

Session 3
Medical Technology and Healthcare Policy
Payment perspectives

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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
- Researchers-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.

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 7 months from submission. It is relatively same time with the fastest getting new coverage as C1 or C2



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

Incentives for Next Innovation (2)

Coverage and reimbursement under the NHI

- Purpose (indication)
- Features
- Foreign List Prices or at Original Cost Price
- Effectiveness with relative devices and technologies (no compulsory about clinical data)

Submission

Sub Advisory
Committee's review
meeting

Preliminary opinion
based on 1st review
If any objection, 2nd
review meeting
happens

Approval to the
opinion by Central
Social Insurance
Medical Council
(CSIMC)

Coverage with
specific
reimbursement rate
by MHLW

※A1, A2, and B will be covered by application and its report to CSIMC.

※20 days is needed for A1 from an application filed. For A2 & B is also 20 days as minimum.

※For C1 at least 6 months and for C2 at least 7 months are needed.

※The Number of applications for C is increasing. 17 in 2010 (until Dec. 15), 16 in 2009, 8 in 2008, 8 in 2007, and 5 in 2006.

Thank you!

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