F5: Advancing Patient Access To Innovative Health Technologies In Asia – The Role Of Real-World Data In The Value Framework: South Korea

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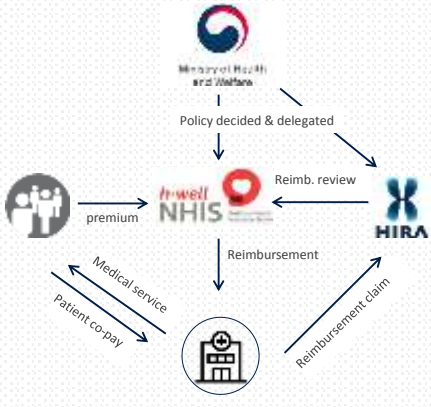
KOREAN HEALTHCARE SYSTEM
NATIONAL HEALTH INSURANCE (NHI) SYSTEM



- MOHW : Ministry of Health and Welfare
- NHIS : National Health Insurance Service
- HIRA : Health Insurance Review and Assessment Service

- Universal healthcare system
- Single payer
- Budget : Premium, Subsidy, Tobacco Tax
- Payment system : Fee-For-Service & Diagnosis-Related Groups (DRGs)
- Out-of-pocket payment:
  - 20% for inpatient
  - 30~60% for outpatient
  - 5% for Cancer patient

HEALTH TECHNOLOGY ASSESSMENT (HTA) LANDSCAPE
PHARMACEUTICAL VS. MEDICAL DEVICE

		Pharmaceutical	Medical Device (including diagnostics)
Legislation	nHTA	National Health Insurance (NHI) Act	Medical Service Act
	Reimbursement coverage		NHI Act
Reimbursement Coverage Listing System		Positive List System	Negative List System
Organization in Charge	nHTA	HIRA, NHIS, MoHW	NECA
	Reimbursement coverage		HIRA / MoHW
Assessment Aspect	nHTA	Pharmacoeconomics evaluation	Safety and Efficacy (Effectiveness)
	Reimbursement coverage		Safety, efficacy (effectiveness) and economic aspects
Assessment Tool	nHTA	CMA; ICER value, determined using CEA or CUA; BIA	Systematic review
	Reimbursement coverage		VAS system

Note) BIA: Budget Impact Analysis; CEA: Cost-Effectiveness Analysis; CMA: Cost-Minimization Analysis; CUA: Cost-Utility Analysis; ICER: Incremental Cost-Effectiveness Ratio; NECA: National Evidence-based Healthcare Collaborating Agency; NHIS: National Health Insurance Service; VAS: Value Appraisal Standard

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BRIEF SUMMARY OF HTA STATUS
PHARMACEUTICAL VS. MEDICAL DEVICE

	Pharmaceutical	Medical Device
Government Agency	• HIRA, NHIS	• NECA, HIRA
Assessment Process	• Pharmacoeconomics evaluation using ICER at HIRA • Price negotiation at NHIS	• Safety and Effectiveness evaluation through Systematic Review (SR) at NECA • Reimbursement coverage and pricing at HIRA
Value Evidence Requirements	• Robust clinical evidences are preferred (i.e., Meta-Analysis, RCT) • CEA evidence for new chemical entities	• Robust clinical evidences are preferred • Non-clinical evidences are also accepted in certain cases
Review Committee	• Drug Reimbursement Evaluation Committee (DREC) at HIRA	• Medical Device Expert Evaluation Committee (MDEEC) at HIRA
Official Timeline	• HIRA (120 days), NHIS (60 days), MoHW (30 days)	• NECA (280 days), HIRA (70 days), MoHW (30 days)

