Drug Reimbursement & Drug Price Adjustment Under Taiwan’s NHI System

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Outline

- The global budget system
- Principles and procedures of drug listing
- Price and volume survey and principles of drug price adjustment
- Managed entry agreements (MEAs)
The Global Budget System
The Framework of NHI

NHIA Taiwan

supportive funding

Premium

NHI IC card

Claim

Co-payment

The insured

Medical service

Medical care providers

Reimbursement
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
  – 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**

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

**MOHW**
- Figure out general parameters for the global budget
  - (Jan. ~ Apr.)
- Estimate budget based on actual spending

**Executive Yuan**
- Approve the global budget parameters
  - (May. ~ Jun.)
- Review by National Development Council

**NHI Committee**
- Negotiate and allocate global budget
  - (Aug. ~ Dec.)
- Allocate expenditure based on approved budget

1. **Payers' willingness to pay**
2. **Financial consideration**
Principles and Procedures of Drug Listing
Classification of Drugs to be Listed

Drugs submit for listing

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

New items

- Originators
- BA/BE generics
- Common generics

Biosimilars

New drugs

- Category 1 new drugs
- Category 2 new drugs (2A, 2B)
Two-level Pricing Mechanism

1. Expert committee → initial proposal
2. Stake Holder Committee (PBRS Joint Meeting) → final decision
Three decisions of Pricing & Reimbursement

1. Listing: Whether the new drug will be listed in pharmaceutical benefits scheme?
2. Pricing: How much will the new drug be paid?
3. Restriction: Whether the restriction on reimbursed indication or pre-utilization review is needed?
Four Criteria of Pricing & Reimbursement

TFDA
Safety/efficacy/quality

NHIA
1. Relative effectiveness
2. CBA/CEA/PE
3. Budget impact analysis
4. Ethical/Legal/Social/Political Impact
PBRS Joint Meeting

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

- Healthcare Providers: 13
- Scholars and Experts: 9
- The Insured: 3
- Employer: 3
- Health Regulatory Authority (MoHW): 1
- Drug Regulatory Authority (TFDA): 1

The Suppliers: 3
Pricing Process of New Drugs

1. Drug supplier
   - Dossiers

2. NHIA
   - Submission
   - Administrative review
   - Expert Committee

3. HTA
4. Patients' opinions

5. PBRS Joint Meeting

6. Decision
   - Notify Drug supplier of the result
     - Agree
     - PVA if needed
       - Disagree & appeal

7. List on NHI
Value-based Pricing

- Relative effectiveness
- CBA/CEA/PE
- Budget impact
- Ethical/legal/social/political impact
- Health Technology Assessment (HTA)
- Comparators
- Subjects
## Incentives for Breakthrough New Drug

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

A-10 reference countries: Australia, Belgium, Canada, France, Germany, Japan, Sweden, Switzerland, US, UK.
Pricing Process for Generics and Biosimilars

1. Submission
2. NHIA
3. Preliminary Pricing Results
4. PBRS Joint Meeting
5. Listing
Principle of Pricing Generics

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

<table>
<thead>
<tr>
<th>Generics</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Originators</td>
<td>100%</td>
</tr>
<tr>
<td>BA/BE generics</td>
<td>90%</td>
</tr>
<tr>
<td>Common generics</td>
<td>80%</td>
</tr>
<tr>
<td>Biosimilars</td>
<td>85%</td>
</tr>
</tbody>
</table>

- Capped at 90% of the lowest price of the listed originators.
- The lowest price of the listed BA/BE generics.
- Capped at 80% of the lowest price of the listed originators.
- The lowest price of the listed BA/BE generics and common generics.
Price and Volume Survey and Principles of Drug Price Adjustment
Trend of NHI Drug Expenditures

Drug expenditure (billion, NTD)

Drug expenditure over total health care expenditure (%)
Price and Volume Survey (1)

- **Pharmaceutical Companies:**
  - All the pharmaceutical companies selling drugs directly to the contracted medical care institutions shall declare to the Insurer the sales data of the previous season within 20 days on the first month following the end of every season.

- **Medical Care Institutions:**
  - **General purchase data survey:** The contracted medical care institutions shall declare to the Insurer the purchase data of the previous season within 20 days on the first month following the end of every season.
  - **Special purchase data survey:** The contracted medical care institutions shall declare items as well as follow the declaration time course as announced by the Insurer.
Price and Volume Survey (2)

➢ Ad hoc Survey:

➢ When being reported as indicated by clear evidence and when the following criteria are met:
  ➢ Sales price is 50% lower than reimbursement price.
  ➢ More than 3 items in the same group.
  ➢ The total declared expenditure exceeds 100 millions.
  ➢ Not basic price.

