumour sites, it was unclear how choices would or should be made in light of multiple proposals from the different DSGs.

Some responses also suggested that manufacturers should be engaged as early as possible to increase efficiency and to leverage global data.

CCO/MOHLTC Response
We agree that DSGs should prioritize initiatives within their own groups and believe that overall prioritization should be done by the EBP Advisory Committee. This committee can consider input from the DSGs and other external stakeholders in a systematic way to incorporate a wide variety of perspectives. It was recognized that different parties may have actual/potential conflicts of interest related to the outcome. Managing conflicts of interest throughout the process is a priority and we acknowledge these will need to be dealt with in a transparent manner.

9. Should the manufacturer's willingness to contribute to the drug funding or data collection costs be part of the evaluation criteria or the prioritization?
Some respondents suggested the initial evaluation of proposals should be solely based on the clinical impact and that manufacturers should be approached after the prioritization process has been completed. Concerns were also raised that a manufacturer's unwillingness to contribute may result in a bias against rarer cancers.

Other respondents felt that manufacturer willingness to contribute should be a consideration. It was further suggested that manufacturer support be incorporated into the budget impact of a proposal.

Where a proposal may affect more than one manufacturer, clarity was sought on how the different manufacturers would be engaged.

CCO/MOHLTC Response
There was no consensus in the responses received. Manufacturers were strongly against providing funding; other stakeholders support requiring the manufacturer to contribute to program costs.

It was agreed that manufacturer willingness should be a factor in the consideration, but not in the initial prioritization process. It was felt that it was important to evaluate drugs only based on the stated prioritization process. Manufacturer willingness would be considered subsequently, as a separate factor in the final decision-making by the Executive Officer.

Drug Consideration Pathway

10. The model proposes that DSGs should be the sole group that can initiate the EBP consideration process. Should other targeted stakeholders have input into this process? When, where and how should stakeholders (i.e., manufacturers and patient groups) be involved in the drug-consideration pathway?

Some responses suggested that manufacturers and patient groups should have the ability to initiate requests to the EBP. Others suggested that stakeholders should be able to provide input throughout the entire process (e.g., submitting proposals to the DSG for consideration, providing input into the prioritization and/or decision-making process). Early and ongoing engagement of manufacturers was also recommended to promote system efficiencies and to ensure that manufacturer's regulatory requirements are met. It was recognized that a formal mechanism for stakeholder engagement in the program is needed to avoid undue influence on the DSGs, especially when the evaluation of the data collection results in a decision to withdraw funding.

Concerns were also raised on the resource intensive nature of EBP proposal development and the need for the DSGs to have timely access to systemic treatment and outcomes data needed during proposal development.

CCO/MOHLTC Response
We agree that stakeholder input would be valuable throughout the process for EBP consideration and evaluation. We do not feel that groups other than the DSGs should initiate proposals; however, we will develop a mechanism that will allow external input directly into the consideration process. In order to maintain the impartiality of the DSGs, we agree that a formal mechanism for stakeholder engagement is important to avoid any external influence on the DSGs, and will build this into the program, outlining clear expectations for all parties.

11. How and when should project prioritization take place?
Some suggested a set project prioritization schedule. Others supported prioritization of drugs on a rolling basis based on their own strength and merit. Prioritization should also take into account the urgency of population needs, as well as the extent of benefit expected.

Concerns were raised with respect to:

- Dependency on program resource availability
- Interference with budget setting cycles

CCO/MOHLTC Response

Initially, we propose to identify a list of EBP projects with the DSG. Prioritization will take place to identify the preliminary work plan. We also believe that accepting additional proposals, as they come in, is the most flexible approach with the launch of the program.

As the program matures the benefits of fixed submission dates will be re-evaluated.

12. What should be considered as part of the appeal process?

Some responses suggested that all stakeholders should be given the opportunity to provide feedback on the initial recommendation prior to the final decision. Further, they said, the ability to appeal should not be restricted to the DSGs. It was also suggested that the appeal committee be independent of the program**.**

Other responses suggested eliminating the appeal process in favor of allowing the DSGs the opportunity to rework and resubmit the proposal. The rationale for the funding decision and the feasibility of a resubmission should be made transparent.

CCO/MOHLTC Response

Greater clarity needs to be provided on what constitutes a resubmission (i.e., additional information) versus an appeal (typically a challenge to policy or process). We feel that these challenges should only be accepted from DSGs. However, the rationale and decision should be publicly communicated in a transparent manner. We will continue to work on providing clarification on this reconsideration/appeal process.

