Europe - Reimbursement Environment

features, observations, evolution

- Markets with established Universal Health Coverage
- Variety of reimbursement models
  - HTA, Evidence, value-informed
- Expenditure/cost increasingly an issue
  - Individual product level rather than system?
- Collaboration seen as option to improve efficiency
  - Eg: HTA clinical evaluations

Source: World Health Organization (WHO), Jan 2017

Understanding the Dynamics of Drug Expenditure. Report by the QuintilesIMS Institute
The European Reimbursement Process

Prices that are set are the outcome of comprehensive processes established by government agencies

Janssen value, access, and pricing framework
- Deliver medicines of value
- Provide timely access to affordable innovation
- Incentivise investment in innovation

External influencers
- (International reference pricing, standard of care, parallel trade)

Competition
- Manufacturer
- Tax
- Pharmacist
- Wholesaler

Budget impact
- Cost-effectiveness
- Clinical value
- Access & affordability

Agreed Prices

Enablers
- (Managed entry agreements)

Varying archetypes across Europe

The European Reimbursement Process

Current practices and prospects in managing reimbursement in Asia Pacific and Europe: what we can do more to bridge the experience and expectation?

2018 ISPOR Panelist Discussion: Reimbursement Systems

Nathorn Chaiyakunapruk
Center of Pharmaceutical Outcomes Research (CPOR)
Naresuan University, Phitsanulok, THAILAND
School of Pharmacy, Monash University Malaysia, MALAYSIA
Disclaimer

I am an advisor of National List of Essential Medicine Subcommittee. My comments are not representative of NLEM or decision makers.

Overall Reimbursement System

• Thailand
  • Semi-reimbursement: 75% UC, 15% SS, and 10% CSMBS
  • NLEM (drug) for all, UC Benefit package (device & program)
  • HTA (efficacy/safety/EE/BIA and other aspects for UHC) for sustainability of healthcare system

• Malaysia: moving toward HTA (CEA and BIA) with limited budget

• Singapore: implementation of HTA (CEA & BIA) for subsidy decision

• Vietnam: Control drug spending & use HTA for reimbursement decision

• Indonesia: UHC implementation & limited public funding

• Philippines: HTA agency was formed and use of HTA for coverage
Thailand: Evolution of reimbursement over time

• With UHC adoption in 2001, Thailand has been trying to balance the access to health services/product, ensuring quality service delivery, optimal financing mechanism, HR, IT development to achieve the goal of UHC

• UHC goal: human right to have access to care with quality for financial risk protection and equity

• Focused on OOP, Impoverishment, equity on PROGRESS (place of residence, race/ethnicity, occupation, gender, religion, education, socio-economic status, social capital and others)

• Financial sustainability: high level exploration for means to increase resources (VAT and a certain tax to be earmarked to Healthcare)

Thailand: reimbursement system performance

• Overall healthcare access to services has improved with limited budget

• Limited evidence on health outcomes and speed of access to innovative products

• Key observations specific to reimbursement
  • Delay access to innovative products
  • With current budget constraints, it is challenging to find ways to ensure access in timely fashion unless strong evidence on clinical outcomes and economic value on particular subgroups can be demonstrated with affordability
  • Fast and efficient system in making a decision on NLEM
Overall Picture - Future Trend

- Recent development of drive value based-healthcare system which is centered around the concept of “SAFE”---Sustainability, Adequacy, Fairness and Efficiency
- Exploration of cost sharing model for benefit package (essential/complementary/supplementary) with a need to improve health literacy of Thai citizen
- Discussion in ongoing on how to improve the following key areas: preventable illness, rational drug use, chronic disease management, appropriate use of health services, hospital acquired conditions, and preventable disabilities
- Sustainability of healthcare system requires contribution of beneficiaries with sufficient health literacy

Current practices and prospects in managing reimbursement in China:
What we can do more to bridge the experience and expectation

Prof. Zhao Kun
Division Director of Policy Evaluation and Health Technology Assessment
China National Health Development Research Center (CNHDRC)
11th September
Tokyo, Japan
• Recent governance reform
• HTA intuitional progress
• Current practice
• More need we can do

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Governance Reform (Recent)

• **13th National People’s Congress--5th March, 2018**
  - New Payer: National Healthcare Security Administration
    - Reimbursement access
    - Pricing (drug, lab test and service)
    - Procumbent (working with NHC)
    - Monitory
    - Merging all Medical Insurance Schemes into One
    - Covering 97% of Chinese Population
  - MoH---NHFPC---NHC (National Health Commission)
HTA Institutional Building Progress