➢ Item of the same group shall be surveyed and dealt.
Principles of Drug Price Adjustment

\[ \Delta P = \text{Reimbursement price} - \text{Trading price} \]

\[ \Delta M = \text{Trading price} - \text{Cost} \]

Declared by Medical providers

Price & volume survey

Cost (? / Variable)

(profit for medical providers)

(margin for pharmaceutical companies)
Principles of Drug Price Adjustment

Old price (before adjustment)

New price

WAP

R-zone

Adjustment
Framework of Drug Price Adjustment

Drugs covered by NHI

- **Special items & orphan drugs**
- **Class 1 (Patented)**
  Priced by brand category
- **Class 2 (Patent expired <5yrs)**
  Priced by brand category
- **Class 3 (Not Class 1 or Class 2)**
  
  - listed ≤ 15yrs (3A)
    Priced by brand category
  - listed > 15yrs (3B)
    Priced by ingredient(s)
# Time course of Drug Price Adjustment

<table>
<thead>
<tr>
<th>Class</th>
<th>Range</th>
<th>Time course</th>
</tr>
</thead>
</table>
| Class 1 | 1. Patented items  
2. Other items from the same group | 1. Once every 2 yrs  
2. Under DET program: When the expenditure target is exceeded |
| Class 2 | 1. Items with patent expired <5yrs  
2. Other items from the same group | Once a year (by items) |
| Class 3 | Items other than Class 1 or 2                  | 1. Once every 2 yrs  
2. Under DET program: When the expenditure target is exceeded |
Price Adjustment- **Class 1 (1)**

- **Equation for adjustment**
  
  (一) $WAP \geq (1-R) \times P_{old}$ : No adjustment
  
  (二) $WAP < (1-R) \times P_{old}$ : Adjust as following

  $$P_{new} = WAP + P_{old} \times R \quad (R : 15\%)$$

  $P_{new}$ : New reimbursement price after adjusting
  
  $WAP$ : Weighted average market trading price
  
  $P_{old}$ : Reimbursement price before adjusting
Price Adjustment- Class 1 (2)

- The upper limit of adjustment range: 40% (except under DET program)
- Set the lowest price within a group:
  - When the reimbursement price for an item after adjusting is 70% lower than the highest reimbursement price within the same group, then its price shall be adjusted to 70% of the highest reimbursement price within the same group.
- $P_{\text{new}}$ shall not be higher than $P_{\text{old}}$.
- Generic shall not be higher than originator.
Price Adjustment- Class 2

➢ Patent expired ≤ 1 year

<table>
<thead>
<tr>
<th>Originator</th>
<th>The lowest A-10 lowest</th>
</tr>
</thead>
</table>

GWAP × (1 + R), \( P_{\text{new}} \leq P_{\text{old}} \)

Items within the same group

Adjustment range based on originator
(If no originator is listed: GWAP × (1 + R), \( P_{\text{new}} \leq P_{\text{old}} \))

➢ Patent expired for 2~5 years

<table>
<thead>
<tr>
<th>Originator</th>
<th>GWAP × (1 + R), ( P_{\text{new}} \leq P_{\text{old}} )</th>
</tr>
</thead>
</table>

Items within the same group

Adjustment range based on originator
(If no originator is listed: GWAP × (1 + R), \( P_{\text{new}} \leq P_{\text{old}} \))

※ \( R = 15\% \), GWAP: Group weighted average market trading price
Price Adjustment - Class 3

Subcategories of Class 3

- Listing of the 1st item with the same ingredient(s) and dosage form
- Listed ≤15 yrs (3A)
- Listed >15 yrs (3B)
- Adjusted by grouping
- Same price for items of the same ingredient(s), specification and category
Price Adjustment- Class 3A (1)

The 1st item with the same ingredient(s) and dosage form has been listed ≤ 15yrs

1. Set temporary price after adjusting
   - GWAP as the target value of the temporary price
   - Items within the same group ≤ 20 trading datas: Use item of other specifications with the highest sales volume in the previous year for calculating the target value (based on the conversion of specifications).
   - Temporary price after adjusting = \( \min\left[ \max\left( \min\left( \text{WAP}, \text{target value} \times 1.05 \right), \text{target value} \times 0.9 \right), \text{Pold} \right] \)
     
     If an item has no WAP, then the temporary price = target value
Price Adjustment- Class 3A (2)

2. Adjustment range and the maximum adjustment range

\[
\text{Adjustment range (AR)} = \frac{P_{\text{old}} - P_{\text{temp}}}{P_{\text{old}}}
\]

\[
P_{\text{new}} = P_{\text{old}} \times \left( 1 - \text{Min} \ (\text{AR}-15\% \ , \ \text{AR}_{\text{Max}}) \right)
\]

★ Under DET program

\[
P_{\text{new}} = P_{\text{old}} \times \left( 1 - (\text{AR}-3\% \ \text{or} \ 5\%) \right)
\]

- Items listed ≤4yrs: 5%
- Items listed >4yrs: 3%
3. Same group, same license holder and same category: prices are adjusted to the price of the item with the lowest price.