13. What challenges do you see in implementing funding decisions that are part of an evidence-building program?

Responses raised challenges with respect to timeliness, transparency, fairness, resource and budgetary constraints. There were recommendations that program scope, review process and timelines, target objectives and decision-making criteria be clearly stated up front, to ensure that stakeholders have a clear understanding of the process, particularly in the event that funding is subsequently withdrawn. It was suggested that the need for program resources (i.e., DSGs and MOHLTC staff) be evaluated and addressed so as not to negatively impact the operations of the already established drug review processes.

Concerns were also raised on the practicality of the EBP evaluations. Some questioned whether sufficient data could be collected within a reasonable time period to allow for a fully-informed final funding decision. Others questioned the flexibility of the program to incorporate and adapt to relevant data from other jurisdictions, should it become available during the process. There were additional comments related to possible legal issues of providing funding for “off-label” (unapproved) uses through the EBP.

CCO/MOHLTC Response
We agree that the program must be properly resourced in order to be effective, and to ensure it does not interfere with other aspects of the public drug review and approval process.

Communication and transparency are priorities for the program. A comprehensive communications strategy will be developed for the EBP.

Other concerns have been noted and will be further considered as the program model is developed.

14. What data should be required as part of initial-funding requests? What resources are required to generate this data? How should clinician input be organized?
Responses largely recommended that initial applications be aligned with the data required to confirm eligibility and to guide prioritization. There was considerable discussion, but no consensus, on the minimum level of evidence required to initiate the EBP consideration process.

Additional factors that were proposed for inclusion in a submission request included:

- Proposed endpoints and data-collection plan
- Known efficacy and toxicity profile in types of patients that would access the drug via EBP
- A summary of data available from other jurisdictions that may already fund the drug/indication
- Expected financial impact

CCO/MOHLTC Response
We concur with the responses we have received. To guide applications into the EBP we intend to standardize the process (using templates) as much as possible. To facilitate preparation of new submissions, we are exploring the type and arrangements of supports needed by the DSGs to generate new requests.

We acknowledge the challenge in setting minimum levels of evidence to support the initiation of projects into the EBP. No specific threshold currently has been set. This will be re-evaluated as the program matures.

Analytic Framework

15. What roles and models could be considered to integrate an analytic framework into the workup of each potential EBP-funded drug?
16. Is the role envisioned for researchers and analytic groups within the EBP one that will meet the program's intent?

There were multiple recommendations made to use third parties to manage data collection and evaluation. Several suggestions were made on the type of models the program should consider, though it was noted that the type of model would depend on the type of intervention that is under review (e.g., use of administrative databases vs. epidemiologic studies). Responses also encourage the use of external groups with health-research methodology and health-economics expertise, provided that relevant patient outcome data are collected, a priori criteria are being followed, and data are analyzed in a timely manner. There was no consensus on when in the process such groups should be engaged with some advocating for inclusion very early in the process with the development of the initial objectives/questions, while others suggesting later in the process.

CCO/MOHLTC Response

Feedback supports the proposal to engage external analytic groups as part of the EBP process. There was no consensus as to when and how groups should be engaged – in part, this may be driven by the complexity of the question being answered. The role is expected to evolve as more experience is gained in moving drugs through the process. CCO has internal informatics expertise, and the program will explore the means by which external analytic groups can support and validate the EBP's work.

17. What additional research and analytic considerations are required as part of implementing EBP funding, particularly for drugs reimbursed through the ODB program?

Challenges in evaluating drugs provided through retail pharmacies were acknowledged. It was suggested that drug dispensing could be restricted (or just the evaluation) to cancer centres with outpatient pharmacies, where data collection may be more feasible. It was also noted that most patients on oral cancer therapies need to visit cancer centres routinely as part of their treatment plan – consequently data collection in this setting may be easier to implement. Even if data collection occurred only among the population accessing drugs via the cancer centres, it could still provide useful data to support an evaluation.

CCO/MOHLTC Response

We recognize the operational challenges associated with incorporating oral cancer therapies into the EBP. Designing EBP evaluations through cancer centre-based outpatient pharmacies is a potential option that will be explored as more experience is gained with the program.

18. What is the best approach to identifying, engaging, and selecting analytic partners to participate in the EBP?

In general, responses highlighted the need to engage groups with expertise in health services research and health economics. There was debate on how best to select and engage experts, with the recognition that there may need to be trade-offs between efficiencies and fairness. Responses did suggest having interested parties register to alert them to request for proposals, though questions would need to be defined up front.

CCO/MOHLTC Response
As part of the ongoing development of the EBP, we will design an engagement process that is transparent, cost-effective, and timely.

