Drug Reimbursement Model and Challenges Under Taiwan’s NHI System

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National Health Insurance Administration, Taiwan
Oct. 1, 2019
Outline

Pharmaceutical Reimbursement System and Expenditure in Taiwan

Principles and Procedures of drug listing

Optimization of Reimbursement Model

Future Challenges and Prospects
Pharmaceutical Reimbursement System and Expenditure in Taiwan
The Framework of NHI

- The insured
- Medical care providers
- NHIA
- Premium
- NHI IC card
- Claim
- Reimbursement
- Co-payment
- Medical service

Supportive funding
The Global Budget System

• The cap on overall expenditure:
  – Set annual budget
    • Prior to the beginning of a next fiscal year based on the estimation on medical costs and the amount of services.
  – Paid under a point-value scale
    • Point-value = (global budget/total amount of medical services)
    • Calculate retrospectively
    • Fixed-value for pharmaceuticals (1 point = 1NTD)
  – Fluctuating point-value
    • When the service volume (actual expenditure) exceeds the cap, the point-value will be reduced.
  – Ensures that the overall expenditure stays under the cap.
**Decision of Annual Global Budget**

**MOHW**
Figure out general parameters for the global budget (Jan. ~ Apr.)

**Executive Yuan**
Approve the global budget parameters (May.~ Jun.)

**NHI Committee**
Negotiate and allocate global budget (Aug.~ Dec.)

- Estimate budget based on actual spending
- Review by National Development Council
- Allocate expenditure based on approved budget

1. Target growth rate of each sector
2. Content of budget increase and expected benefit
3. Revise relevant formulas
4. Consult NHI committee

1. Payers' willingness to pay
2. Financial consideration
Trend of NHI Drug Expenditures
(exclusive of Chinese medicines)

<table>
<thead>
<tr>
<th>Year</th>
<th>Drug expenditure (billion, NTD)</th>
<th>Drug expenditure over total healthcare expenditure</th>
<th>Growth rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>146.7</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>2014</td>
<td>153.0</td>
<td>8.8%</td>
<td>8.8%</td>
</tr>
<tr>
<td>2015</td>
<td>154.6</td>
<td>4.3%</td>
<td>-</td>
</tr>
<tr>
<td>2016</td>
<td>162.3</td>
<td>1.1%</td>
<td>1.1%</td>
</tr>
<tr>
<td>2017</td>
<td>175.3</td>
<td>4.9%</td>
<td>4.9%</td>
</tr>
<tr>
<td>2018</td>
<td>186.5</td>
<td>8.0%</td>
<td>6.4%</td>
</tr>
</tbody>
</table>
Annual growth rate of cancer patients: 4.5% (approx. 648,000 (2016) → 708,000 (2018))

<table>
<thead>
<tr>
<th>Year</th>
<th>Cancer drug expenditure (billion, NTD)</th>
<th>Drug expenditure for cancer patients (billion, NTD)</th>
<th>Medical service expenditure for cancer patients (billion, NTD)</th>
<th>Drug expenditure for cancer patients/medical service expenditure for cancer patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
<td>22.35</td>
<td>32.23</td>
<td>84.52</td>
<td>38.1%</td>
</tr>
<tr>
<td>2017</td>
<td>24.73</td>
<td>35.83</td>
<td>93.27</td>
<td>38.4%</td>
</tr>
<tr>
<td>2018</td>
<td>27.06</td>
<td>39.16</td>
<td>100.80</td>
<td>38.8%</td>
</tr>
</tbody>
</table>

Annual growth rate:
- Cancer drug expenditure: 10.0%
- Drug expenditure for cancer patients: 10.2%
- Medical service expenditure for cancer patients: 9.2%
Principles and Procedures of Drug Listing
Value-based Pricing

Comparators
Relative effectiveness
CBA/CEA/PE
Budget impact
Ethical/legal/social/political impact

Subjects
Health Technology Assessment (HTA)
Principles of Pharmaceutical Reimbursement

Positive Listing

The National Health Insurance Pharmaceutical Benefits and Reimbursement Schedule (>17,000 items)

