2018 ISPOR Panelist Discussion

BREAKOUT SESSION
Tuesday, 11 September 2018
10:45 AM - 11:45 AM

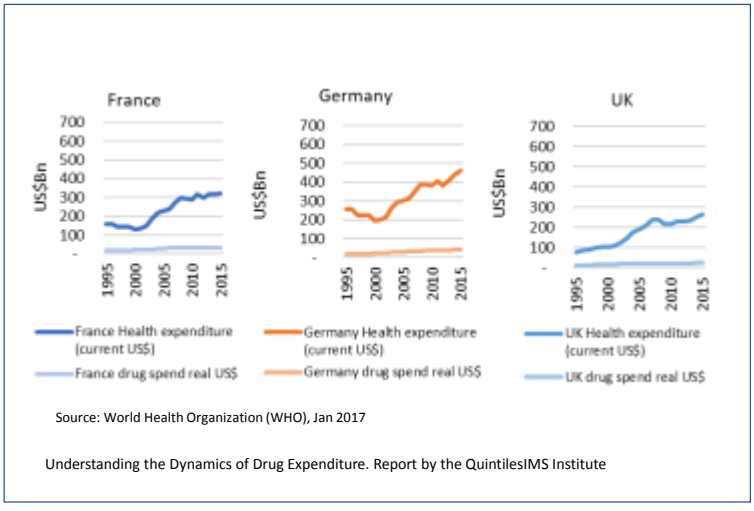
CURRENT PRACTICES AND PROSPECTS IN MANAGING REIMBURSEMENT IN ASIA PACIFIC AND EUROPE: WHAT WE CAN DO MORE TO BRIDGE THE EXPERIENCE AND EXPECTATION?

Adrian Griffin, Johnson & Johnson (panel moderator)
Nathorn Chaiyakunapruk, Professor of Health Economics at Naresuan University
Zhao Kun, Professor at Division of Health Technology
Makoto Tamura, Research Professor, International University of Health and Welfare

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

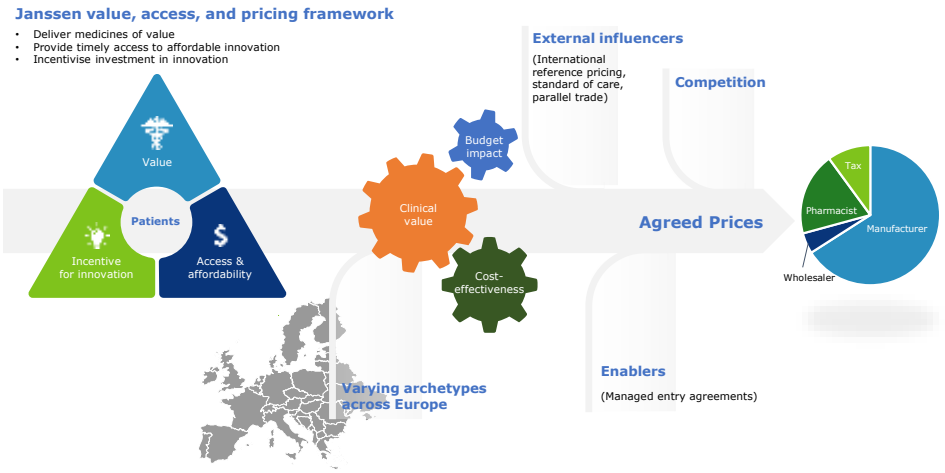


Source: World Health Organization (WHO), Jan 2017

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



ISPOR Asia Pacific 2018
8-11 September 2018, Tokyo, Japan

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

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Naresuan University, Phitsanulok, THAILAND

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Disclaimer

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

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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

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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)

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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

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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

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- 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)

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HTA Institutional Building Progress

- National Center for Health echnology Comprehensive Assessment (will be released in this Oct), located in CNHDRC
- *<Guidance on Strengthening H* countersign by ministers)
- *<Guidance on Comprehensive Services>* (issued, July 2018. Regulate Clinical Behaviors ar