19. How should the analytical findings be presented?
Overall, responses suggested tailoring the presentation of findings to various audiences (e.g., public, policy makers, scientific community) and in a manner that will be accessible and understandable to each stakeholder group. Findings should be linked back to the original question and associated with a final funding decision.

Responses suggested that findings could be reviewed by the involved drug manufacturer prior to public presentation, due to regulatory obligations by manufacturers to monitor efficacy and safety data.

CCO/MOHLTC Response
As noted in the policy document, our intent is that the results of all evaluations will be publicly available and accessible. We acknowledge the feedback provided and will work to incorporate these elements into the communication strategy for the program.

Data Collection

20. How should the EBP design its data-collection processes to maximize efficiency?
Responses suggested reviewing models used in other jurisdictions/internationally, with the intent that data collection be kept simple and relevant. The use of administrative databases was widely supported, though there were concerns with sample size and data capture feasibility.

CCO/MOHLTC Response
We share the desire to minimize the overall administrative burden of the program, but note that a fully seamless data collection process may not always be possible in order to address the uncertainty in question. In some cases, more interventional data collection processes may enable more rigorous and timely evaluations. The program should aim to obtain sufficient information to support reducing the uncertainty in question, in order to inform a final funding decision – nothing more.

21. What is the best approach to communicate with the appropriate members of the cancer care team (e.g., oncologist, pharmacist) regarding individual patient enrolment and data-collection issues?
Email communication with pharmacists, physicians and other stakeholders was overwhelmingly favored. For communication regarding patient registration and eligibility, it was suggested that the pharmacist (or pharmacy contact) be copied as required.

For general program communication, distribution to multiple members at each site was recommended, to ensure that all pharmacists and physicians have access to program

information. It was also suggested to create a mailing list whereby people can register if they want to be informed of future program communications and updates.

There was mixed opinions about the program's current data upload tool. Some appreciated the ability to upload clinical documents, while others preferred faxing. Differences were driven by hospital-specific technological limitations, usually related to electronic health records.

CCO/Ministry Response
Feedback on communication has been very useful and will be incorporated into future communication and program operational plans. As much as possible it is intended for all information to be transmitted electronically, by email and on the EBP website. CCO will consider an email distribution list to facilitate program updates.

22. What opportunities exist to collect additional (e.g., community pharmacy) data to inform EBP evaluations?
Respondents recognized the importance of capturing data from the private and cash-paying market. However, it was noted that the existing infrastructure does not currently support such data collection. Examples of barriers cited include the lack of continuity of care between clinics and community pharmacies, the lack of community pharmacist training in this area, and the lack of reimbursement models to compensate community pharmacies for efforts in patient-level data collection. Some responses supported the notion that cancer drugs should be dispensed within a cancer centre to ensure proper data collection.

CCO/MOHLTC Response
We recognize the challenges in gathering data through community pharmacies. Consequently, oral cancer therapies will be excluded at this time. As noted in our response to Question #17, further options will be explored as more experience is gained with the program.

Transparency

23. Are there specific elements of the EBP's work that should not be publicly disclosed? If yes, why?
Multiple responses identified that the specific funding arrangement between the government and manufacturers should not be disclosed, as it is commercially confidential information. It was suggested that manufacturers should have the right to see relevant drug-specific communication and redact or make changes to confidential information before release to the public. Embargo periods were recommended to ensure confidential information is not released.

Several responses suggested that full transparency was essential with respect to: the expert committee members and meetings, the inclusion criteria, priorities, protocols and results, the decision process and rationale, and the volume of work at each stage. Patient-level data, however, should be kept confidential.

CCO/MOHLTC Response
We will make most of the information about the program's operations public. There is no intention that the EBP will participate in, or disclose, any confidential reimbursement funding arrangements between the MOHLTC and any specific manufacturer.

24. What are the best means of making ongoing program information available?
Responses suggested several methods of communication (e.g., email, Bulletin Board System (BBS) notifications, ongoing updates on the CCO website, subscription-based list serve, RSS (write out) feeds, regular meetings) to provide program and project updates. In addition, it was noted that patients enrolled to receive EBP drugs should be updated on program changes. It was also stressed that communication must be timely and allow for sufficient lead time so that stakeholders can review and prepare accordingly.

CCO/MOHLTC Response
This feedback on communication methods will be incorporated into future plans for EBP and other reimbursement programs, where possible. Direct patient communication is not expected – we anticipate this will be coordinated through the patient's oncologist.

