




INNOVATION EWRA

IP14. Managed Entry Schemes: Hype vs. Reality

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Korean System

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National Health Insurance system



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Korean System: Institutions

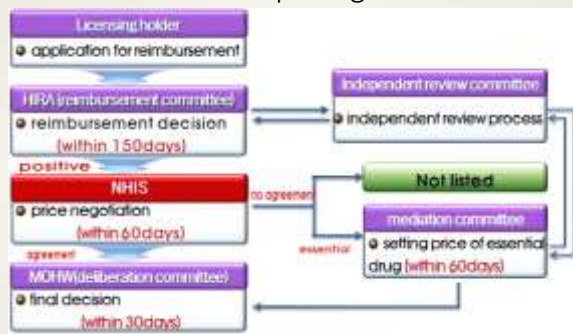
	Drugs	Medical Devices	Diagnostics and Procedures
HTA research	National Evidence-based healthcare Collaborating Agency (NECA)	National Evidence-based healthcare Collaborating Agency (NECA)	National Evidence-based healthcare Collaborating Agency (NECA)
Approval	Korean Food and Drug Administration (KFDA)	Korean Food and Drug Administration (KFDA)	Committee for New Health Technology Assessment (CNHTA)
Review and Recommendation	Health Insurance Review and Assessment Services (HIRA) / National Health Insurance Corporation (NHIS)*	Health Insurance Review and Assessment Services (HIRA)	Health Insurance Review and Assessment Services (HIRA)
Decision Making	Ministry Of Health and Welfare (MOHW)	Ministry Of Health and Welfare (MOHW)	Ministry Of Health and Welfare (MOHW)

*For drugs, HIRA does dossier review and NHIS does price negotiation

From Ahn et al. 2012. Social Values and Healthcare Priority Setting in Korea. *Journal of Health Organization and Management* 26(3):343-350

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Drug Reimbursement and pricing Process in Korea



Price Volume Agreement (PVA) and Risk Sharing Agreement (RSA) are available in Korea

Korean Risk Sharing Agreement

Based on Prof. Taejin Lee's presentation at the KAHTA Spring Conference 2018 but all the errors are mine

Eligible Drugs

- Anticancer drug which is non-substitutable or non-equivalent drug exists
- Drugs for rare disease which is life threatening
- Other drugs which is recommended by the Drug Reimbursement Evaluation Committee (DREC) for an additional contract considering disease severity, social impact, and other impact on healthcare

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Operationalization of eligibility

- **Non-equivalence**
 - Main indication based decision if there are multiple indications
 - No drug is listed for the NHI formulary for same indication
 - RSA subcommittee of DREC will make initial judgement based on
 - First in the class
 - Difference in mechanism of action
 - Significant improvement in clinical outcomes
 - DREC will finalize
- **Life threatening disease**
 - DREC will consider severe progression of disease or less than 2 years of life expectancy and other factors

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Types

- **Four basic types are preferred but open to other type suggested by the sponsor**

1. Conditional treatment continuation plus refund

- Health outcome performance based
- Reimbursement continues for the patients above predefined threshold but refund for those do not meet the threshold

2. Maximum budget cap

- Finance based
- 130% of expected volume for anticancer drugs or rare disease drugs
- 100% of expected volume for CEA exempted drugs or equivalent drugs

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Types

3. Refund

- Finance based
- Contracted percentage of claimed amount is refunded

4. Per patient cap

- Finance based
- Cap per patient in terms of volume or claim amount is contracted and pre-defined percentage of excess claim amount is refunded

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Extension of RSA contract

- No extension allowed for maximum budget cap type
- HIRA notify the sponsor for extension of RSA but the maximum allowable price can be adjusted

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Risk Sharing and High Price

- As of July 1, 2018, Korean National Health Insurance Services have 49 risk sharing contracts with about 20 companies
- Most of drugs are high price ones
- 22/49 contracts are of maximum budget cap type and 21/49 contracts are of refund type

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Risk Sharing can be a Solution

- **Just like many other countries, risk sharing scheme can be a solution to deal with access issue to a high cost drugs in Korea**
- **Financial risk sharing contracts such as maximum budget cap type or refund type are popular in many countries because it can restrict budget impact effectively**
- **RSA is a tool to overcome International Reference Pricing (IRP)**
 - Korean drug price (maximum allowable price) is published on line
 - Countries referencing the Korean drug price are increasing and it is likely to have a negative impact on Korean patient access to the innovative medicine
 - RSA results in higher published price which may help overcoming IRP

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Any other country in the region needs RSA or Managed Entry Scheme?

Any questions?

Thank you !

Gracias Danke Tak Gràcies
Obrigado Dankjewel Grazas
Terima kasih धन्यवाद 謝謝
Kiitos 謝謝 Merci
Grazie Dziękuję Eskerrik asko
Ačiū Go raibh maith agat Takk
Maururu koe ありがとう
Tack Спасибо 감사합니다