Medical Devices HTA in Korea

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HTA system overview

<table>
<thead>
<tr>
<th>Flow of benefit decision in NHI</th>
<th>New health technology categories</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval in use</td>
<td>Medical procedure</td>
</tr>
<tr>
<td>Reimbursement assessment</td>
<td>NECA</td>
</tr>
<tr>
<td>Pricing</td>
<td>HIRA</td>
</tr>
<tr>
<td>Final decision</td>
<td>HIRA</td>
</tr>
</tbody>
</table>

MOHW (Ministry of Health and Welfare), MFDS (Ministry of Food and Drug Safety), HIRA (Health Insurance Review & Assessment Service), NHIS (National Health Insurance Service), NECA (National Evidence-based Healthcare Collaborating Agency)

Jang J. HTA in Korea – focused on Drug and Reimbursement system, 2013. 10. 4
Pharmaceuticals HTA 2006

- NHI introduced positive list system for the new drugs based on cost-effectiveness

![Diagram of pharmaceuticals HTA process]

Medical devices HTA

- Health Technology Assessment for new procedures with medical devices (2006)
  - Systematic review for safety and effectiveness of procedures (nHTA)

![Diagram of medical devices HTA process]

- MFDS : Ministry of Food and Drug Safety
- NECA : National Evidence-based Healthcare Collaborating Agency
- HIRA : Health Insurance Review & Assessment Service
Medical devices HTA improvement

- Parallel process of approval, nHTA, and review for NHI coverage introduced in 2014
  - Improve patient accessibility to shorten the process

Medical devices HTA improvement 2

- Conditional use of health technologies (2013)
  - Government supports health interventions for safety and effectiveness evidence generation
  - Urgent need for rare and severe diseases without alternative treatments
  - Only in designated hospitals during prescribed time period

<table>
<thead>
<tr>
<th>Technology</th>
<th>Period</th>
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<tbody>
<tr>
<td>Therapeutic Use of Autologous Peripheral Blood Stem Cell in MI</td>
<td>2014.10–2017.09</td>
</tr>
<tr>
<td>Pancreatic Cancer Irreversible electroporation</td>
<td>2015.09–2018.08</td>
</tr>
<tr>
<td>PET-CT for C-11-Methionine</td>
<td>2016.08–2019.07</td>
</tr>
<tr>
<td>Autologous Platelet Rich Fluid to Vitreous body</td>
<td>2016.11–2019.10</td>
</tr>
<tr>
<td>Smart PreP2 BMAC to Diabetic Critical Limb Ischemia</td>
<td>2018.01–2020.12</td>
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<tr>
<td>Autologous Adipose-Derived Stem Cell Therapy</td>
<td>2018.05–2021.04</td>
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New policy for medical devices

- **Fast tract for In Vitro Diagnostics**
  - nHTA exemption, and RWE
  - Early dialogues from development stage with related agencies
  - development stage: MFDS
  - nHTA: NECA
  - NHI coverage: HIRA

- **Real One-stop service system**
  - Unified service team: MFDS, NECA, and HIRA
  - Parallel process of regulatory review and nHTA

- **R&D support for evidence generation**

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Differences with Pharmaceutical HTA

- Less mature industry
  - less experience preparing submission
  - lower quality evidence (historically, and ethically difficult)

- Less obvious patent protection
  - short life-cycle
  - frequent functional, minor improvements

- Evidence fundamental
  - pharmaceutical oriented researchers, experts
  - data insufficiency (weaker surveillance system)
Challenges

- New policies are focusing on non-invasive leading edge medical devices
- Guidelines for early dialogues need to be developed
- RWE generation supported by government and industry
- RWE generation needs stronger multidisciplinary approaches and experts of research methodology and data
- International cooperation for improving HTA capacity is important

Thank You!!