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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

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Price Negotiation on 18 Cancer Drugs

		Brand/manufacturer	Generic name	TA
Hematology（6）	1	Imbruvica/Jassen	Ibrutinib 伊布替尼	CLL, MCL
	2	Jakavi/NVS	Ruxolitinib 芦可替尼	MF(Myelofibrosis) 骨髓纤维化
	3	Ninlaro/Takeda	Ixazomib 伊沙佐米	MM(Multiple myeloma)多发性骨髓瘤
	4	Tasigna/NVS	Nilotinib 尼洛替尼	CML 慢性粒细胞白血病
	5	Vidaza/Beigene	Azacitidine 阿扎胞苷	MDS 骨髓增生异常综合症
	6	艾阳/恒瑞	Pegaspargase 培门冬酶	ALL 急性淋巴细胞白血病
Solid Tumor（12）	7	Tagrisso/AZ	Osimertinib 奥希替尼	NSCLC 非小细胞肺癌
	8	Zykadia/NVS	Eritinib 塞瑞替尼	NSCLC 非小细胞肺癌
	9	Gilotrif/BI	Afatinib 阿法替尼	NSCLC 非小细胞肺癌
	10	Xalkori/Pfizer	Crizotinib 克唑替尼	NSCLC 非小细胞肺癌
	11	福可维/正大天晴	Anlotinib 安罗替尼	NSCLC 非小细胞肺癌
	12	Zelboraf/Roche	Vemurafenib 维莫非尼	MM(malignant melanoma) 黑色素瘤
	13	Erbitux/Merck	Cetuximab 西妥昔单抗	CRC 结直肠癌
	14	Stivarga/Bayer	Regorafenib 瑞戈非尼	HCC-2L 肝细胞癌二线，CRC-3L 结直肠癌三线
	15	Votrient/NVS	Pazopanib 培唑帕尼	RCC 肾细胞癌
	16	Sutent/Pfizer	Sunitinib 舒尼替尼	RCC 肾细胞癌
	17	Inlyta/Pfizer	Axitinib 阿昔替尼	RCC 肾细胞癌
	18	SandostatinLAR/NVS	Octreotide Microspheres 奥曲肽微球	NET 神经内分泌肿瘤

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Industry Dossier

- **Basic Product Info**
- **Clinical Efficacy information**
  - Reference Drug Information
    - Registration. Reimbursement
  - Comparative Study on Efficacy
    - OS, PFS, ORR
- **Pharmacoeconomic I**
  - Mainland China Studie
  - Producing Country, Re
- **Product Price Inform**
  - China Price Informatic
    - Product Price (CIF-Cos
  - Country, Recommende
    - Country Specific Price,
- **Production Market I**
  - Mainland China Market Information
    - Sales, Budget Impact Analysis Key Information
  - Market Information of Producing Countries
    - Sales, Epi data,
- **Drug Negotiation Intention Paymen**

一、Basic Product Info

1.Generic name：_____； 2.English name：_____；

3.Brand name：_____； 4. specification：_____；

5. Formulation：_____； 6.ATC code：_____；

7. Indication（Fill in according to the instructions）：_____；

（2）Budget impact analysis key information

Epidemiological data in China（Year：_____）：

Incidence rate:_____Prevalence:_____

mortality rate:_____Five-year survival rate:_____

Forecast of drug market share in 2019-2020

（**Calculated by negotiating intention payment standard**）：

Forecast market share in 2019:_____ Patient number:_____

Forecast market share in 2020:_____ Patient number:_____

Forecast of drug costs in 2019-2020

（**Calculated by negotiating intention payment standard**）：

Forecast medical expenses in 2019:_____

Forecast medical expenses in 2020:_____

Remarks:

Submit relevant calculation basis according to the requirements of the attachment.