25. EBP analyses could lead to the withdrawal of funding if a drug fails to meet pre-defined clinical or economic endpoints. What data should be available following an evaluation to explain these reimbursement changes? How should this be communicated?
Many responses highlighted the importance of setting *a priori* criteria and establishing endpoints prior to the start of the evaluation. The proposal question, methodology, data analysis, evaluation and rationale for funding withdrawal need to be made transparent at the initiation of funding of the drug product. Stakeholder communication (via emails, website, and bulletin boards) and engagement throughout the processes was also felt to be essential. It was noted that manufacturers have a unique interest in the findings due to potential regulatory implications related to product safety and efficacy.

Responses also suggested the need to support clinicians in helping patients understand the reasons for withdrawal. Questions were raised on whether funding withdrawal would apply to patients who are responding well to the treatment and whether an appeal process will be in place to allow stakeholder input prior to the final funding decision.

CCO/MOHLTC Response
We agree with the feedback received and will incorporate this into our program plan. With respect to ongoing funding of stabilized patients in the event of a funding withdrawal, no *a priori* policy has been developed, as each circumstance would differ. . The decision could vary based on the reason a drug's funding is being withdrawn (e.g., safety concerns). In most cases, we anticipate that stabilized patients will be "grandfathered" and could continue to receive the drug.

Governance and Stakeholder Input

26. An advisory committee has been proposed. Beyond Ministry and CCO staff, what types of individuals or groups should be included in an advisory committee of this nature? Why?
Responses suggested representation from different stakeholder groups (e.g., patients and advocacy groups, clinicians, DSGs, manufacturers, academic researchers, other policy makers). It was also noted that the committee's role and objectives, as well as the terms of reference, need to be clarified prior to identifying committee membership. The selection process, the committee membership and terms of reference, also need to be publicly available.

CCO/MOHLTC Response
Stakeholder input in design and operations is a key success factor. Before defining participants, work will be done on the model and terms of reference for the advisory group. The information provided will be considered during the design of the advisory committee.

27. What should be included in the advisory committee's terms of reference?
Responses suggested that the following be included in the committee's terms of reference - transparency, fairness, equal (stakeholder) representation, quality, accountability and reporting. Rules around conflict of interest need to be developed and potential conflicts/biases reported. Some responses suggested that the advisory committee should not be involved in project prioritization, but rather serve an oversight function on program development, process refinement, program evaluation and ongoing program reporting.

CCO/MOHLTC Response
The information provided will be considered during the design of the advisory committee. Once developed, the terms of reference, will reflect issues identified during the consultation and will be made publicly available.

28. What role do you see for the public/organizations in the EBP?
Responses suggested the need to clarify the roles and mandates of the proposed advisory and governance committees. However, there appears to be support for public/organizational involvement throughout the entire EBP process, from proposal submission, prioritization, and review to public education of the EBP findings.

CCO/MOHLTC Response
We agree that the terms of reference for advisory bodies need further elaboration. We acknowledge the interest in public and organization involvement and intend to evaluate membership against the strategic and operational needs of the program.

Conclusion

Since the initiation of this work, it has been our intent to seek stakeholder input into the policy and program framework. Our commitment to transparency and ongoing program improvements will be built into the program and is a key part of our consultation process. We sincerely appreciated the feedback provided during the consultation. This process has significantly improved and enhanced the EBP policy and program planning.

Over the next few months, we will develop the program infrastructure and evaluation framework, create a governance structure, and detail processes for reviewing and assessing proposal submissions.

Appendix A – List of organizations that participated in the consultation

Pharmaceutical Manufacturers
AMGEN Canada Inc.
AstraZeneca Canada
BIOTECanada
Boehringer Ingelheim
Celgene Inc.
Eli Lilly Canada Inc.
Hoffmann-La Roche
Janssen Inc.
Lundbeck Canada Inc.
Novartis Pharma Canada Inc.
Rx & D
Sanofi-aventis Canada

Associations and Partners
Canadian Breast Cancer Network
Canadian Cancer Action Network
Canadian Organization for Rare Disorders
Cancer Advocacy Coalition
CML Society of Canada
Kidney Cancer Canada
Lung Cancer Canada
Lymphoma Foundation Canada
Melanoma Network of Canada
Myeloma Canada
Institute for Optimizing Health Outcomes
Rethink Breast Cancer
Thyroid Cancer Canada
Wellspring Cancer Support

Researchers and Academics
Institute for Clinical Evaluative Sciences
Toronto Health Economics and Technology Assessment (THETA) Collaborative
Ontario Clinical Oncology Group
Applied Health Research Centre
Programs for Assessment of Technology in Health (PATH) Research Institute

Hospitals and Regional Cancer Centres
Sunnybrook Odette Cancer Centre
Grey Bruce Health Services
Headwaters Health Care Centre

Mount Sinai Hospital
Juravinski Cancer Centre

Other Organizations
University of Ottawa
Program in Evidence-Based Care