- National Center for Health Technology Comprehensive Assessment (will be released in this Oct), located in CNHDRC
- <Guidance on Strengthening HTA Work in China> (in process of countersign by ministers)
- <Guidance on Comprehensive Supervision and Regulation in Health Services> (issued, July 2018. Mentioned to use HTA to Regulate Clinical Behaviors at

HTA current practice in national government decision in 2018

Industry provided HTA dossiers:
- Pricing negotiation for 18 generic cancer drugs
- HTA Reports are mandatory included in industry dossiers. The price was dropped by 40-60% (Done by 2017)

HTA conducted when evidence absent or insufficient:
- National Essential Drug List updating, (2018)—Issued soon
  - Last version of NEML was at 2012
- Public Health Service Package updating (with 41 interventions, funded by MoF 60 billion/year RMB) (just start)
- List of Appropriate Technologies in county level hospitals
## Price Negotiation on 18 Cancer Drugs

<table>
<thead>
<tr>
<th>Brand/manufacturer</th>
<th>Generic name</th>
<th>FA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hematology (6)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. <em>Imbruvica/Jassen</em></td>
<td>Ibrutinib 伊布替尼</td>
<td>CLL, MCL</td>
</tr>
<tr>
<td>2. <em>Jakavi/NVS</em></td>
<td>Ruxolitinib 芦可替尼</td>
<td>MF (Myelofibrosis) 骨髓纤维化</td>
</tr>
<tr>
<td>3. <em>Ninlaro/Takeda</em></td>
<td>Ixazomib 伊沙佐米</td>
<td>MM (Multiple myeloma) 多发性骨髓瘤</td>
</tr>
<tr>
<td>4. <em>Tasigna/NVS</em></td>
<td>Nilotinib 尼洛替尼</td>
<td>CML 慢性粒细胞白血病</td>
</tr>
<tr>
<td>5. <em>Vidaza/Beigene</em></td>
<td>Azacitidine 阿扎胞苷</td>
<td>MDS 骨髓增生异常综合症</td>
</tr>
<tr>
<td>6. <em>艾力达</em></td>
<td>Pegaspargase 培门冬酶</td>
<td>ALL 急性淋巴细胞白血病</td>
</tr>
<tr>
<td><strong>Solid Tumor (12)</strong></td>
<td></td>
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</tr>
<tr>
<td>7. <em>Tagrisso/AZ</em></td>
<td>Osimertinib 奥希替尼</td>
<td>NSCLC 非小细胞肺癌</td>
</tr>
<tr>
<td>8. <em>Zykadia/NVS</em></td>
<td>Erlotinib 埃索美拉唑</td>
<td>NSCLC 非小细胞肺癌</td>
</tr>
<tr>
<td>9. <em>Gilead</em></td>
<td>Alfatacin 阿达替尼</td>
<td>NSCLC 非小细胞肺癌</td>
</tr>
<tr>
<td>10. <em>Xalkori/Pfizer</em></td>
<td>Crizotinib 克唑替尼</td>
<td>NSCLC 非小细胞肺癌</td>
</tr>
<tr>
<td>11. 福可维/正大天晴</td>
<td>Axitinib 阿昔替尼</td>
<td>NSCLC 非小细胞肺癌</td>
</tr>
<tr>
<td>12. <em>Zellor/Szas/Beigene</em></td>
<td>Vandetanib 维坦坦尼</td>
<td>MM (malignant melanoma) 黑色素瘤</td>
</tr>
<tr>
<td>13. <em>Erlotinib/Merck</em></td>
<td>Cetuximab 西妥昔单抗</td>
<td>CRC 结直肠癌</td>
</tr>
<tr>
<td>14. <em>Stivarga/Bayer</em></td>
<td>Regorafenib 西立昔替尼</td>
<td>HCC-2L 肝细胞癌二线，CRC-3L 结直肠癌三线</td>
</tr>
<tr>
<td>15. <em>Votrient/NVS</em></td>
<td>Pazopanib 培唑帕尼</td>
<td>RCC 肾细胞癌</td>
</tr>
<tr>
<td>16. <em>Sutent/Pfizer</em></td>
<td>Sunitinib 舒尼替尼</td>
<td>RCC 肾细胞癌</td>
</tr>
<tr>
<td>17. <em>Inlyta/Pfizer</em></td>
<td>Axitinib 阿诺替尼</td>
<td>RCC 肾细胞癌</td>
</tr>
<tr>
<td>18. <em>Sandostatin LAR/NVS</em></td>
<td>Octreotide Microspheres 奥曲肽微球</td>
<td>NET 神经内分泌肿瘤</td>
</tr>
</tbody>
</table>