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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

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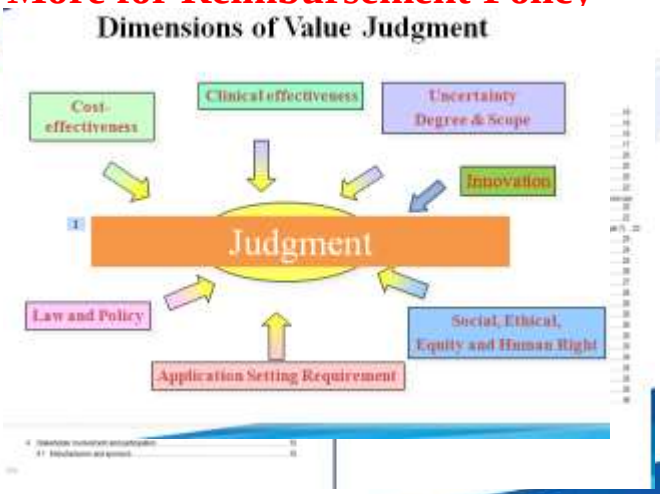
What We Can More for Reimbursement Policy

- Capacity Building (Worksh
- HTA Methodology /Guidel
- HTA Mechanism and Syste
- Dimension of Value Judgen
- RWD Supporting HTA



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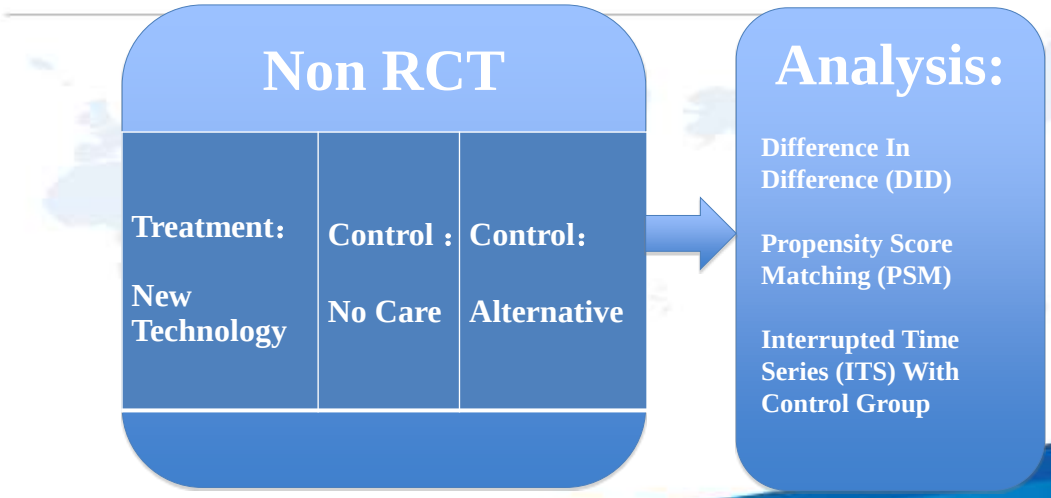
How To Use The RWD Data For HTA



