Health Technology Assessment: A Provincial Payer Perspective

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Ontario, and its Drug System

Ontario

- 12 million people, and one of the most multi-cultural societies in the world
- Provincial budget almost $100 billion in 2009/2010

Ontario Ministry of Health and Long-Term Care

- Budget of approx. $43 billion, representing close to 50% of provincial spending
- Provide services such as physician visits, hospital visits, drug benefits, long-term care, home care, community and public health, among others
- Regulates hospitals, nursing homes; coordinates EMS; operates medical labs

Publicly funded drug programs

- $4.2 billion, or 10% of total healthcare spending
- 2.8 million eligible people (2.2 million seniors)
- One of most generous drug plans in Canada; fund > 4,000 drug products (DINs)
Drug Funding Review Process

1. Manufacturer submits

2. Health Canada Issues NOC & DIN

   NOC= Notice of Compliance
   DIN= Drug Identification Number

   - Common Drug Review products
     (NCE / new combination product)
     CEDAC recommendation to drug plans
   - Non-CDR products/Cancer products

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

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

4. Final decision made by Executive Officer
# Roles and Responsibilities

## Committee to Evaluate Drugs (CED)

- Advisor to decision maker

- 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

- **Accountability:** Executive Officer, Ontario Public Drug Programs

## 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:** Deputy Minister, Minister and Cabinet
Use of HTA in the CED review process

- Fundamental question: "Will drug provide good clinical value and good use of scarce health care resources if it is funded?"

- Types of evidence reviewed
  - Clinical/scientific evidence
    - Efficacy: Does it work in comparison to other available therapies?
      - Assess clinical impact/benefits in comparison to alternative treatments; expect new drug at least as good as already funded to treat disease
    - Safety: Does it cause no more harm than other available therapies?
      - Assess drug's side effects in comparison to alternative treatments; expect new drug will be at least as safe as what is already funded to treat the disease
  - Evidence of value for use of scarce resources
    - Pharmacoeconomic data
    - Budget impact analysis
  - Patient impact
    - Patient CED members and soon to be launched patient-evidence submission process
Use of HTA in decision making

• As a tool, informs decisions...but not sole determinant e.g., ethical considerations, political priorities, legal obligations

• Summarizes what is known in a systematic and unbiased manner...but on its own cannot interpret information and context

• Shines a light on what is not known...but there is not always consensus on how to reduce that uncertainty

• Can help to evaluate harms that may not get captured early in drug development...but even reasonable, well-intentioned people ignore the “smoke signals”

• Opens a window to dialogue on what you get (from a new technology) and what you have to give up (from a resource allocation perspective)...but on its own will not ensure that dialogue happens and need to have parties who want to and who understand each others’ perspectives
Challenges of applying HTA to decision making

- **Increased public pressure for rapid drug reviews**
  - Complex and expensive decisions – clinical and economic price of “getting it wrong”
  - How to balance speed against thoroughness and input from clinicians, patients, society?

- **What about drugs for different diseases?**
  - If all diseases are (as are all patients) unique, should there be different evaluation standards depending on the disease?
  - Do you need to ensure equity? If so, how? If not, when?
    - End of life, rare diseases, severe / catastrophic disease

- **“Values” questions depend on whose values:**
  - Should we fund an expensive drug that provides a small benefit?
  - Should we fund a drug that has weak evidence of potentially large benefit?
  - At what point is a drug too expensive to fund?
  - Whose perspective should dominate and when?
Moving Forward

• Rapid Review process
  – For pre and post-NOC submissions where drug is either clinically or economically compelling

• Compassionate Review Policy
  – Make consistent and fair funding decisions
  – Balance patient needs with fair consideration of policy implications

• Product Listing Agreements
  – Provide patients with improved access to drugs, under certain conditions which are based on CED recommendations
  – Improve accountability and enforcement by supporting funding decisions through a negotiated process between the Ministry and brand manufacturers

• Drugs for Rare Disorders
  – Recognize current tools to evaluate efficacy, effectiveness, and cost-effectiveness are not helpful in this circumstance
  – Working group has developed evaluation framework; initial consultations conducted