### Industry Dossier

- Basic Product Info
- Clinical Efficacy information
  - Reference Drug Information
  - Registration Reimbursement
  - Comparative Study on Efficacy
- Pharmacoeconomic
  - Mainland China Studies
  - Producing Country, Region
- Product Price Information
  - China Price Information
    - Product Price (CIF-Cost Insurance and Freight) Price & Retail Price
    - Country, Recommended
    - Country Specific Price
- Production Market Information
  - Mainland China Market Information
    - Sales, Budget Impact Analysis Key Information
    - Market Information of Producing Countries
- Drug Negotiation Intention Payment
Updated National Essential Drug List

- From 520 (2012) to 685 (2018) items
  - Medicine 417 items, TCM 268 items
- Disinvested 22
- Newly Added:
  - Focus on Cancer (i.e. Antineoplastic Drug-12 items)
  - Pediatric (i.e. High-Demanding -22items)
  - NCD
  - Pan-genotype Hep-C
- Rules in Priority setting
  - Burden of Diseases
  - Clinical Needs and Preferable
  - Clinical Effectiveness
  - Cost Effectiveness
- Consistency Evaluation for Generic Drug

What We Can More for Reimbursement Policy

- Capacity Building (Workshop & Academic Activities)
- HTA Methodology /Guideline/ Manual
- HTA Mechanism and System
- Dimension of Value Judgement
- RWD Supporting HTA
How To Use The RWD Data For HTA

Non RCT

Treatment: New Technology

Control: No Care

Control: Alternative

Analysis:

- Difference In Difference (DID)
- Propensity Score Matching (PSM)
- Interrupted Time Series (ITS) With Control Group

THANK YOU !!!
Reimbursement Policy in Japan -Challenges and future-

Makoto Tamura Ph.D
International University of Health and Welfare
Healthcare System Planning Institute (HSPI)

Overview of Japan Healthcare System

MHLW Chuikyo
(Government reimbursement advisory council)

Payer # of insured
Local govn (36 million)
Employer (73 million)
Special for (16 million)
Elderly

Payment

Reimbursement rule
Outpatients -- FFS
Inpatients – PPS for DPC hosps
FFS for other hosps
Device/Drug -- FFS, but PPS for DPC hosps (surgery related cost is FFS)

Manufacturers
Medical devices
Pharmaceutical

Request
Products/Purchase

Provider
Hospital 8,480
Clinic 100,995
Dental 68,737
Pharmacy 58,326
(as of 2015)

Patients Citizens

Co-payment
(30%, 10-20% for elderly)

Public Expenditure

Insurance Premium

National/local government

Healthcare Service

FFS: Fee for service
PPS: Prospective Payment System
DPC: Diagnosis and Procedure Combination
Key Characteristics of Japan NHI system

Universal health insurance scheme
Covering all citizens (combination of different insurers)
Comprehensive healthcare coverage

Medical expenditure/GDP
10.9%: the sixth highest among OECD countries

Substantially Single payer
The government and its advisory council, Chuikyo, decide reimbursement tariff, though there are formally more than a thousand payers

Mostly FFS except DPC (Diagnosis Procedure Combination) hospitals
Per diem payment is applied to 1730 DPC hospitals out of 8500 hospitals
Even for DPC hospitals, surgery is reimbursed based on FFS

Lower copayment
30% copayment in addition to about 80,000 yen Max-Out-of-Pocket cap (US$ 770) for monthly health expenditure

Regulatory approved technologies are generally reimbursed
In most cases, reimbursement listing 2-3 months after approval for drug (5-6 months for devices)

Brief history of NHI around healthcare technology

<table>
<thead>
<tr>
<th>Event/Reform</th>
<th>Background</th>
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<tbody>
<tr>
<td>Establishment of universal coverage (1961)</td>
<td>• Demand for healthcare</td>
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<tr>
<td></td>
<td>• Direction to welfare state</td>
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<tr>
<td>Zero copayment for elderly people (1972)</td>
<td></td>
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<tr>
<td>Increase copayment for elderly people and others (1981- )</td>
<td>• Healthcare expenditure growth</td>
</tr>
<tr>
<td>DPC (diagnosis-procedure combination) payment is introduced (2003)</td>
<td></td>
</tr>
<tr>
<td>Shared billing scheme (regulated mixed payment) is extended (2006)</td>
<td>• Drug lag, Device lag</td>
</tr>
<tr>
<td>New drug development promotion premium (Price Maintenance Premium: 2010)</td>
<td></td>
</tr>
<tr>
<td>Early introduction premium for medical devices (2012)</td>
<td></td>
</tr>
<tr>
<td>HTA trial (2016)</td>
<td>• Emergence of expensive technology</td>
</tr>
<tr>
<td>Fundamental reform of drug pricing rule (2018)</td>
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</tbody>
</table>
Key Challenges
International Comparison of General Government Debt (in % of GDP)

In GDP terms, the Japan's gross general government debt condition has rapidly deteriorated and now stands at the highest level among major advanced countries, which steadily proceeded with fiscal consolidation during the late 1990s.