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GENERAL HTA DECISION PROCESS
PHARMACEUTICAL VS. MEDICAL DEVICES

Pharmaceutical

PHARMACOECONOMICS → PRICE NEGOTIATION → FINAL APPROVAL

Medical Device

nHTA → COVERAGE & PRICING → FINAL APPROVAL

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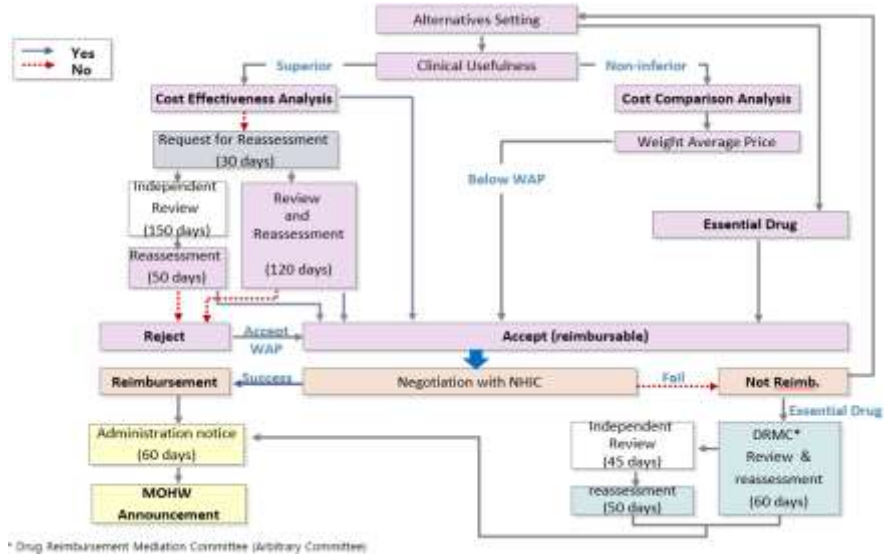
HTA DECISION PROCESS
PHARMACEUTICAL



Ref: Kim SH. KRPIA **2014**

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HTA DECISION PROCESS
MEDICAL DEVICES: NEW HEALTH TECHNOLOGY ASS

Ref: Center for nHTA. NECA. July 2014

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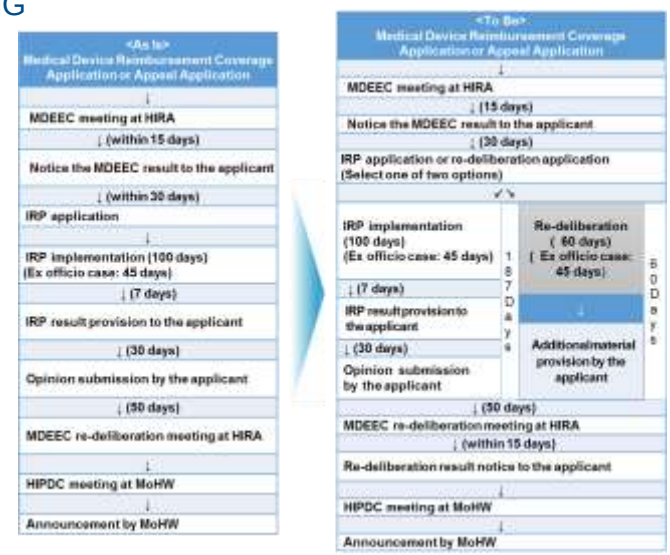
HTA DECISION PROCESS
MEDICAL DEVICES: REIMBURSEMENT COVERAGE & PRICING



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REAL-WORLD DATA AND REAL-WORLD EVIDENCE
DEFINITION

Real-World Data (RWD)	Data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources

- Data from electronic health records (EHRs)
- Claims and billing data
- Data from product and disease registries
- Patient-generated data
- Data gathered from other sources that can inform on health status, such as mobile devices
- Others

Real-World Evidence (RWE)	Clinical evidence regarding the usage, and potential benefits or risks, of a medical product derived from analysis of RWD

Ref: https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm513027.pdf

RWE REALITY
LIMITATION AND OPPORTUNITY

Pharmaceutical	Medical Device
• RWE is little or no accepted at PE and price negotiation	• No restriction on RWE utilization
• However, theoretically RWE can be used under “Risk-Sharing Agreement (RSA)” program (enforced in January 2014) ○ RSA: to improve patient access to medication for the four major diseases (cancers, cardiovascular, cerebrovascular diseases, and rare diseases) while maintaining the principle of positive list system	• However, there exists timing issues in decision-making of HTA, reimbursement coverage and pricing ○ No post-market evidence locally accumulated and aggregated at the time of the decision-making ○ Potentially useful at the time of appealing or health technology reassessment stage → Leveraged at the time of reassessment for “Selective Benefit” and “Preliminary Benefit” program

ADMINISTRATIVE CLAIMS DATASETS
ADVANTAGE AND DISADVANTAGE

National Health Insurance Service–National Sample Cohort (NHIS-NSC)

- Population-based cohort established by the NHIS / HIRA since July 2014
- Publicly available and contain all medical / demographic information of 2% (1 million) of randomly selected people from the total Korean population (about 50 million)
- To provide public health researchers and policy makers with representative, useful information regarding citizens' utilization of health insurance and health examinations

LIMITATIONS

- Not sufficient information on rare diseases
- Disease codes listed may not represent true disease status because the code was created to claim health insurance serviced to beneficiaries
- Non-covered benefits data such as cosmetic surgeries and OTC drugs are not included
- Specific medical treatment evaluation is difficult if the claims were made under DRGs

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Thank You for Your Attention

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