• Citizen’s Council
  – Add societal values to drug review/reimbursement process
  – Will help provide direction to the Ministry on how to allocate resources
Compassionate Review Policy

- Vast majority of funding decisions continue to be based on rigorous review of best clinical and economic evidence available

- Instances where a review has not occurred and where a patient is in dire clinical circumstances (e.g., immediately life, limb or organ threatening) may now be considered under newly defined Compassionate Review policy of the Exceptional Access Program

  http://www.health.gov.on.ca/english/providers/program/drugs/eap_mn.html

- Policy outlines six specific criteria against which individual funding requests are assessed. Aim is to make assessment of requests on compassionate grounds consistent and fair

- EO may also request CED to perform a review and provide recommendation for a drug or indication in the absence of a manufacturer submission for the purposes of consideration under EAP.

- EAP will consider requests for drugs approved through Health Canada’s Special Access Program (SAP) **IF** criteria for Compassionate Review policy are met
Listing Agreements: Context

• Written agreement process prior to Bill 102
  – Limited to financial forecasting for impact of reimbursement decisions
  – <5 written agreements with accountability provisions were in place

• Impetus for change
  – Opportunity to provide access to specific patient populations that would benefit most (and where General Benefit was not appropriate)
  – Inability to leverage purchasing power to achieve better prices
  – No ability to enforce financial accountability with written agreement forecasts or to encourage appropriate marketing / utilization
  – Limited ability to re-evaluate listings
  – Reliance on administrative barriers (e.g., ICR) to drive utilization

• Evolving role of CED, in relation to newly created role of Executive Officer and under landscape of a national Common Drug Review process
Listing Agreements: Components

- **Clinical**
  - Criteria for funding (criteria; prescribing notes; etc)
  - Appropriate use promotion e.g., targeted educational initiatives, disease management programs, adjudication tools, post-marketing surveillance evaluations

- **Financial**
  - Reduced price (transparent)
  - Price Volume Discount
  - Cost off-sets
  - Risk-sharing with price caps: Soft & hard caps

- **Monitoring/Surveillance**
  - Funding health system research e.g. observational studies, effectiveness studies, pharmacoeconomic studies with real world data
Drugs for Rare Diseases (DRD) Review Process

- In absence of a national strategy, Ontario has moved forward to develop a draft framework to evaluate Drugs for Rare Diseases (DRD) for funding consideration.

- No restriction on eligible diseases that can be considered for, as long as they meet the interim eligibility criteria (*including an incidence of < 1:150,000 and the inability/lack of RCT data that is adequately powered to detect significant differences in clinically relevant outcomes*).

- Approach acknowledges inherent difficulties for these types of drugs to generate scientific evidence, including evidence on meaningful clinical outcomes and value for money.

- Evaluation includes the construction of predictive models that are based on an in-depth review of what is known about the natural history of the disease and its impact on patients, involving experts to fill in any knowledge gaps, and the potential effects of the drug in question.
Ontario’s Citizen Council

• Evolved out of the ministry’s need to meaningfully engage the public on an on-going basis in health care policy making and provide a mechanism for citizens to provide input into drug policies and priorities

• Creation was included in the Transparent Drug System for Patients Act (TDSPA) as part of the Government’s comprehensive plan to reform Ontario’s drug system. It is part of an effort to improve the transparency and legitimacy in the Government decision-making processes by ensuring patient involvement in the development of drug and health policy

• Also enshrined in legislation, is the principle that funding decisions for drugs are to be made on the best clinical and economic evidence available. However, with new drugs constantly coming to market and limited public funds available, drug funding decisions have become increasingly complex and the ministry realizes that there is need to consider additional societal values in the decision-making framework

• The ministry is relying on the new Citizens’ Council to identify the additional values and societal considerations that we as decision makers should keep in mind so that we align our actions with the values of Ontarians’ as we shape drug funding policies to ensure a sustainable and more effective drug system for Ontarians.
Status Update: Citizens’ Council

- 25 Members have been recruited through a public campaign

- In November 2009, a training session was held to review purpose and mandate for the Citizens’ Council

- The first Council meeting was January 29 – 31, 2010

- As their first question, the Council discussed under what situations and/or conditions should the Ontario Government (i.e., taxpayers) should pay for drugs for rare diseases

- The Council’s opinions will be provided to the Executive Officer, Ontario Public Drug Programs, in a report

- The Executive Officer will then publicly respond as to how the Council’s recommendations/advice will be used

On the horizon

- Patient evidence submission process to provide disease specific context in funding decisions

- Setting some principles from a provincial perspective on managing the “adequate” vs. “feasible” divide in evidence generation, synthesis, interpretation and application

- Coverage with Evidence development?

