Speaker

Tae-jin Lee, MPH, PhD
Seoul National University
Korea Association of Health Economics and Policy
Seoul, South Korea

[ISPOR 7th Asia-Pacific Conference]

Health Technology Assessment and Health Policy in South Korea

September 4, 2016

Tae-Jin Lee
Graduate School of Public Health
Seoul National University

Outline

- Introduction
  - Increase in demand: UHC, new drugs
  - Role of HTA
- Evolution of HTA in Korea
  - Positive list
  - Risk sharing agreement
  - Exemption of economic evaluation
- Discussion and lessons

Universal Health Coverage

- UHC as a global agenda
- Three dimensions of UHC
  - Population coverage, benefit coverage, cost coverage
- Many countries achieved or trying to achieve Universal Population Coverage
- Benefit coverage and/or cost coverage vary significantly depending on countries

Trend in new drugs

- Highly effective only for a limited and defined group of patients
- Very expensive

- Price is not based on costs, but on value
  - Kalydeco for cystic fibrosis priced at $307,000 per year in the US
  - Crizotinib for non-small cell lung cancer priced at $100,000 per year in Korea
  - Sofosbuvir for hepatitis C at $84,000 for 12 weeks in the US

- Inclusion of such expensive new drugs in the benefit package means significant burden on budget, which has implication in terms of opportunity cost

Role of Health Technology Assessment

- To expand benefit package for UHC
- But with limited resource
- Need to include quality, cost-effective healthcare services in the benefit package
- HTA should help with priority setting

Korean Health Care System

- National health insurance (NHI)
  - Universal coverage
    - 97% of population
    - 3% covered by Medicaid
  - Single payer system: NHIS
  - Financing by contributions (partially by government general revenue)
  - Limited coverage of services: MRI, Ultrasono, some expensive therapies not covered by NHI
  - Fee-for-service as a dominant method of payment/reimbursement

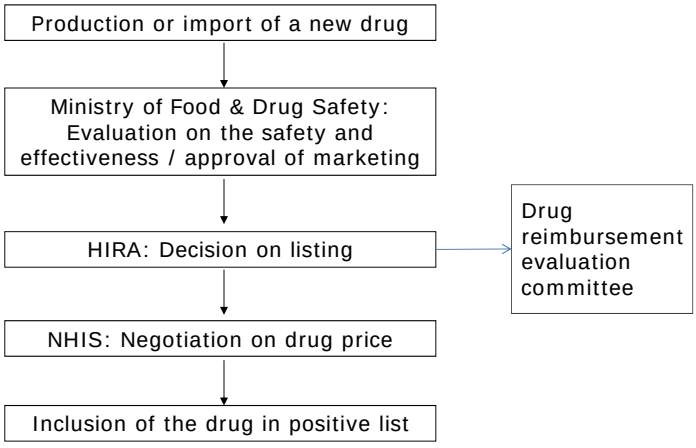
Medicines in Korean NHI

- Delivery
  - Separation of prescribing from dispensing since 2000
  - For prescription, need to visit doctors/hospitals
  - Non-prescription drugs can be purchased at pharmacies
- Financing
  - All prescription drugs and some over-the-count (OTC) drugs covered by NHI
- Patients' cost sharing
  - 30% of expenditures on drugs covered by NHI
  - 5% for patients with cancer and rare diseases

Positive List System

- Positive List system introduced in December 2006
  - To contain drug expenditures
- Its main characteristics were
  - Selective listing of drugs
    - Enhanced importance of cost effectiveness in addition to clinical effectiveness for reimbursement
  - Separation of decision on listing from pricing
    - New procedure for price negotiation with NHIS

Procedure for reimbursement decision on new drugs in Korea



Listing new drugs

- Submission of pharmaco-economic evidence
  - Mandatory for new drugs with improved therapeutic benefit from 2008
- Criteria for reimbursement decision considered by Drug Reimbursement Evaluation Committee of HIRA
  - Clinical benefits such as severity of disease and potential to replace existing therapies,
  - Cost-effectiveness,
  - Budget impact based on target population, expected sales and substitution effect
  - Whether and at what price the medicine of interest is reimbursed in other countries, and
  - Other impact on health of the population

