Individual Patient Funding Programs:
Policy Considerations

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Presented by:
Glenn McAuley, Senior Pharmacist, Drug Programs Services, Ontario Public Drug Programs
Scott Gavura, Director, Provincial Drug Reimbursement Programs, Cancer Care Ontario

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Acknowledgements

Rohini Naipaul
Pharmacist, Provincial Drug Reimbursement Programs, CCO

Sherry O’Quinn
Senior Pharmacist, Drug Programs Services, OPDP

Lyndee Yeung
Program Manager, Provincial Drug Reimbursement Programs, CCO

Brent Fraser
Director, Drug Program Services, OPDP

Amanda Chan
Project Coordinator, Provincial Drug Reimbursement Programs, CCO
Overview

- How does Ontario structure its public drug programs?
- Why “exceptional” and “compassionate” access?
- Why develop a policy and program just for cancer drugs?
- How is Ontario’s Case-by-Case Review program structured?
  - How does it compare to the rest of Canada?
- What international examples exist?
- What are the policy lessons?
Key facts of Ontario’s Public Drug Programs

Several distinct programs
- e.g. Ontario Drug Benefit (ODB) Program, New Drug Funding Program (NDFP)
- The ODB program includes the Exceptional Access and Trillium Programs

$4.3 billion in expenditures
- Almost 10% of total provincial healthcare spending

3.5 million recipients
- Including 2 million seniors

3,800 distinct DINs funded on the ODB formulary
- Additional 850 DINs through the Exceptional Access Program
The Evolution of “Exceptional Access”

“Section 8”

Individual Clinical Review

Exceptional Access Program
Growth of the Exceptional Access Program from 2000 to 2010

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th># of EAP Beneficiaries (in thousands)</th>
<th># Requests Received (in thousands)</th>
</tr>
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<tbody>
<tr>
<td>2000-01</td>
<td>28</td>
<td>50</td>
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<tr>
<td>2001-02</td>
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<td>2008-09</td>
<td>108</td>
<td>191</td>
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<tr>
<td>2009-10</td>
<td>126</td>
<td>163</td>
</tr>
</tbody>
</table>
Why a “Compassionate Review Policy”?

Why
- Rare circumstances
- Immediately life-, limb-, or organ-threatening conditions
- No funded drug, and no funding review expected (i.e., off-label use)

What
- Considers funding requests in absence of formal review
- Not intended to circumvent normal funding consideration processes

How
- Criteria* developed to promote consistent and fair decisions
- Some published evidence to support use must be provided

All 5 criteria must be met for CRP consideration

EAP requests reviewed by the CRP: from 2009-2013

- 1,196 requests assessed
- 744 requests approved
- 81 drugs funded
- $1.3M in expenditures (2009-10 only)
Why develop a special program for cancer?

CRP applies to treatments provided by outpatient pharmacies only

- Not intended for hospital- or NDFP-based IV treatments
- No compassionate access mechanism to fund cancer drugs outside of NDFP criteria

CRP interpretation is challenging in the context of cancer

- Most or all cancers are compassionate “life-threatening” cases by default
- Criteria is not disease-specific

Compassionate cancer cases are often unique

- Difficulty in obtaining disease-site expertise
- Time-consuming process for EAP pharmacists to research requests
The evolution of “compassionate” access to cancer drugs

- **CCO Piloted Special Access Program**
  - 2002-3

- **Proposed Special Authorization Program**
  - 2006

- **CRP Policy published**
  - 2009

- **CCO-OPDP Policy work**
  - 2009-10

- **CBCRP Launch**
  - 2011
OPDP/CCO policy work identified how CRP could be adapted to cancer drugs

Special funding requests received by CCO 2009/10

- Dose/regimen modification: 65%
- Not fundable: 30%
- Compassionate: 5%
# The Case-by-Case Review Program Proposal

## Policy
- Extends and adapts CRP to hospitals
- Accepts requests for oral and injectable drugs
- Rare clinical circumstances, no other funded options
- Immediately life-threatening situations
- Not intended to fund in advance of formal evaluation through other channels (e.g. pCODR)

