Balancing the Goals of Drug Plan Coverage to Optimize Patient Outcomes and Financing – Payor’s Perspective

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Ontario’s Health Expenditures: 2012

- **Hospitals & Other Institutions**: 42.7% ($21.5B)
- **Physicians & Other Profes.**: 24.1% ($12.7B)
- **Public Health & Admin.**: 10.1% ($5.3B)
- **Capital**: 5.4% ($2.8B)
- **Other**: 5.7% ($3.0B)
- **Drugs**: 9.0% ($4.5B)

Total health expenditures in Ontario: $49.8 Billion

Source: Forecast from the Canadian Institute for Health Information (CIHI), 2012
Overview of Ontario’s Public Drug Program

- 3.6 million eligible people (including 2.0 million seniors)
- Ontario Drug Benefit (“ODB”) Budget Breakdown FY 12/13 $4.5 billion
- The ODB program funds **over 3,800 drugs** listed in the Formulary, and an **additional 850** through the Exceptional Access Program.
- The ODB Program provides drug benefits for Ontarians who are:
  - 65 years of age or older;
    - Single seniors <$16,018 & couple seniors <$24,175 combined pay no deductible & $2 co-payment per prescription
    - Single seniors >$16,018 & couple seniors >$24,175 combined pay $100 deductible PLUS up to $6.11 per prescription
  - 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
Pressures on the Public Drug Funding System

- All forced to do more with less – focus on efficient resource utilization
- Aging population – number of claimants increasing by 4% year over year
- Drug costs are on the rise, and are now nationally the second largest health-care expense (public and private) after hospitals (*National Health Expenditure Trends 1975-2012*, CIHI)
- Pressure to fund new drugs and technologies: newer technologies are becoming increasingly targeted e.g. “personalized medicine,” resulting in high cost products focusing on care for a smaller number of recipients
- Absence of robust data in the specific population, and uncertainties related to effectiveness, safety, and cost-effectiveness
- Many new products, particularly those for small patient populations, do not meet traditional benchmarks of cost-effectiveness. The studies performed are often limited in providing information on whether the drugs affect important outcomes for patients.
- Sustainability of public drug funding in the context of overall health care spending is a concern for all public payers
Understanding the Drug Funding Process

Manufacturer submits

Health Canada
Issues NOC & DIN

Manufacturer submits

pCODR Products
(NCE / new combination product / new indication)
pERC recommendation to drug plans specific to oncology drugs

Common Drug Review products
(NCE / new combination product / new indication)
CDEC recommendation to drug plans

Non-CDR products / non-pCODR products

Ontario’s CED reviews Health Canada status, CDR recommendation, pCODR recommendation and conducts Ontario-specific review.

CED provides recommendation to Executive Officer to reimburse (or not) through publicly funded program

Interim decision made by Executive Officer

Negotiations

Final decision made by Executive Officer

NOC = Notice of Compliance – indicating drug is safe and effective
DIN = Drug Identification Number
CDR = Common Drug Review
CDEC = Canadian Drug Expert Committee
pCODR = pan-Canadian Oncology Drug Review
PERC = pCODR Expert Review Committee
NCE = New Chemical Entity

Up to 2 years
Non-transparent

Up to 1 year
Transparency

Up to 2 mths
Transparent

~ 1 month

Open ended
Ontario’s Drug Decision Making Process

Committee to Evaluate Drugs (CED)

• Advisor to decision maker
• CED is made up of physicians, pharmacists, and an economist who have expertise in a wide range of specialties including geriatrics, infectious disease, family medicine, pharmacology, health economics, epidemiology and other disciplines, as well as patient members to provide meaningful public input into the overall drug-funding recommendation process
• Make recommendations on funding, taking into consideration:
  • Systematic evaluation of new drug in comparison to currently available therapies to treat the same disease
  • Clinical evidence and therapeutic role*
  • Cost-effectiveness
  • Societal values
  • Patient Evidence Submission
• Accountability: Executive Officer

Ontario base drug funding decisions on health benefits of the drug relative to existing treatment options while accounting for budgetary constraints and the best available evidence. Evidence (including current published evidence, clinical safety and effectiveness, etc.) is used to guide decision-making process. Evidence must answer a number of questions:

<table>
<thead>
<tr>
<th>Should A New Therapy Be Made Available?</th>
<th>Is the Therapy Good Value for Health Spending?</th>
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<tbody>
<tr>
<td>• Evaluate if a therapeutic entity works to: reduce symptoms, improve quality of life, and/or prolong life</td>
<td>• Does the therapy work, based on clinical trials? (Benefits compared to standard care, benefits relative to harms)</td>
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<tr>
<td>• Is it safe for long-term use, with other patients?</td>
<td>• Is the therapy the best value for health dollars? (Benefits of new and alternative treatments, total costs of treatments including adverse effects)</td>
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<td>• What indicates how well it is working?</td>
<td>• Is therapy better value than other uses for health care dollars? (Cost-effectiveness, societal values)</td>
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<td>• How much should be given, for how long?</td>
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<td>• What are the “serious” potential harms or side effects?</td>
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<td>• Do the benefits outweigh the risks?</td>
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Executive Officer (EO)