Items not covered

A. OTC/non-prescription drugs
B. Not clinically essential (contraceptives, hair restorers, shampoo...)
C. Used for clinical trials
D. Immunization
E. Methadone therapy for drug addiction
F. Not complying with approved indications or reimbursement restrictions
Classification of Drugs Listed

Drugs submitted for listing

• New active ingredient(s)
• New dosage form
• New route of administration
• Combined preparation with new effect

New drugs

Category 1 new drugs
Category 2 new drugs (2A, 2B)

New items

☑️ Originators
☑️ BA/BE generics
☑️ Common generics

Biosimilars
### PBRS Joint Meeting

composed of stakeholders to ensure decision making for drug listing and reimbursement

<table>
<thead>
<tr>
<th>Stakeholder</th>
<th>Number</th>
<th>Icon</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthcare Providers</td>
<td>13</td>
<td><img src="healthcare_providers.png" alt="Icon" /></td>
</tr>
<tr>
<td>Scholars and Experts</td>
<td>9</td>
<td><img src="scholars_experts.png" alt="Icon" /></td>
</tr>
<tr>
<td>The Insured</td>
<td>3</td>
<td><img src="the_insured.png" alt="Icon" /></td>
</tr>
<tr>
<td>Employers</td>
<td>3</td>
<td><img src="employers.png" alt="Icon" /></td>
</tr>
<tr>
<td>Health Regulatory Authority (MoHW)</td>
<td>1</td>
<td><img src="health_regulatory.png" alt="Icon" /></td>
</tr>
<tr>
<td>Drug Regulatory Authority (TFDA)</td>
<td>1</td>
<td><img src="drug_regulatory.png" alt="Icon" /></td>
</tr>
<tr>
<td>The Suppliers</td>
<td>3</td>
<td><img src="the_suppliers.png" alt="Icon" /></td>
</tr>
<tr>
<td>Patients</td>
<td>2</td>
<td><img src="patients.png" alt="Icon" /></td>
</tr>
</tbody>
</table>
## Participants of PRBS Joint Meeting

<table>
<thead>
<tr>
<th>Category</th>
<th>Assignment Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health and drug regulatory authority</td>
<td>Assigned by competent authorities</td>
</tr>
<tr>
<td>Scholars and experts</td>
<td>Designated by insurer</td>
</tr>
<tr>
<td>The Insured (employers and lay members)</td>
<td>Recommended by related association and then designated by insurer</td>
</tr>
<tr>
<td>Healthcare providers</td>
<td>Assigned by related association</td>
</tr>
<tr>
<td>Pharmaceutical industry</td>
<td>Assigned by related association to seat in the meeting but do not have right to vote</td>
</tr>
<tr>
<td>Patients</td>
<td>Assigned by patient group to seat in the meeting but do not have right to vote</td>
</tr>
</tbody>
</table>
Pricing Process of New Drugs

- Drugs and Medical Devices listing applications
  - Dossiers

  - Submission
    - Administrative review
      - Expert Committee meeting
        - *PBRs Joint Meeting

  - NHIA
    - HTA (Health Technology Assessment)
      - Patients’ opinions
    - Decision
      - Notify supplier the result
        - Agree
          - Final
          - Listing

- Disagree & appeal
  - *PVA/agreement

*PBRs: Pharmaceutical Benefits and Reimbursement Schedule
*PVA: Price Volume Agreement
Approval given:
1. Before 15\textsuperscript{th} (inclusive) of the month: take into effect on the 1\textsuperscript{st} day of the following month.
2. After 15\textsuperscript{th} of the month: take into effect on the 1\textsuperscript{st} day of the second month after the approval.
# Incentives for Breakthrough New Drug

<table>
<thead>
<tr>
<th>Category</th>
<th>Pricing</th>
<th>Mark-ups</th>
</tr>
</thead>
</table>
| **1** Breakthrough | Median price of A-10 countries | • local clinical trials (10%)  
• local pharmaco-economic study (up to 10%)  
• better therapeutic effects (up to 15%)  
• greater safety (up to 15%)  
• more convenient (up to 15%)  
• pediatric preparations with clinical implications (up to 15%) |
| **2A** Me-better | Capped at A-10 median price  
• lowest price in A10  
• price in original country  
• international price ratio  
• treatment-course dosage ratio  
• a combination drug is priced at 70% of the sum of each ingredient’s price, or at the price of the single active ingredient. | |
| **2B** Me-too | | |