## Eligibility
- For all Ontario residents:
  - NDFP (hospital therapies)
  - ODB (out-patient therapies)

## Method of application
- Treating physician submits request via CCO website
Cancer-specific adjudication criteria

Refer to the full policy at www.cancercare.on.ca/cbcrp
CBCRP Consideration process

Physician uploads request

Request screened by CCO pharmacist

Literature search and summary conducted

Evaluation and recommendation to MOHLTC

At least 2 reviewers must support request

Request forwarded to up to 3 clinical experts

Executive Officer Decision

CCO notifies physician and hospital (as req’d)

Public funding commences

Appeal Process
Policy and program challenges

Physician uploads request

Request screened by CCO pharmacist

Literature search and summary conducted

Evaluation and recommendation to MOHLTC

At least 2 reviewers must support request

Request forwarded to up to 3 clinical experts

Executive Officer Decision

CCO notifies physician and hospital (as req’d)

Public funding commences

Appeal Process
CBCRP Results: Nov 2011 to Feb 2013

101 requests for funding

28 approved requests

14 drugs funded (oral and injectable)

$490,542 projected expenditure

$261,270 actual expenditure

11-day turnaround
How does the rest of Canada do it?

9 provinces surveyed
7 provinces offer similar programs

More than 6,700 patients funded per year*

*depending on the definition
Programs and policies are more different than they are similar
Do any of the following inform your eligibility criteria or decision-making process?

- Alternative access options
- Frequency of requests
- Rarity of cancer
- Clinical appropriateness
- Supporting evidence
- Alternative treatment options

Patient denied from clinical trials, Manufacturer access programs, etc.
The adjudication process

Standard sequence of events:

- Evaluation and review by group or individual medical consultant(s)
- Final decision made by head of program

<table>
<thead>
<tr>
<th>Adjudicators</th>
<th>Decision-makers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advisory committee (chair)</td>
<td>Executive director /officer</td>
</tr>
<tr>
<td>Medical consultant/reviewer</td>
<td>Medical consultant</td>
</tr>
<tr>
<td>Pharmacist</td>
<td>Medical director</td>
</tr>
<tr>
<td>Medical director</td>
<td>Advisory committee</td>
</tr>
</tbody>
</table>

# of provinces

0 1 2

1 2 3
Opportunities to appeal

5 programs offer opportunities to appeal funding decision

- Appeal process offered: 5
- No appeal process: 2

Appeal assessment:

- Oncology physicians
- Sr. medical officer
- Program director
- Committee chair
- Medical director
- Tumour group
- Systemic treatment designate
- Clinical experts
How does Canada compare internationally?

Cancer patients facing race against clock for drugs in fund 'betrayal'

Drug firms cash in on David Cameron's £650million cancer fund sparking new lobbying row

Drugs fund axe 'will hit 16,000 cancer patients' as experts claim access to medication will be worst in Europe
England’s Cancer Drugs Fund is the closest international comparator

**Why**
- Fund drugs not reviewed by NICE
- Fund drugs not recommended by NICE
- Interim approach to new national funding scheme

**What**
- National list of drugs/indications routinely funded
- Special application process for unfunded drugs
- £200m/year budget, ends March 2014

**How**
- Was a regional program, national as of April 1
- Standard Operating Procedure
- Reviewed by panels of clinicians; appeal process in place

**Who**
- Rare conditions (<20/year in England) OR
- Off-label use and no national policy on use OR
- “Clinical exceptionality”

What are the key learnings?

• Craft your policy carefully
  • Be specific: what’s eligible and what’s not
  • Rely as much as possible on objective criteria
• Public commitments to transparency are preferred
  • Consult to ensure policy is well understood
• Expert clinician engagement in the process adds credibility to evaluations
  • Reviewer training and review templates help ensure consistency in reviews
• Establish an appeal process
• Don’t underestimate the complexity and workload required
• Commit to performance measures and report on them
For more information

Policies:
OPDP’s Compassionate Review Policy:
CCO’s Case-by-Case Review Program:
http://www.cancercare.on.ca/toolbox/drugs/cbcrp/

Contacts:
glenn.mcauley@ontario.ca
scott.gavura@cancercare.on.ca