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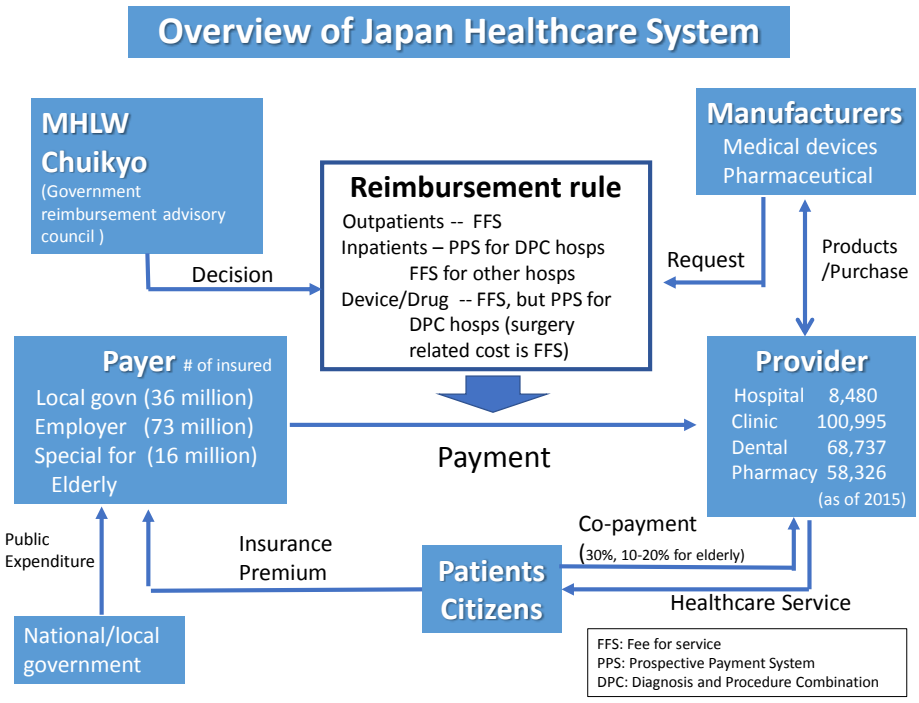
THANK YOU !!!

Reimbursement Policy in Japan -Challenges and future-

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



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

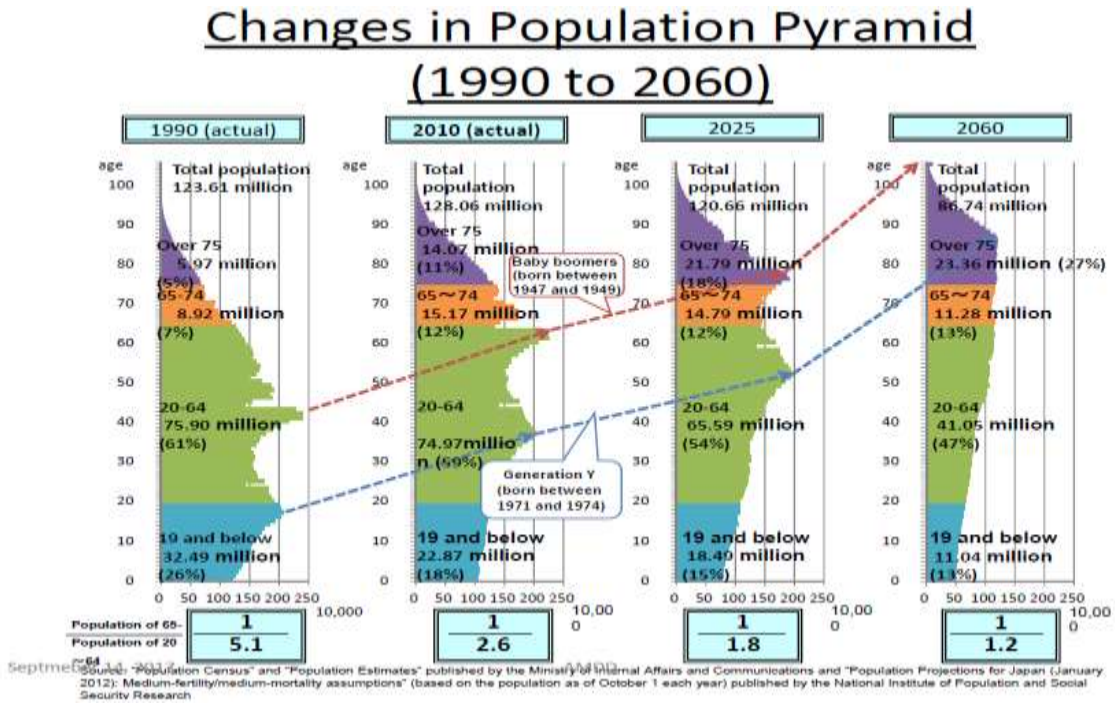
Regulatory approved technologies are generally reimbursed

In most cases, reimbursement listing 2-3 months after approval for drug (5-6 months for devices)