• Decision maker
• Makes actual funding decision, taking into consideration:
  • CED recommendation
  • Managing ODB and other public drug program budgets
  • Advice from other advisory bodies e.g., Citizen’s Council
  • Negotiations with manufacturers
  • Others e.g., political, ethical, legal

• Accountability: Minister and Cabinet (Deputy Minister for ADM responsibilities)
Integrating Public Perspectives within the Decision-Making Process for Optimal Patient Outcomes

- Reimbursement decision making for pharmaceutical products is complex and is inherently a multi-factorial decision making process.
- While clinical efficacy, safety and cost-effectiveness are important, it is recognized that drug reimbursement decisions involve input from stakeholders, deliberating about the full range of relevant values, within a process that is transparent and responsive.
- Ontario has put in place the following mechanisms to engage the public in a meaningful way and to operate transparently to the extent possible for all persons with an interest in the drug system:

  1. **Patient Evidence Submission**
     - Established a formal process in April 2010 for patients or caregivers, through an advocacy group, to submit evidence for new drugs undergoing funding review. The CED will take into consideration this information as well as the clinical evidence, the cost effectiveness and Ontario’s budget impact analysis when making their recommendation.

  2. **Citizens Council**
     - Established a Citizens' Council to engage ordinary citizens in discussions about societal values that should be considered in making drug policy decisions. Members discuss specific policy questions related to the province’s public drug programs, and provide their views to the Executive Officer and the Minister. This information is used to inform the ministry as it develops its health policies and programs.

  3. **Cancer Care Ontario’s Disease Site Groups**
     - The Disease Site Groups (DSG) are comprised of clinicians and content and methodological experts who work together to define practice questions, identify all relevant evidence, appraise and interpret the literature, and come to consensus on recommendations for specific cancer-related treatments.
     - In certain cases, submissions may be provided from the DSG to support funding recommendations.
Building on Evidence Based Approach

- **Ontario’s Evidence Building Program & Case-by-Case Review Program**
  - In March 2011, Ontario announced a new Evidence Building Program (EBP) for cancer drugs. The EBP is intended to provide funding for cancer drugs already funded through the New Drug Funding Program where there is some evidence supported expanded indications.
  - Data collected through the EBP will be evaluated and will inform a final funding decision by the Executive Officer.

- **Ontario’s Drugs for Rare Diseases Framework**
  - In absence of a national strategy with federal involvement, Ontario moved forward to develop a funding framework for Drugs for Rare Diseases (DRDs). This framework recognizes that an innovative approach is required for DRDs and considers the level of available clinical evidence, patient need, and the current funding gap. The framework takes into consideration the uniqueness of rare diseases and the drugs to treat them; it considers the “best achievable evidence” upon which we can make our funding decisions for DRDs.
  
  - To date, seven drug reviews under the DRD framework have been completed: Elaprase for Hunter Syndrome; Myozyme for Late Onset Pompe Disease; Zavesca for Niemann Pick Type C (NPC); Naglazyme for Maroteaux-Lamy Syndrome (MPS VI); Aldurazyme for MPS I; Zolinza for the treatment of Cutaneous T-Cell Lymphoma (CTCL); and Ilaris for cryopyrin associated periodic syndrome (CAPS).
Ontario’s Cost Containment Initiatives to Address Drug Funding Pressures

• Address competing funding pressures through:

• Two rounds of significant drug reforms:
  • 2006 focused on achieve better results and have better access to drugs as well as addressing the need for governance, transparency and accountability within the system
  • 2010 focused on better value for money for generic drugs compared to other jurisdictions and considering payments within the drug system (e.g. eliminate professional allowances)
    ▪ Shift in reimbursement model to focus on clinical pharmacy services - new investments to compensate pharmacists for professional services provided to patients
    ▪ Expanded MedsCheck programs – MedsCheck LTC, At home, Diabetes; Smoking Cessation for program for ODB recipients; Pharmaceutical Opinion program
    ▪ Increasing dispensing fee for all prescriptions dispensed under the public program; additional increase for eligible pharmacies in rural and underserviced areas
  • These two sets of reform have resulted in an estimated savings of over $1B that has been reinvested into the drug system

• Aggressive management continues:
  • Seniors Income Testing Project for high income seniors
  • Obtaining better value for money for high use generics
  • Pan-Canadian Initiatives on Pricing and Reimbursement