A-10 reference countries: Australia, Belgium, Canada, France, Germany, Japan, Sweden, Switzerland, US, UK.
### New Drug Listing Time Course
(from submission to listing)

<table>
<thead>
<tr>
<th>Year of listing</th>
<th>No. of cases</th>
<th>No. of items</th>
<th>Minimum (month)</th>
<th>Average (month)</th>
<th>Maximum (month)</th>
<th>Median (month)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>19</td>
<td>26</td>
<td>4.2</td>
<td>7.8</td>
<td>12.9</td>
<td>7.7</td>
</tr>
<tr>
<td>2014</td>
<td>23</td>
<td>45</td>
<td>4.0</td>
<td>8.4</td>
<td>14.9</td>
<td>7.9</td>
</tr>
<tr>
<td>2015</td>
<td>22</td>
<td>40</td>
<td>6.3</td>
<td>11.5</td>
<td>22.0</td>
<td>10.0</td>
</tr>
<tr>
<td>2016</td>
<td>17</td>
<td>26</td>
<td>7.3</td>
<td>11.3</td>
<td>21.1</td>
<td>10.4</td>
</tr>
<tr>
<td>2017</td>
<td>29</td>
<td>50</td>
<td>7.3</td>
<td>12.0</td>
<td>31.3</td>
<td>8.9</td>
</tr>
<tr>
<td>2018</td>
<td>26</td>
<td>51</td>
<td>7.3</td>
<td>11.7</td>
<td>28.2</td>
<td>10.2</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>136</strong></td>
<td><strong>238</strong></td>
<td><strong>4.0</strong></td>
<td><strong>10.6</strong></td>
<td><strong>31.3</strong></td>
<td><strong>8.9</strong></td>
</tr>
</tbody>
</table>
## Review Results

### 2nd NHI

<table>
<thead>
<tr>
<th>Expert committee (items)</th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>PBRS Joint meeting</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Agree</td>
<td>62</td>
<td>56</td>
</tr>
<tr>
<td>Disagree</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>62</td>
<td>56</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PBRS Joint meeting</th>
<th>Agree</th>
<th>Disagree</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2017</td>
<td>62 (98.4%)</td>
<td>0</td>
<td>62 (98.4%)</td>
</tr>
<tr>
<td>2018</td>
<td>56 (94.9%)</td>
<td>3</td>
<td>59 (100%)</td>
</tr>
</tbody>
</table>

- **2017**: 62 Agree, 0 Disagree, Total: 62 (98.4%)
- **2018**: 56 Agree, 3 Disagree, Total: 59 (100%)
Interfering Factors of Pricing Process

- Drug suppliers disagree with the pricing results, resubmit, or submit additional documents
- Uncertainty in efficacy/ cost-benefits (ex: Cancer IO therapy)
- Limited improvement in efficacy or similar in value compared to existing therapy, but more expensive
- High-expenditure innovative drugs with huge budget impact (ex: DAAs for Hepatitis C)
Pricing Process for Generics and Biosimilars

1. Submission
2. NHIA
3. Preliminary Pricing Results
4. Expert Committee meeting (Biosimilar)
5. PBRS Joint Meeting
6. Listing
**Principle of Pricing Generics**

By classification (originators, BA/BE generics, common generics or Biosimilars)

- **Originators**:
  - Capped at 90% of the lowest price of the listed *originators*.
  - The lowest price of the listed *BA/BE generics*.

- **BA/BE generics**:
  - Capped at 90% of the lowest price of the listed *originators*.
  - The lowest price of the listed *BA/BE generics*.

- **Common generics**:
  - Capped at 80% of the lowest price of the listed *originators*.
  - The lowest price of the listed *BA/BE generics* and *common generics*.
Optimization of Reimbursement Model
Current Challenges

- Aging population
- Escalating cost of new drugs (e.g. IO, cell/gene therapy)
- Limited NHI resources vs. unlimited medical needs
- Uncertainties in clinical efficacy of new drugs (e.g. due to fast tract approval)
Optimization of Reimbursement Model

I. Managed Entry Agreement
II. Good Submission Practice
III. Improve Treatment Outcome through Biomarkers
III. Refined HTA
IV. Utilization of Real World Evidence
I. MEAs Models in Taiwan

- Any one (or more than one) of the models be chosen on a case by case basis.
- Mutual share of drug expenditure between the supplier and the insurer via refund / payback.