Brief history of NHI around healthcare technology

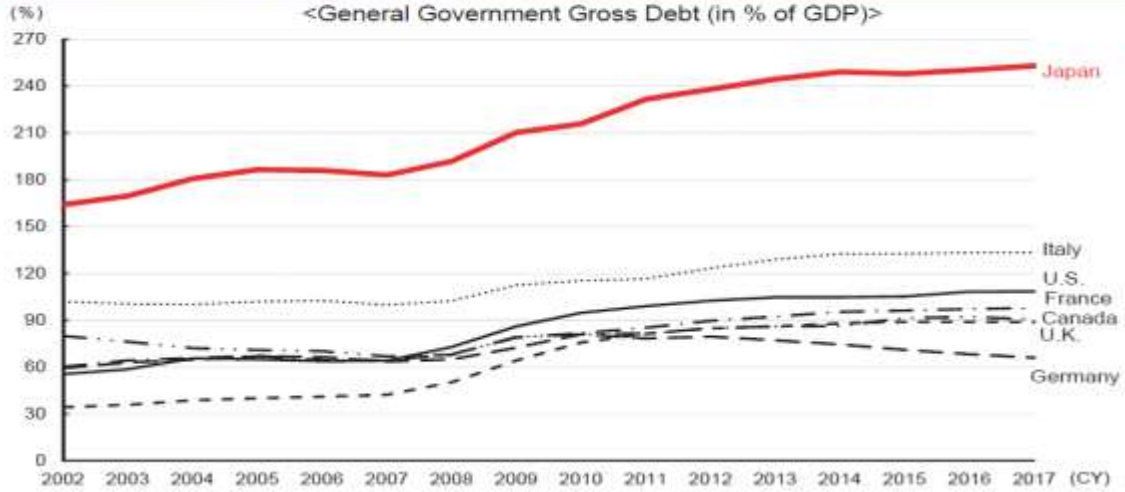
Event/Reform	Background
Establishment of universal coverage (1961)	• Demand for healthcare • Direction to welfare state
Zero copayment for elderly people (1972)	
Increase copayment for elderly people and others (1981-)	• Healthcare expenditure growth
DPC (diagnosis-procedure combination) payment is introduced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

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.



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 1.5%.
* "Advancement of medical care, etc." includes influences of advancement of medical care, review of copayment, and other factors.

	FY2003	FY2004	FY2005	FY2006	FY2007	FY2008	FY2009	FY2010	FY2011	FY2012	FY2013
Growth of medical expenditure (1)	1.9%	1.8%	3.2%	-0.0%	3.0%	2.0%	3.4%	3.9%	3.1%	1.6%	2.2%
Revision of fee schedule (2)		-1.0%		-3.16%		-0.82%		0.19%		0.004%	
Influence of increasing population (3)	0.1%	0.1%	0.1%	0.0%	0.0%	-0.1%	-0.1%	0.0%	-0.2%	-0.2%	-0.2%
Influence of aging population (4)	1.6%	1.5%	1.8%	1.3%	1.5%	1.3%	1.4%	1.6%	1.2%	1.4%	1.3%
Advancement of medical care, etc. ((1) – (2) – (3) –(4)) - Advancement of medical care - Review of copayment, etc.	0.2%	1.2%	1.3%	1.8%	1.5%	1.5%	2.2%	2.1%	2.1%	0.4%	1.1%
Revision of system	April 2003 30 percent copayment for employees, etc.			October 2006 30 percent copayment for elderly who earn income equivalent to their preretirement level, etc.		April 2008 20 percent copayment for children under compulsory education age					

Note 1: Growth of medical expenditure represents growth of national medical expenditure until FY2012 and estimates of medical expenditure for FY2013 (medical expenditure calculated by review and reimbursement services organization), representing the sum of medical expenditure paid by medical insurance and public expenditure.

2: The influence of aging population in FY2013 is an estimate based on the national medical expenditure by age group (5-year group) in FY2012, and the population by age group

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

Thank you