HOW CAN RISK-SHARING AGREEMENTS IN KOREA BE IMPROVED?

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Payer’s Perspectives
Government

- Enforcement of benefit coverage extension for 4 main severe diseases since 2013

Industry

- Demand for reflecting a proper value of new drug on price
- Desire to maintain global price

Begin to discuss on Risk Sharing Agreement (RSA) to increase patients’ access to new drug

Stakeholders’ Opinion

**PROS**

**Patients’ Group**

- To strengthen patients’ access to new drug

**Pharmaceutical Industry**

- To strengthen patients access to new drug
- To minimize effects of External Reference Pricing

**CONS**

**Civic Group and Insurant Group**

- Misused as an easy entry method by MNC
- Against the principle of PLS
- Lowering transparency of drug pricing policy
- Threatening health right
- Increasing drug price and patients’ co-payment

MNC: Multinational pharmaceutical corporation
PLS: Positive Listing System
Available for limited drug
- Anti-cancer or rare disease treatment with no alternative

Within Positive Listing System
- Need to prove cost-effectiveness of new drug

Major difference from ordinary drugs
- F2F deliberation in Health Insurance Policy Deliberative Committee
- Re-evaluation before expiring of contract
- Restriction of reimbursement criteria expansion during contract period

No increase of patients’ co-payment
- If additional patient’s co-payment occurred, refund the difference to patient

Total 11 drugs (8 Refund, 2 Expenditure Cap, 1 CED)

<table>
<thead>
<tr>
<th>No.</th>
<th>Product</th>
<th>Active Compound</th>
<th>Company</th>
<th>RSA Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Evoltra</td>
<td>Clofarabine</td>
<td>Genzyme</td>
<td>CED</td>
</tr>
<tr>
<td>2</td>
<td>Revlimid</td>
<td>Lenalidomide</td>
<td>Celgene</td>
<td>Refund</td>
</tr>
<tr>
<td>3</td>
<td>Erbitux</td>
<td>Cetuximab</td>
<td>Merck</td>
<td>Refund</td>
</tr>
<tr>
<td>4</td>
<td>Xtandi</td>
<td>Enzalutamide</td>
<td>Astellas</td>
<td>Refund</td>
</tr>
<tr>
<td>5</td>
<td>Xalkori</td>
<td>Crizotinib</td>
<td>Pfizer</td>
<td>Refund</td>
</tr>
<tr>
<td>6</td>
<td>Pirespa</td>
<td>Pirfenidone</td>
<td>Ildong</td>
<td>Refund</td>
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<tr>
<td>7</td>
<td>Soliris</td>
<td>Eculizumab</td>
<td>Handok</td>
<td>Refund</td>
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<tr>
<td>8</td>
<td>Caprelsa</td>
<td>Vandetanib</td>
<td>Genzyme</td>
<td>Expenditure Cap</td>
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<tr>
<td>9</td>
<td>Naglazyme</td>
<td>Galsulfase</td>
<td>Samoh</td>
<td>Refund</td>
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<tr>
<td>10</td>
<td>Vimizim</td>
<td>Elosulfase</td>
<td>Samoh</td>
<td>Expenditure Cap</td>
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<tr>
<td>11</td>
<td>Stivaga</td>
<td>Regorafenib</td>
<td>Bayer</td>
<td>Refund</td>
</tr>
</tbody>
</table>

CED: Coverage with Evidence Development
Procedure for termination of a contract before expiration ('15. Dec.)

- If the company wants to terminate the contract before expiration, it can be terminated through the same process as when the contract expires:
  - DREC evaluation + negotiation with NHIS
- Early termination would not be allowed in case of:
  - Specific RSA type (i.e., CED, Expenditure cap)
  - Failure of negotiation about the price that is supposed to be applied after the termination

DREC: Drug Reimbursement Evaluation Committee
CED: Coverage with Evidence Development

Amendment (2/2)

Procedure for reimbursement criteria expansion during the contract period ('16. Jul.)

- The expansion range should be subject to risk-sharing agreement, if not, cost-effectiveness in expansion range has to be proved
- The contents of contract has to be changed through the negotiation between NHIS and company, after the evaluation of DREC
- In negotiation process, additional budget impact, administration cost of substitutes and foreign countries’ price will be considered

* Internal guideline of NHIS and HIRA will be amended in Sep. 2016

DREC: Drug Reimbursement Evaluation Committee
HIRA: Health Insurance Review and Assessment Service
‘Consultative Body for Improving drug price policy’ will examine and discuss overall operation methods of RSA (2nd half of 2016)

- Currently, the research about eligible drugs, re-evaluation method is in progress by Health Insurance Review and Assessment Service
- Based on result of the research and opinions of industry, improvement plans will be discussed

RSA is a tool for listing within the principle of Positive List System

PE analysis is possible for most of the risk sharing scheme except for specific type (i.e. CED)

Eligible drugs for RSA and exemption of PE are different
- RSA: necessity of reimbursement
- PE exemption: necessity of reimbursement + possibility of performing PE analysis

Similar methods with weighted ICER, MCDA are used in current decision making process in Korea
- Flexible ICER threshold for anti-cancer/rare disease treatment
- PE exemption for essential drug
NHIS’s opinion about raised issues (2/5)

Refund for patients who pay for the whole cost

- Necessary to prevent additional burdens of patients due to RSA
  * For the same purpose, NHIS also refunds the difference of co-payment to patients who paid part of the drug cost

- The difference between list price and net price should be refunded to patients directly to give benefits to patient who paid additional cost

- Until now, possibility of refund rate exposure seems to be low

NHIS’s opinion about raised issues (3/5)

Value Added Tax (VAT)

- The drug price in Korea is basically including VAT
  - List price and net price in RSA also include VAT
  - It is reasonable that VAT is included in refund amount to NHIS, because VAT in list price is bigger than that of net price

- The problem is that company pays VAT to NTS based on list price, even though net price, which is associated with company’s profit, is low
  - Return of VAT relevant to the difference between list price and net price should be discussed with MOSF and NTS

MOSF: Ministry of Strategy and Finance
NTS: National Tax Service
Operating Expenses

- Operating Expenses are inevitable to operate RSA
  
  **Financial Cost**
  - Interest cost generated between the period, as NHIS first pay the drug cost at a high price and receive the refund from the company afterward

  **Security**
  - Safety device to minimize the damage of health insurance finance in case of company’s being incapable of refunding to NHIS
  - Adjustable in method of setting security by negotiation (i.e. divided security term)

- NHIS also bears the cost for administration, labors and establishing IT system for the post-management of RSA

Contract Renewal

- Contract renewal also follows the rule of RSA
  - Only possible when RSA contracted drug is still eligible for RSA
  - If product replaceable or equivalent therapeutic position is available, contract cannot be renewed

- It would be an excessive favor to first drug, if contract renewal is possible regardless of alternatives
  - The latecomers did not have even chance to apply for RSA
• RSA has contributed to improving patients’ access to new drug

• As a part of the drug pricing system, RSA should be
  - operated within the principle of drug pricing system
  - in harmony with other drug pricing system

• RSA is not a general pathway for listing in Korea
  - It is a last resort, not an option
  - It is the tool of improving patient access to new drugs, not listing all new drugs

• Various factors have to be considered in discussion of RSA
  - principle of reimbursement, financial situation, possibility of operation, etc.
  - social consensus