<table>
<thead>
<tr>
<th>Category</th>
<th>Mechanism of MEAs Models</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Performance-based</td>
<td>1. Ensure the improvement in overall survival</td>
</tr>
<tr>
<td></td>
<td>2. Ensure the progression-free survival</td>
</tr>
<tr>
<td></td>
<td>3. Refund / payback based on response rate etc.</td>
</tr>
<tr>
<td>2. Financial-based</td>
<td>1. Fixed-rate refund / payback</td>
</tr>
<tr>
<td></td>
<td>2. Free doses</td>
</tr>
<tr>
<td></td>
<td>3. Payback for co-prescribed drugs</td>
</tr>
<tr>
<td>3. Mutual share by negotiation</td>
<td>Mutual share of refund / payback among pharmaceutical products with the <strong>same ingredient</strong> or pharmacological category.</td>
</tr>
</tbody>
</table>
II. Good Submission Practice (GSP)

- Specify the dossier required for submission
- Create the check-lists for submission dossier and MEA proposal
- Create the self-assessment sheet for cost-benefit analysis

Improve the completeness and quality of submission dossier

Accelerate pricing review process
III. Improve Treatment Outcome through Biomarkers (1)

Ex: Examination of PD-L1 expression prior to the treatment with cancer immuno-therapies

Identify Patient + Identification of biomarkers + Diagnostic test results inform treatment decision = Improved patient outcomes
III. Improve Treatment Outcome through Biomarkers (2)

- Submission of co-dependent technology
  - Co-dependent: two related technology (ex: gene examination to be done before the use of medication)
  - If the reimbursement of a new drug may give rise to additional expenditure on a technology that is not yet covered by NHI, the technology shall be submitted for listing at the same time.
III. Refined HTA

Strike a balance between new drug accessibility and affordability

- Horizon scanning
  - Regulation
  - Budget

- Assess for new drugs and medical devices
- Research for risk sharing scheme
- Establish domestic cost-benefit model (ex: ICER)

- Re-assess the reimbursement efficiency of listed medical products

Optimization of technology use
IV. Utilization of Real World Evidence

- DAAs used for the treatment of Hepatitis C
- Cancer immunotherapy
WHO’s target:
1. 90% reduction in new chronic infections with HBV and HCV
2. 65% reduction in mortality from HBV and HCV infections
3. 80% service coverage in treatment of HBV and HCV infections
Taiwan’s Target: Elimination of Hepatitis C by 2025

Treatment of chronic HCV infections covers 0.25 million patients by 2025
Reimbursement of DAAs for Hepatitis C

