Session 3 Medical Technology and Healthcare Policy Payment perspectives

Chiaki Sato, Ph. D., LL.M.
Graduate School of Public Policy, University of Tokyo
Visiting Scholar, Engelberg Center for Healthcare
Reform, Brookings Institution

Payment schemes are important for realizing innovation

- Incentives are needed for everyone
 - Physicians and the other medical practitioners-Clinical trials and new therapies
 - Manufacturers-R&D
 - Component suppliers-R&D
 - Reseachers-New findings and solutions
 - Patients-faster and better care
- Payment is a strong incentive for innovation but inevitably affects our society
 - Limited resources
 - Race to increasing payment and advanced technologies
 - Possible barriers to realizing more effective healthcare delivery

Payment Models More bundled and fee for performance

- Regulations
 - Free market or Regulated
- Payment for what
 - Service (Pay for service) or Performance (Value based payment)
- Payment for whom
 - Physicians
 - Hospitals and Clinics
 - Manufacturers
- Targets for payment
 - Products
 - Procedures
 - Hospitals
 - Hospital networks
- Measurements for payment
 - > Cost
 - Clinical Effectiveness
 - Cost/Effectiveness
 - Comparative Effectiveness
 - Patients' satisfaction

Less burden to hospital, physicians, other medical practitioners, and society, etc. Source: e.g., Fulton B.D., et al., Coverage, Cost-Control Mechanism, and Financial Risk-Sharing Alternatives of High-Cost Health Care Technology, Oct. 8, 2009

Payment is not independent from Regulatory Affairs

- Incentives must meet business models for medical devices, which have shorter product cycles than pharmaceuticals
- Regulatory Affairs works assuring safety and efficacy, but the trend is the number of applications seems decreasing on generic and few changing in improved devices (without clinical data)
- Timely reviews must be a core for regulatory affairs in medical devices

*How should we review medical devices which are almost inevitably linked with procedures? Products themselves, processes, practitioners' trainings, hospital managements?

- *What is a proper balance between Pre-market review and Post-market surveillance?
- FY 2010 Second Half Year, Approved Cases/Median Review Time (month)
 - New MD (priority) 2/18.8m
 - New MD (normal) 4/12.3m
 - Improved (with clinical data) 26/12.0m
 - > Improved (without clinical data) 94/15.9m
 - Generic 657/8.7m
- Dropped Applications
 - New MD 17%, Improved (with CD) 4%, Improved (without CD) 8%, Generic 7%.

Incentives for Next Innovation (1-1) Data collection period for new coverage

- Advanced therapy program works as a financial support for transition periods from regulatory clearance to coverage by specially permitting dual use of covered services and those of uncovered
- Advanced therapy specially allows registered physicians for national healthcare insurance services to provide uncovered services with covered services on specific conditions by getting out of pocket payment from patients for uncovered services. Without such permission, they cannot provide uncovered services basically under Health Insurance Act and its regulations.
- Cost for covered services patients must pay can be different among hospitals.
- Neither stringent cap nor cost adjustment exists for advanced therapies
- Purposes: Assuring people's safety, more options to medical cares, and more accessibility with preventing heavy cost burden of patients
- Shared uncertain risk and benefit by patients' payment to uncovered services
- Pathways after advanced therapy program: stopping, continuing, or new coverage

Incentives for Next Innovation (1-2) Data collection period for new coverage

※1: The whole processes will be 6 or 7months from submission. It is relatively same time with the fastest getting new coverage as C1 or C2

Submission from hospitals (not manufactures)

Advisory
Committee's
meeting on
advanced
therapy

Reviewing specific applicable procedures

Reviewing institutions for providing such procedures

Reviewing providing plans (including cost)

Permission for dual use of an uncovered procedure with covered services

Advisory
Committee's
meeting on
advanced therapy
-applicable therapies
-competent
institutions

Submission from hospitals (not manufactures)

Reviews by special institutes

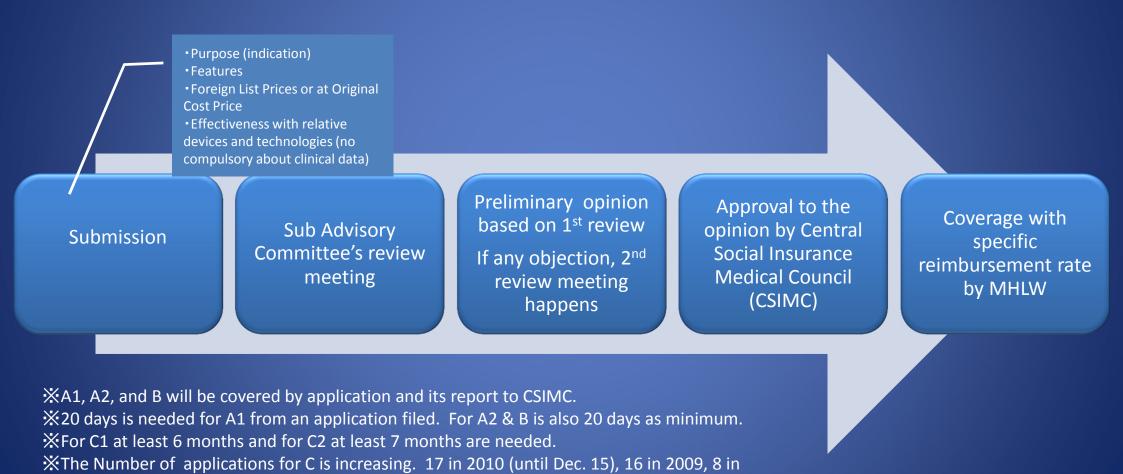
Reviewing providing plans (including cost)

Permission for dual use of an uncovered procedure with covered services

<u>※2 New highway plan will set review time as 3 months from submission with pre-settings on target therapies and competent institutions</u>

Source: Central Social Insurance Medical Council, Advanced therapies highway plan, available at http://www.mhlw.go.jp/stf/shingi/2r98520000033s56-att/2r98520000033scf.pdf

Incentives for Next Innovation (2) Coverage and reimbursement under the NHI



Source: See MHLW, The Summary of Reimbersement Reforms in Insured Medical Materials, Nov. 11, 2012, available at http://www.mhlw.go.jp/stf/shingi/2r9852000002o0is-att/2r9852000002o0ml.pdf; Nakano, S., Coverage for Innovative Medical Devices and Development Incentives, MDSI Symposium, Mar. 25, 2013.

2008, 8 in 2007, and 5 in 2006.

Thank you!

chiakist@pp.u-tokyo.ac.jp

