The HTA Developments in the Central and Eastern European Region: Lock, Stock & Barrel in Challenging Times

Recent Developments in the Process of Updating the National List of Health Services in Israel

Dan Greenberg, Ph.D.
Ben Gurion University of the Negev and ISPOR-Israel

The Israeli Healthcare System

- A semi-public system, dominated by the Ministry of Health (and the Ministry of Finance) and the country’s four health plans (HMOs)
- The National Health Insurance Law (NHIL) enacted in 1995 has made health insurance both compulsory and universal
- The NHIL stipulates a National List of Health Services (NLHS) which all residents are entitled to from their health plans (A positive list)

The Process of Updating the NLHS

- The NLHS has been updated annually since 1998
- Every year, as part of the annual budgeting process, the government determines the budget that will be available to fund new technologies to be added to the NLHS
- Submission of dossiers according to guidelines published by the Ministry of Health

The Process of Updating the NLHS

- Rapid screening and assessment of the proposed technologies
- Comprehensive evaluation and ranking of technologies
- Discussions and recommendations made by the Public National Advisory Committee (PNAC)
- Government approval, legislation and allocation of funds to health plans
The Process of Updating the NLHS

Recent Developments

- New guidelines for submission of economic evaluations
- Risk-sharing agreement applied for the first time

Submission Guidelines

- Clinical and epidemiological data
  - Clinical/pharmacological profile
  - Pharmacoepidemiological data
  - The new treatment equilibrium
  - Supporting clinical information

- Economic evaluation
Submission Guidelines

- Submission of economic evaluations has been previously required
  - Submission was not mandatory
  - Detailed submission guidelines did not exist
  - Technology sponsors were not required to submit the actual model (e.g., Excel, Data TreeAge)
- As of 2010, sponsors of expensive technologies (>\$30,000 per patient per year) are required to submit results of a cost-effectiveness analysis

Requirements for Economic Evaluations

- Detailed guidelines for submission of economic evaluations published in January 2010
- A training session presenting the guidelines was held in February 2010
- Deadline for submissions - April 15, 2010
- Submissions reviewed by the MOH and the Israeli Center for Technology Assessment in Health Care

Use of Economic Evaluations

- A total of 22 economic evaluations were submitted
  - 17 drugs (including 4 orphan drugs)
  - 5 medical devices
- Only 10 of the submissions were mandatory (>\$30,000 per patient per year)
Use of Economic Evaluations

- Summary reports of each economic evaluation were submitted to members of the PNAC
- Nine technologies were presented at PNAC sessions close to the end of the deliberations
- No evidence that cost-effectiveness analyses have been considered in the decision-making process

Lessons

- It is unrealistic to perform and present economic evaluations for all submitted technologies
- Priority should be given to technologies with a high budget impact (rather than a high cost per patient)
- Economic evaluations should be presented to PNAC members earlier in the decision-making process

Budget Impact Projections

- A sub-committee of representatives from the MOF, MOH and the four health plans provides the PNAC with the anticipated budget impact of each technology considered
  - Product of the annual treatment costs per patient and the projected number of patients in need of the technology
- Projections consider rates of market growth and the proportions at which the new drug will replace an intervention already included in the NLHS for the same indication

Risk-Sharing Agreements

- Performance-based risk-sharing schemes
  - Less relevant in Israel
- Financial-based risk-sharing schemes
  - The aim is to reduce budget impact uncertainty
  - Relevant when there is a considerable uncertainty about the size of the population that will benefit from the technology
  - The allocated budget may be insufficient for covering the cost of the drug
Risk-Sharing Agreements

- Risk-sharing agreement regarding the drug sapropterin dihydrochloride (Kuvan®, Merck-Serono) indicated for PKU patients
  - Suggested by the Ministry of Health
  - Based on expert opinions, the maximum number of eligible patients was set at 49
  - Merck-Serono agreed to bear the extra cost of treatment if the actual use will exceed the expected quantity required normally for 49 patients
  - This pilot agreement will be valid for three years and will be then re-assessed

Risk-Sharing Agreements

- The Ministry of Health and health plans officials, as well as technology sponsors became more supportive towards exploring the feasibility of risk-sharing agreements
- The feasibility of a double-sided risk-sharing agreement is currently explored as part of an academic study
- It is unclear whether other risk-sharing agreements will be introduced in the near future

Thank you!