ECONOMICS IN FORMULARY DECISION MAKING

EXPERIENCES FROM ONTARIO

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Disclaimer

- Views here are my own
  - Not the committees’ I’ve been a member of

- All data presented are publicly available

- I can’t disclose confidential information
  - Recommendations that have not been made public
  - Data which are not freely available
Outline

- Role of economics within current mechanisms for deciding on which drugs are reimbursed in Ontario

- Why it's not so easy to make recommendations for funding
ROLE OF ECONOMICS WITHIN THE CURRENT MECHANISMS FOR DRUG REIMBURSEMENT IN ONTARIO
Current mechanisms for drug reimbursement in Ontario

Industry submits evidence to Common Drug Review
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Review of submission by CDR and recommendation for funding by CDEC
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- Recommendation sent to Ontario Public Drugs Program and considered by Committee to Evaluate Drugs
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Recommendation sent to Ontario Public Drugs Program and considered by Committee to Evaluate Drugs

CED makes recommendation for funding
Committee to Evaluate Drugs

- Initially established in 1968 as the Drug Quality and Therapeutics Committee
- Drug submissions similar to CDR
- Considers drugs previously considered by CDR
- Includes submissions not considered by CDR
  - e.g. Line extensions, oncology products
- 16 members including 2 patient representatives
CED and OPDP

- CED advises the Ontario Public Drug Programs
- Recommendations
  - Do not list (no means no)
  - Exceptional access
  - General benefit
  - Conditional listing
- Not all recommendations from CED adopted by OPDP
  - Role of OPDP to negotiate price discounts and other listing agreements
  - Political pressures
Role of Economics within CED

- Economist reviews economic submission from manufacturer.
- Consideration of cost effectiveness one aspect of CED discussion.
- One health economist member on CED since 2006.
Current mechanisms for drug reimbursement in Ontario

Industry submits evidence to Common Drug Review

Review of submission by CDR and recommendation for funding by CDEC

Recommendation sent to Ontario Public Drugs Program and considered by Committee to Evaluate Drugs

CED makes recommendation for funding

OPDP Executive officer/ADM makes funding decision
Criteria considered in funding recommendations

- Quality of clinical evidence
- Effect size
- Safety

- If effective/safe then can focus on cost effectiveness
  - Unofficial benchmark of around $50,000 per life year gained or QALY gained.

- Budget impact
# Review of CED recommendations

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Subcriteria (Evidence)</th>
<th>Definitions</th>
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<tbody>
<tr>
<td>Overall clinical benefit</td>
<td>Effectiveness</td>
<td>Potential impact on health compared to alternatives measured in terms of relevant patient outcomes including mortality, morbidity, and quality of life of persons</td>
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<td>Safety</td>
<td>Frequency and severity of the adverse effects specific to the new health technology compared to the available alternatives</td>
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<td>Burden of illness</td>
<td>Burden of illness on society as evidenced by the incidence, prevalence or other measure of disease burden</td>
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<td>Need</td>
<td>Availability of an effective alternative to the technology. Need may be great if no other alternatives are available</td>
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<td>Consistency with societal and ethical values</td>
<td>Societal values</td>
<td>Broadly shared values in society which bear on the appropriate use and impact of the technology</td>
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<tr>
<td></td>
<td>Ethical values</td>
<td>Potential ethical issues inherent in using or not using the technology. Relevant ethical issues should be listed</td>
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<tr>
<td>Value for money</td>
<td>Economic evaluations (e.g., incremental cost-effectiveness or cost-utility, cost-effectiveness acceptability curves, or cost consequence analysis)</td>
<td>Measure of the net cost or efficiency of the health technology compared to available alternatives. OHTAC does not use a value for money threshold</td>
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<tr>
<td>Feasibility of adoption into health system</td>
<td>Economic feasibility</td>
<td>Net budget impact derived by determining all relevant costs and savings to the healthcare system in Ontario. The default perspective for the budget impact analyses will be that of the funder of the health system. OHTAC may request alternative perspectives if they would better inform the decision-making process</td>
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<td>Organizational feasibility</td>
<td>Ease with which the health technology can be adopted will be evaluated by looking at the health system enablers and barriers to diffusion within the health system infrastructure (operational, capital, human resources, legislative, and regulatory)</td>
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Review of CED recommendations of 44 single source drug submissions: July 2010-July 2011
WHY ITS NOT SO EASY TO MAKE RECOMMENDATIONS FOR FUNDING
Process issues

- For new submissions: committee can only review evidence submitted by industry and published literature
  - No commissioned research

- Have to consider a large number of drugs
  - Typically between 10-15 in a 4 ½ hour meeting

- Many drugs that are covered have a Product Listing Agreement
  - Could cover cost, budget caps, education etc.
  - Committee does not have details of PLAs
Non “economic” reasons that make decision making difficult

- Quality of clinical evidence
- Relevance of clinical evidence
- Lack of safety data
- Linking clinical trial outcomes to long term patient related outcomes
- No direct comparisons of treatment alternatives
- Patent issues
- Unclear budget impact
“Economic” issues that make decision making difficult

- Inappropriate assumptions
  - Choice of parameter values favourable to the product
- Inappropriate modelling methods
  - e.g. use of partitioned survival models
- Lack of transparency in modelling
- Product listing agreements
- Companion diagnostics
Issues that “dilute” the role of economics

- Therapeutic gap
- Rarity
- Disease severity
Burgeoning issues to consider

- How much are special cases worth?

- Limited consideration of opportunity cost
  - Isolation bias

- Preponderance of confidential PLAs limit the ability to make consistent decisions

- Increase in biologics and pharmacogenomics
  - Likely to lead to a reduction in the ability to pay for a health benefit
Conclusions

- Economics plays a “role” in decision making within the Ontario drug plan

- Other factors play more major role

- Developments likely to make decision making more difficult with respect to restraining the OPDP drug budget