Listing new drugs

- Increased role of economic evaluation
  - New drugs with similar or non-inferior efficacy to existing drugs can be listed only at a price lower than the weighted price of existing drugs in the same therapeutic group
  - New drugs with improved therapeutic effects can be listed only when they prove cost-effectiveness
- Decisions to reimburse new drugs decreased significantly
  - Among new drugs that applied for reimbursement in the NHI, about 30% were denied reimbursement
  - About 80% of those denied drugs lacked evidence on cost-effectiveness

Pricing new drugs

- Pricing process became separate from decision making on reimbursement from 2007
  - Once HIRA decides to reimburse a new drug in the NHI, the manufacturer has to negotiate its price with the National Health Insurance Service (NHIS)
- Factors considered for price negotiation
  - Assessment report by DREC of HIRA,
  - Budget impact,
  - Price of the drug in foreign countries including OECD,
  - Patent status, and
  - Domestic R & D expenditures
- Negotiation has been successful for most drugs
  - About 83% reached agreement
  - Settlement rate is lower for essential drugs and orphan drugs

Exemption of Economic Evaluation

- Submission of economic evaluation for essential drugs is exempted when all the following 4 requirements are met:
  1. no alternative intervention exists
  2. the medical condition is severe and expected to lead to premature death
  3. the condition applies to a small number of patients
  4. the medicine provides a worthwhile clinical improvement such as a significant extension of life
- Similar to Rule of Rescue

Changes to Positive List System

- Risk sharing agreement introduced
- Exemption of Economic evaluation extended

Background to recent changes

- NHI cost coverage rate remained relatively low at 62-63% of households' total health expenditure
- The government initiated coverage expansion for 4 severe diseases
  - In December, 2013
  - Cancer, cardiovascular, cerebrovascular, and rare diseases
  - Patients' access to medicine, less cost-effective
- New pathways to get around conventional EE added

Risk sharing agreement

- Introduced to Korea in December 2013
- Applies when the condition is severe and life-threatening such as cancer and rare diseases and when there exists no alternative intervention
- Risk related to reimbursement of new drugs shared between payer and company
- Patient's copayment reduces to 5%

Number of RSA by year and type

Year	2013	2014	2015	~2016.8
Number of drugs	1	3	4	4

Type	Conditional Treatment Continuation + Money Back Guarantee	Fixed cost per patient	Refund	Expenditure Cap
Number of drugs	1	0	9	2

Source: HIRA

Special Exemption of Economic Evaluation

- Introduced in May 2015
- Economic Evaluation exempted if the following 3 requirements are met:
  1. the condition is severe and life-threatening such as cancer and rare diseases and when there exists no alternative intervention
  2. it difficult to generate evidence because of a paucity of patients
  3. the drug is listed in at least 3 countries out of A7 countries (France, Germany, Italy, Japan, Switzerland, UK, and US)

Effects of recent changes

- The proportion of decision to reimburse new drugs increased
- The settlement rate of price negotiation increased
- Patients' access to new medicine improved
- Budget impact not known, though significant

Further thoughts

- To ensure access to medicine, it should be not only available but also affordable
- Sustainability questioned considering the very expensive new drugs
- Various pathways generated to ensure access to highly expensive drugs
- Drugs getting more expensive due to those various entry schemes?
- Regulatory capture? (G. Stigler)
  - Regulatory agency to prioritize the interests of firms over the interests of the public

Further thoughts

- Is policy based on HTA? Or does policy or politics dominate HTA?
- Is HTA hurdle too high? Or are drug prices too high?

Lessons from HTA in Korea

- Given the increasing demand for expensive new technologies and limited financial resources, HTA should play an important role in reimbursement decisions
- Access to medicines can be improved through various entry schemes
- Health policy should be based on evidence, but not dominate HTA
- Drug price control should still play a key role in increasing the affordability of medicines and the sustainability of healthcare system