4. Set the lowest price within a group:
   - $P_{\text{new}} < 60\%$ the highest reimbursement price: Adjusted to 60% of the highest reimbursement price within the same group, but $P_{\text{new}} \leq 2 \times P_{\text{old}}$. (e.g. $P_{\text{new highest}} = 100$, $P_{\text{new}} = 50 \rightarrow P_{\text{new}} = 60$; $P_{\text{old}} = 100$, $P_{\text{new}} = 20 \rightarrow P_{\text{new}} = 40$)

5. The price of lower specification shall not be higher than higher specification (same license holder).

6. The price of generic shall not be higher than originator within the same group.
Price Adjustment - Class 3B

The 1st item with the same ingredient(s) and dosage form has been listed >15yrs

1. Set the **target value of adjustment**
   - GWAP as the target value of adjustment for each individual item.
   - The price of lower specification shall not be higher than higher specification.

2. Equation for adjustment
   - \( P_{new} = \text{Min} \left[ \text{Target value} \times (1 + 15\%), \text{Maximum } P_{old} \text{ within the same group} \right] \)
## Price Adjustment - Basic Price

> For items complying with PIC/S GMP

<table>
<thead>
<tr>
<th>Dosage Form</th>
<th>The lowest price in the dosage form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tablets /Capsules</td>
<td>NT$1.5 /Tab or Cap (standard packing /originators: 2 NT$/Tab or Cap)</td>
</tr>
<tr>
<td>Oral solutions</td>
<td>NT$25/Bot</td>
</tr>
<tr>
<td>Solutions for IV infusion (≥100 mL, &lt;500 mL)</td>
<td>NT$22/Bot</td>
</tr>
<tr>
<td>Solutions for IV infusion (≥500 mL, &lt;1L)</td>
<td>NT$25/Bot</td>
</tr>
<tr>
<td>Solutions for IV infusion (&gt;1L)</td>
<td>NT$35/Bot</td>
</tr>
<tr>
<td>Injectables with penicillins/ cephalosporins /estrogens</td>
<td>NT$25/Bot</td>
</tr>
<tr>
<td>Other Injectables</td>
<td>NT$15/Amp or Vial</td>
</tr>
<tr>
<td>Suppositories</td>
<td>NT$5/piece</td>
</tr>
<tr>
<td>Ophthalmic preparations</td>
<td>NT$12 (NT$4/Bot for daily-dose packaging eye drops)</td>
</tr>
<tr>
<td>Small package of granule/powder /suspension</td>
<td>6 NTD/pack</td>
</tr>
<tr>
<td>Ointment /Cream</td>
<td>10NTD</td>
</tr>
</tbody>
</table>
DET Pilot Program

- Article 62, National Health Insurance Act

- In case the payment of expense exceeds the preset total of drug expense ratio target, exceeding the targeted amount, the Insurer shall adjust the drug expense payment and payment schedule for the following year.

- DET Pilot Program was first promulgated by NHIA on Feb. 8\(^{th}\), 2013.

- The program was amended on Sep. 13\(^{th}\) 2017 and it was announced that the program continue for another 3 years from 2017 onwards.
How a Target Amount is Set

Target amount = Basal value \times [1 + \text{Growth rate}(\%)]

- **Basal value:**
  - The 1\textsuperscript{st} year (2017): the target amount of 2016 (exclusive of the payment for drugs used in AIDS, Hepatitis C, Rare Diseases and Hemophilia)
  - From the 2\textsuperscript{nd} year onwards: the target amount of the previous year

- **Growth rate (\%) :**
  - The growth rate of the general part of the global budget (exclusive of the budget for Chinese medicine)
Principles of Price Adjustment under DET program (1)

- Drugs in **Class 1 & 3** are subject to adjustment.

- The amount in excess of the target amount is shared among classes (Class 1, 3A and 3B), based on the proportion of the total amount adjusted in each class to the overall adjusted amount.