Stage 1
- Fibrosis: ≥ F3
- Prior treatment: Treatment failure with interferon

Genotype: Type 1
Treatment course: 12~24 wks

Stage 2
- Fibrosis: ≥ F3
- Prior treatment: no restriction

Genotype: Type 1, 4
Treatment course: 12~24 wks

Jan. 24, 2017
May 15, 2017
Aug. 1, 2017

Jan. 1, 2018
Jan. 1, 2019

Stage 3
- Fibrosis: no restriction
- Prior treatment: no restriction

Genotype: Type 1~ 6
Treatment course: 8~24 wks

Jan. 1, 2018
Aug. 1, 2018
# Registry System for DAAs for Hepatitis C

<table>
<thead>
<tr>
<th>1. 治療前 (6個月內)：</th>
<th>HCV RNA病毒量</th>
<th>293,000 IU/mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. 治療中 (4個月)：</td>
<td>HCV RNA病毒量</td>
<td>0 IU/mL</td>
</tr>
<tr>
<td></td>
<td>S-GOT/AST</td>
<td>20 U/L</td>
</tr>
<tr>
<td></td>
<td>S-GPT/ALT</td>
<td>17 U/L</td>
</tr>
<tr>
<td></td>
<td>Total Bilirubin</td>
<td>mg/dl (0.0-99.99)</td>
</tr>
<tr>
<td></td>
<td>Direct Bilirubin</td>
<td>mg/dl (0.0-99.99)</td>
</tr>
<tr>
<td>3. 治療結果：</td>
<td>ProD: 12週 HCV RNA病毒量</td>
<td>X IU/mL</td>
</tr>
<tr>
<td></td>
<td>S-GOT/AST</td>
<td>14 U/L</td>
</tr>
<tr>
<td></td>
<td>S-GPT/ALT</td>
<td>8 U/L</td>
</tr>
<tr>
<td></td>
<td>Total Bilirubin</td>
<td>mg/dl (0.0-99.99)</td>
</tr>
<tr>
<td></td>
<td>Direct Bilirubin</td>
<td>mg/dl (0.0-99.99)</td>
</tr>
<tr>
<td>4. 治療後12週：</td>
<td>HCV RNA病毒量</td>
<td>X IU/mL</td>
</tr>
<tr>
<td>1. 白血球 WBC</td>
<td>4860 /μL (0-9999)</td>
<td></td>
</tr>
<tr>
<td>1. 中性白血球 Neutrophils</td>
<td>% (0-99.9)(腫瘤)</td>
<td></td>
</tr>
<tr>
<td>2. 血紅蛋白 Hemoglobin, Hb</td>
<td>14.3 g/dl (9.0-99.0)</td>
<td></td>
</tr>
<tr>
<td>3. 血小板 Platelet</td>
<td>131,000/μL (9999.9)</td>
<td></td>
</tr>
<tr>
<td>4. 凝血酶原時間 Prothrombin Time, PT</td>
<td>10.5 秒 (9.99)</td>
<td></td>
</tr>
<tr>
<td>4. 凝血酶原時間(INR)</td>
<td>1.00 (0-9.99)</td>
<td></td>
</tr>
</tbody>
</table>
Treatment Outcome of DAAs for Hepatitis C

Cure Rate (SVR12)
(No virus detected after 12 weeks of treatment as indicator)
Positive Feedback Cycle of Anti-HCV Policy

**Budget**

**Patient**
- Remove restriction:
  - Fibrosis: ≥F3 → no restriction
  - Prior treatment: treatment failure with interferon → no restriction

**Product**
- Expansion of indication:
  - Children
  - Genotype: type 1~6

**RWE**

Elimination of Hepatitis C by 2025
Reimbursement of IO Drugs
(one year scheme in 2019)

Quota: 800 patients

8 cancer types

11 indications

• MM
• NSCLC
• UC
• HL

• HNSCC
• GC
• RCC
• HCC

Drug expenditure cap: 800 millions NTD

3 drugs

Pembrolizumab
Nivolumab
Atezolizumab

MEA: Financial-based agreements

Keep listing price preferable to pharmaceutical company-- Using local PE study to markup

Registry System for Cancer Immuno-therapies (1)

Drug expenditure cap for IO: 800 millions NTD (2019)

Quota: 800 patients (2019)
*May be adjusted depending on remaining budget

Submit for using IO for a particular indication

1. Qualification review
2. Pre-authorization review

Start treatment
To evaluate the value of cancer immuno-therapies and to regularly review their reimbursement restrictions, NHIA has established a registry system for these medicines to collect data including:

- Type and stage of cancer
- Results of genetic examinations (ex: EGFR/ALK wild type)
- Results of biomarker examinations
- Treatment outcomes
- Severe side effects
- Reasons for treatment withdrawal
Future Challenges and Prospects
Future Challenges

Long-term safety/ efficacy
(e.g. gene/cell therapy)

Clinical
(e.g. IO)

Cost
(e.g. DAAs for Hepatitis C)
How to cope with uncertainties (1)
How to cope with uncertainties (2)

- Good Submission Practice (GSP) / co-dependent test
- MEA regulations
- Uncertainties in Cost
- The Submission Principles for High Expenditure Cancer New Drugs
- Mandatory PE study for high expenditure new cancer drugs (start from 2020)
4-Win Situation

NHIA

Patients

Pay for Value

Medical Care Providers

Industry
THANK YOU FOR YOUR ATTENTION