<General Government Gross Debt (in % of GDP)>

Factor Analysis of the Growth of Medical Expenditure

- Division of growth of medical expenditure in recent years into factors shows "aging population" pushed up expenditure by around 1.3%.

"Advancement of medical care, etc." includes influences of advancement of medical care, review of copayment, and other factors.

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</tr>
</thead>
<tbody>
<tr>
<td>Growth of medical expenditure</td>
<td>(1)</td>
<td>1.9%</td>
<td>1.8%</td>
<td>3.2%</td>
<td>-0.0%</td>
<td>3.0%</td>
<td>2.0%</td>
<td>3.4%</td>
<td>3.9%</td>
<td>3.1%</td>
<td>1.0%</td>
</tr>
<tr>
<td>Revision of fee schedule</td>
<td>(2)</td>
<td>-1.6%</td>
<td>3.16%</td>
<td>0.8%</td>
<td>-0.82%</td>
<td>0.0%</td>
<td>0.19%</td>
<td>0.004%</td>
<td>0.19%</td>
<td>0.004%</td>
<td>0.2%</td>
</tr>
<tr>
<td>Influence of increasing population</td>
<td>(3)</td>
<td>0.1%</td>
<td>0.1%</td>
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</tr>
<tr>
<td>Influence of aging population</td>
<td>(4)</td>
<td>0.1%</td>
<td>1.5%</td>
<td>1.8%</td>
<td>1.3%</td>
<td>1.5%</td>
<td>1.3%</td>
<td>1.4%</td>
<td>1.6%</td>
<td>1.2%</td>
<td>1.4%</td>
</tr>
<tr>
<td>Advancement of medical care etc. (1) - (2) - (3) - (4)</td>
<td>0.2%</td>
<td>1.2%</td>
<td>1.3%</td>
<td>1.8%</td>
<td>1.5%</td>
<td>1.5%</td>
<td>2.2%</td>
<td>2.1%</td>
<td>2.1%</td>
<td>0.4%</td>
<td>1.1%</td>
</tr>
</tbody>
</table>

Revision of system: April 2003 (Pay raise for employees, etc.)
Update 2005 (Update pension for adults who are over 65 years old, etc.)
Update 2005 (Update pension for children with disability, etc.)
Options for policy reform

Change of copayment

- Introduction of deductible
  - Such as 10,000 yen for each month

- Multilevel copayment for drug
  - Lower copay for serious disease, such as cancer
  - Higher copay for light disease

- Macroeconomic slide
  - Similar to pension macroeconomic slide benefit
  - When medical expenditure grows significantly fast, copayment rate would be increased
HTA (Cost-Effectiveness analysis)

- MHLW/Chuikyo have seriously discussed the introduction of HTA since 2012

- Pilot program was done for 7 drugs and 6 devices
  - The discussion for 4 drugs and 1 device still continues (originally the result should be fixed by the March of 2018)

- Official program would be introduced from 2019
  - It was agreed at Chuikyo that HTA is used for price adjustment, but MOF is still insisting HTA should be used for judgement whether the product should be reimbursed or not
  - ICER threshold would be 5 million yen

Wider shared billing scheme

- Mixed payment is not allowed in Japan
  - Mixed payment means NHI covered technology/service and non-covered are provided under a series of the treatment

- Existing shared billing scheme (exceptions for the mixed payment)
  - Elective care (Sentei Ryoyo)
  - Evaluative care (Hyoka Ryoyo)
  - Patient requested care (Kanja Moshide Ryoyo)

- Another type of shared billing scheme may be considered
  - Technologies which do not have enough effectiveness/efficiency evidence would be subject to the new type (not expected to be reimbursed in the future)
## Pros & Cons of reform options

### Change of copayment

**Pros**
- Simple scheme
- Possibly high impact

**Cons**
- Strong opposition from many stakeholders
- Patients access could be delayed (could increase the healthcare cost)

### HTA

**Pros**
- Legitimate direction
- Value based

**Cons**
- High burden for MHLW and manufacturers
- Complex method

### Wider shared billing scheme

**Pros**
- Additional fund
- Patient preference centered

**Cons**
- Against equality concept of NHI
- Opposition from some stakeholders

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**Thank you**