Patient Involvement in Drug Coverage Review

Ontario Public Drug Programs
Patient Evidence Submissions

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Overview

- **Background**
  - Ontario Public Drug Programs
  - Drug Funding Process in Ontario
  - Ontario Initiatives on Public & Patient Engagement

- **Patient evidence submission**
  - How to make a submission
  - How patient evidence submissions are used
  - Providing meaningful patient evidence
  - Experience to date
  - Next Steps

- **Questions & Comments**
Ontario Public Drug Programs (OPDP)

Ontario Drug Benefit (ODB) Program

• Approximately 3,300 drugs listed in the Drug Benefit Formulary/Comparative Drug Index (Formulary), and an additional 850 through the Exceptional Access Program.

• Provides drug benefits for Ontarians who are:
  • 65 years of age or older;
  • Residents of long-term care homes and homes for special care;
  • Recipients of professional home care services;
  • Recipients of social assistance, including Ontario Works and Ontario Disability Support Program;
  • Recipients of the Trillium Drug Program
Ontario Public Drug Programs (OPDP) (cont’d)

New Drug Funding Program (NDFP)
• Drug benefits for newer, intravenous cancer drugs, typically administered in hospitals and cancer care facilities.

Special Drugs Program (SDP)
• Drug benefits for Ontarians for certain expensive outpatient drugs used to treat specific diseases or conditions. (e.g. end stage renal disease, cystic fibrosis).

Inherited Metabolic Diseases (IMD) Program
• Covers certain outpatient drugs, supplements and specialty foods used in the treatment of specific metabolic disorders.

Others
• Visudyne Program
• Synagis Program
Ontario’s Drug Review & Funding Process

1. Health Canada issues market authorization
2. Manufacturer submits clinical & economic evidence
3. Common Drug Review (CDR): CEDAC recommendation to drug plans
4. iJODR / pCODR / CED-CCO Subcommittee
5. Ontario’s CED conducts review in the Ontario context. CED provides recommendation to Executive Officer.
6. Final funding decision made by Executive Officer

CEDAC = Canadian Expert Drug Advisory Committee
CED = Committee to Evaluate Drugs
CED-CCO = Committee to Evaluate Drugs - Cancer Care Ontario
iJODR = Interim Joint Oncology Drug Review
pCODR = pan-Canadian Oncology Drug Review
Committee to Evaluate Drugs (CED)

• An expert advisory group that makes recommendations to the Executive Officer on drug funding and related issues.

• Membership includes:
  • Physicians
  • Pharmacists
  • Health economists
  • 2 patient members (since June 2007)

• Key considerations for CED drug reviews:
  • Clinical efficacy and safety of the drug product relative to available alternatives
  • Cost-effectiveness (i.e. evidence of value for money) of the drug product relative to alternative treatments
  • Patient impact
  • Impact on other health care services
Executive Officer

- Makes final drug funding decisions taking into consideration:
  - CED recommendation
  - Advice from other advisory bodies, e.g. Citizen’s Council
  - Patient and societal impact, public interest
  - Product listing agreements with manufacturers
  - Drug program budgets
  - Other factors, e.g. government priorities
Public & Patient Engagement Initiatives

Public Engagement – Ontario Citizen’s Council

• An advisory body to the Executive Officer. The first of its kind in Canada, and one of only a handful in the world.
• Made up of 25 Ontarians representing a broad cross-section of the public.
• To meaningfully engage ordinary citizens about specific policy questions related to the province’s public drug programs.
• Recent discussions:
  • Management of Ontario’s drug formulary (April 2011)
  • Development of a values framework for the stewardship of Ontario’s drug formulary (June 2011)
Public & Patient Engagement Initiatives (cont’d)

Patient Engagement

• Executive Officer has regular and frequent meetings with patient groups to hear concerns and seek input.
• Transparency of decision making: clear and concise communication on drug funding decisions and the rationale.
• Two patient members appointed to the CED since June 2007.
• Patient impact is a key consideration for drug funding recommendations and decisions. (Patient impact is specifically outlined in the CED Terms of Reference.)
• Process for submission of patient evidence established in April 2010.
Patient Evidence Submission

Objective:
• To put in place a formal framework to systematically incorporate patient evidence into the drug review and funding process.