- Total amount adjusted in each class:
  \[
  \sum \left( (P_{\text{old}} - P_{\text{temp}}) \times \text{volume} \right)
  \]
Principles of Price Adjustment under DET program (2)

Equation:

\[ P_{\text{new}} = P_{\text{old}} - \left[ (P_{\text{old}} - P_{\text{temp}}) \times \frac{Y'}{Y} \right] \]

e.g. 95 = 100 - \left[ (100 - 80) \times \frac{30}{120} \right]
Price Adjustment of Drugs for Treating Rare Diseases and Special Items

- Article 24, Drug Price Adjustment Scheme
  - Drugs for treating rare diseases and special items are subject to price adjustment every 2 years based on:
    - Median price in A-10 countries (of the drug itself or its similar product)
    - Cost
Managed Entry Agreements (MEAs)
Managed Entry Agreements (MEAs)

- New technologies being listed under agreements made between the suppliers and the insurer.
- Various risk-sharing models involved.
- To increase the accessibility of new drugs to patients, to cope with uncertainties in the efficacy of new drugs and to control budget impact.
Examples of MEAs Models

• Financial-based:
  – Price-volume agreements
  – Expenditure-capping
  – Dose-capping
  – Conditional discounts
  – Rebate

• Performance-based:
  – Outcome guarantees
  – Risk-sharing
  – Coverage with evidence development
  – Conditional treatment continuation
  – Cost-sharing
Drugs with MEAs

- High-cost
- Uncertainty in cost-benefit
- Uncertainty in therapeutic value

Ex: immuno-oncology agents
### MEAs Models Under Planning 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 insured via refund payback.

<table>
<thead>
<tr>
<th>Category</th>
<th>Mechanism of MEAs Models</th>
</tr>
</thead>
</table>
| 1. Performance-based     | 1. Ensure the improvement in overall survival  
2. Ensure the delay in progression-free survival  
3. Refund payback based on therapeutic effect |
| 2. Financial-based       | 1. Fixed-rate refund payback  
2. Free doses  
3. Payback for co-prescribed drugs |
| 3. Mutual share by negotiation | Mutual share of refund payback among pharmaceutical products with the **same ingredient or pharmacological category**. |
Performance-based (1) - Ensure the Improvement in Overall Survival (OS)

- $O_{\text{New drug}} < \text{Median } O_{\text{Ct}}$: payback total drug expenditure
- $O_{\text{New drug}} > \text{Median } O_{\text{Ct}}$: payback a certain proportion of the total drug expenditure

Payback total expenditure (Patient A)

Median $O_{\text{Ct}}$

Payback a certain proportion of the total expenditure (Patient B)

Expiration (Patient A)

Expiration (Patient B)

Expiration (Patient C)

No payback (Patient C)

Survival of Patient
Performance-based (2) - Ensure the Delay in Progression-free Survival (PFS)

- Payback the expenditure generated beyond the median PFS. (NHI covers expenditure generated within the median PFS)
Payback a certain proportion of the total expenditure generated before assessment of therapeutic effect.

- Payback a certain proportion of the total expenditure (Patient B)
- Covered by NHI (Patient B)
- Survival of Patient
- Payback a certain proportion of the total expenditure (Patient A)
- D.C. (Patient A)
- Assessment of therapeutic effect
- D.C. (Patient B)
Financial-based (1)-Fixed-rate Refund Payback

A supplier shall propose a fixed rate for refund payback.

Rate for refund payback (e.g. 20%)

Drug expenditure claimed

Payback
A supplier shall pay for initial doses or additional doses used for the treatment.

Ex: Suppose that a supplier is willing to pay for the initial doses used in the first 2 months and the average treatment duration in the clinical trial is 10 months → equals to 20% refund payback (=2/10=20%)

☆ Payback with condition (Initial doses)

☆ Payback with condition (additional doses)

☆ Payback with condition: Involves negotiation with the supplier depending on different products (e.g. total cost)
Financial-based (3)- Payback for Co-prescribed Drugs

- If a new drug has to be used in combination with other drugs, the new drug supplier shall payback a certain proportion of the expenditure generated from the other drugs.

<table>
<thead>
<tr>
<th>Original treatment</th>
<th>Drug A (Old drug)</th>
<th>Covered by NHI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Combined treatment</td>
<td>Drug A (Old drug)</td>
<td>Payback a certain proportion of the expenditure of Drug A</td>
</tr>
<tr>
<td></td>
<td>Drug B (New drug)</td>
<td>Covered by NHI</td>
</tr>
</tbody>
</table>
Points of Consideration Regarding Implementation of MEAs

- **Fairness** of the agreements:
  - Controversies may arise as the proposals differ among different companies or different products.
  - Taiwan has not yet adopted ICER threshold.

- **How to present in** the PBRS Joint Meeting:
  - MEAs are confidential.
  - We need to conceal the contents of the agreements and win the trust from the PBRS Joint Meeting.
THANK YOU FOR YOUR ATTENTION