

August 23, 2006

Delivered by email to: helen.stevenson@moh.gov.on.ca

Helen Stevenson
Executive Lead, Drug System Secretariat
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Dear Ms Stevenson:

Thank you for your continuing efforts to ensure that Bill 102 and its related Regulations and policy framework will serve the needs of patients. We remain grateful for your obvious commitment to delivering the best possible drug plan for Ontario.

Cancer is a life-threatening disease even when a number of treatments are available: there is no cure, no security of one's life-expectancy following any treatment regimen, no assurance the disease will not return. Advances in cancer treatment are incremental over many years, one seemingly "marginal improvement" at a time. Access to the newest treatments is a matter of life and death.

The major concerns of the Cancer Advocacy Coalition are in the mechanisms intended to improve prescriber/patient access to new cancer treatments: rapid review of breakthrough products, conditional listings during the review process, exceptional access, fairness review, transparency and disclosure.

We understand that many of these issues are being addressed through policy rather than the legislation or regulations and that working groups have been struck to address implementation details for exceptional access, conditional listings, role of the Citizen's Council, etc. While the policy approach affords greater flexibility for adjustment and refinement it does create some unease about how secure some of these initiatives might be into the future.

Exceptional Access

It is extremely important to cancer patients that the Ministry ensure hospital-based cancer treatments become more accessible, more quickly and with less paperwork. Most of the focus in Bill 102 and its regulations is on Drug Benefit; we urge you to take equal care in addressing the barriers to hospital-based cancer treatments.

We have described in earlier submissions how this should work but it bears repeating now.

1. The new process should not limit the number of drugs that are available for exceptional access. Any drug that a physician has evidence could benefit a patient should be available through this mechanism.
2. Oncologists are qualified and knowledgeable about cancer drugs and can easily figure it out in a matter of minutes. If untrained individuals are going to make these decisions, we need to know who they are and what guidance they are following.
3. When other treatments have failed, a cancer patient is in dire need of a new choice and cannot wait for an answer.
4. An online application is the most efficient way to handle exceptional access. A simple one page form that the oncologist can use to fill in the data and click to send would be preferred to fax, telephone or any other process.
5. The best process would give an immediate approval and require the oncologist to report on results in two months. If the treatment has been successful, it should continue. If not, the exceptional access can stop.
6. If one of these drugs is used successfully and the patient has improved, the better health status should not lead to rejection of a renewal. Evidence of benefit could be a criterion for continued use.
7. Ontario does not pay for many cancer drugs that are proven effective and are widely used elsewhere. Apparently, cost is the deciding factor. The only condition that should apply to use of a cancer drug is whether it is effective.

Conditional listing during the review process

From the outset, the ministry promised an effective mechanism to ensure access to new drugs during the review period.

We recognize that the Ministry would not want to subvert its review process by inadvertently displacing a review with a long term conditional listing. It would be reasonable to put a time limit on conditional listings that are offered during the review process, such as a six months maximum with an option for one extension at the discretion of the Ministry. In this way, both the Ministry and the manufacturer have a clear understanding of what is expected and some unavoidable, no-fault delays in the review are reasonably accommodated. It should be clear however that if the conditional listing expires patients must be maintained on that treatment at the physician's discretion as if the listing had not expired.

- For breakthrough drugs: if the review has not been completed when NOC is issued, an immediate conditional listing on the date of NOC is appropriate.
- For products that have not qualified as breakthrough, but are a life-extending option in the treatment of a life-threatening disease: conditional listing is appropriate within one week of the product submission to MOHLTC.
- For products that ameliorate the debilitating side effects of a life-threatening disease: a conditional listing decision should be made within two weeks of the original submission.

- For products that treat non-life-threatening disease: a conditional listing decision should be made within one month of the original submission.

Evaluation

Annual reports from the Executive Officer must take on a new format in order to offer meaningful evaluation of the impact of this legislation. The historical focus on drug utilization and costs does not provide taxpayers with an adequate tool to measure the success or failure of these critical initiatives.

Not only do we need to see qualitative information about the improved health status of Ontarians (in cancer this would be survival rates) but we ask that annual reports include information on:

- Surveillance reports from the use of new treatments provided through conditional listings and exceptional access; in cancer this would mean months/years of life extended;
- Cost-effectiveness reports on the outcomes associated with individual drugs, classes of drugs, and the related diseases;
- Timeliness and the approval/rejection rates of reviews, appeals, applications for exceptional access;
- Time between submission date and final written agreements, conditional listings, and final decisions;
- Number of products rejected solely on the basis of cost;
- Number of complaints received and investigated from patients, prescribers, pharmacists and manufacturers;
- The effectiveness of written agreements in achieving savings;
- The effectiveness of competitive agreements in achieving savings; and
- Assessment of whether the legislation, regulations and policies have accomplished the goals stated by the Minister at the outset.

We would be pleased to meet with you and discuss this point further, as the evaluation itself needs more attention than this one letter can offer. Essentially, we agree with the remarks of many other groups that reporting and evaluation must incorporate patient outcomes, not just process and dollars.

Competitive Agreements

CACC remains concerned whether competitive agreements will be used to accomplish therapeutic substitution. If we find ourselves in a situation where the Ministry enters into contracts through competitive bidding, to select one drug that will be the only one covered from an entire group of similar drugs, then the Ministry is creating therapeutic substitution even farther away from the point of care.

Transparency and Disclosure

Again, although we have raised this point before it bears repeating. Disclosure of the rationale for rejecting a cancer drug cannot be cryptic. It will not be enough to report that the treatment is too expensive: cancer patients want to know how that determination was made and at what point the expense of their treatment became prohibitive. In that

context, patients also want to see a rational presentation of the relative expense of cancer survival compared to other major life-threatening diseases.

We understand that several working groups are now addressing the policy issues and that their reports will be made public in the near future. Those reports will become the final step in designing the implementation of the Minister's promises.

The CACC Board would be pleased to discuss any of these matters with you and to continue our fruitful dialogue on implementation details.

Sincerely



Colleen Savage
President & CEO