- Other suggestions?
Backup slides
Ontario Public Drug Programs

• Systematic consolidation of drug benefit programs across MOHLTC
  – Ontario Drug Benefit (ODB) Program
  – Cancer Care Ontario (CCO) New Drug Funding Program (NDFP)
  – Special Drugs Program
  – Trillium Drug Program
  – Exceptional Access Program (EAP)
  – Inherited Metabolic Diseases (IMD)
  – Visudyne
  – Respiratory Syncytial Virus Prophylaxis for High-Risk Infants Program

• Many programs are historical / legacy decisions
• Differ in eligibility, application of cost-sharing mechanisms, administration and operations
Highlights of Ontario Public Drug Program

- Program is mandated in legislation and regulations (Transparent Drug System for Patients Act)
- Chief Executive Officer that makes all decisions re funding, operations, etc.
- Enter into listing agreements with brand manufacturers; negotiated prices, caps, prescribing notes, etc.
- Rapid review process to speed up review of “truly innovative” drugs
- Regulate prices for generic products (90% are regulated at 50% of brand price)
- Require generic substitution, where available
- Reimburse pharmacy for cost of drug plus 8% mark-up plus $7 dispensing fee
- Reimburse pharmacy for one-on-one medication review with patients, $50/MedsCheck
- Conduct regular audits of pharmacies to ensure compliance with law
Funding Options

- **General Benefit**
  - Open; may be freely prescribed by physicians
  - “Behind the scenes”, ministry may have a product listing agreements, which includes financial parameters, prescribing notes, Facilitated Access prescribing, etc.

- **Limited Use**
  - Requires that physician notes Limited Use code
  - Being phased out

- **Exceptional Access**
  - Criteria under which drug may be funded
  - Case-by-case review, according to criteria
  - Some cases sent out for external review
Exceptional Access Program

- Provide access to specific drugs on an exceptional basis
  - New drugs that do not have robust evidence regarding comparative efficacy, safety and / or cost-effectiveness
    - Efficacy vs. comparators relatively small
    - Efficacy not convincingly demonstrated
    - Price much higher than comparator(s)
    - Cost-effective only in a sub-group of patients
  - High cost therapies and associated with risks of usage outside approved indications
Rapid Review Mechanism - process

- 3-member CED panel (incl. CED chair) struck to assess RR request
- MOH screening: 2 weeks
- RR assessment by CED panel: 2-4 weeks
  - depends on complexity of request
  - economic requests will be sent to external reviewer for abbreviated clinical opinion to validate underpinnings of PE model or BIA
- External clinical and PE review: 4 weeks
- CED meeting: next available, 1st item on agenda
- MOH funding decision
  - If submitted 60-90 days pre-NOC, benchmark of funding decision within 30 days of NOC or NOC/c issuance
  - If submitted <60 days pre-NOC or anytime post-NOC, funding decision made as soon after CED as possible, subject to PLA negotiation
Compassionate Review Policy

Intended to:

- Make consistent and fair funding decisions
- Balance patient needs with due diligence
- Obtain best information on which to base funding decisions
- Align with other drug review policies

NOT intended to:

- Fund every drug for every possible use
- Circumvent or bypass current regulatory and review process
- Act as a substitute to proper clinical trial evaluation
- Transition patients from manufacturer sponsored expanded access programs
Listing Agreements: Process

- Agreements have made significant impact on improving access to therapies by reducing administrative barriers
- More accurately estimating financial exposure of funding decisions and overall spending growth = better management of the program
- Negotiating and monitoring agreements is resource intensive, but process improvements (e.g., standardized contract provisions, creation of work flow framework, monthly monitoring team meetings) are being designed as more experience is gained
- OPDP is actively monitoring listing agreements on an ongoing basis, including those that are listed with conditions