Rationale:
• Patients and caregivers can provide valuable information and insight about the impact of a disease and new and existing drug treatments.
• Patients and caregivers can identify areas of most importance to patients in the particular disease.
• This information can help set the context for the evaluation of clinical and economic data.
How to make a submission

- Patient evidence submissions are accepted from registered patient groups only. Individual patients are encouraged to contact an organized patient group if they wish to make a submission.
- Each patient group must submit a complete registration form, either prior to or at the time of submission.
- A drug review schedule is posted on the ministry’s website outlining all new drugs undergoing funding review. Patient groups are encouraged to check the drug schedule regularly and to provide their patient evidence submission on the Ministry’s template by the posted deadline.
  - Approximately a 3-month time period from posting on the drug review schedule to the submission deadline
  - Shorter deadline if the drug is undergoing “rapid review”
  - Balance: providing adequate time for groups to compile submissions while not delaying drug review and access

http://www.health.gov.on.ca/english/providers/program/drugs/patient_evidence/drugreview_schedule.htm
How to make a submission (cont’d)

• The patient evidence submission template form and the “how to guide” are posted on the Ministry’s website.
  http://www.health.gov.on.ca/english/providers/program/drugs/patient_evidence.html

• Submission template:
  • Author information
  • Conflict of interest declaration
  • Impact of the disease/condition
  • Outcomes that matter most to patients
  • Information from patients who have used this drug
How patient evidence submissions are used

- Patient evidence submissions are collated by the ministry and are provided to the CED.
- A CED patient member presents a summary of the patient evidence submission to the CED during drug funding deliberations.
- Patient impact is taken into consideration by the CED in its recommendation to the Executive Officer.
How to provide meaningful submissions

Information not required:
• Scientific evidence (e.g. clinical trial data) regarding the efficacy and safety of the drug product and its comparators. The CED already has this information.

Valuable patient information:
• The symptoms of the illness that are most difficult for patients.
• The treatment outcomes that are most important to patients.
• The most important aspects of the illness that patients would like the drug therapy to address.
• The shortcomings of existing therapies (that the new drug may or may not be able to address).
• Other practical aspects of the illness that should be taken into consideration (e.g. associated costs of living with the disease).
• By prioritizing the most important aspects of the illness and treatment outcomes, patient evidence can help set the context for weighing the clinical and economic data and understanding the therapeutic gaps that may exist.
Experience to date

<table>
<thead>
<tr>
<th>Patient evidence submission launched</th>
<th>April 2010</th>
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</thead>
<tbody>
<tr>
<td>Number of patient groups that have registered with the ministry</td>
<td>42 (include national patient organizations &amp; local patient groups)</td>
</tr>
<tr>
<td>Number of drug reviews for which the ministry has invited patient submissions</td>
<td>47</td>
</tr>
<tr>
<td>Number of patient evidence submissions received</td>
<td>30 submissions from 24 different patient groups (0 – 4 patient submissions per drug review)</td>
</tr>
</tbody>
</table>

- Consensus among patient groups, CED members, ministry staff and other stakeholders that patient evidence is an important and valuable component of the drug review and funding process.
- Opportunities for improvement
Next Steps

• A formal evaluation of the existing framework is currently underway to assess the current framework and to identify possible enhancements.

• We will be engaging with patient groups and other stakeholders over the coming weeks.

• Your feedback and suggestions are important to us.
Questions & Comments

Contact Information:
OPDP Patient Submission
5700 Yonge Street, 3rd Floor
Toronto, Ontario  M2M 4K5
Fax: 416-327-8123
Email: PatientSubmission.OPDP@ontario.ca

Patient evidence submission:

Ontario Public Drug Programs:
http://www.health.gov.on.ca/english/providers/program/drugs/drugs_program_mn.html