Dynamic Adjustment Mechanism For National Drug Formulary

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Dynamic Adjustment Mechanism for National Drug Formulary: China case

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Tokyo, Japan
Major National Healthcare Insurance Schemes

- Basic medical insurance system for urban employees was established in 1998.
- New Cooperative Medical Scheme for rural population and MA for poor rural residents were established in 2002.
- Social Medical Insurance Scheme was established in 2007.
- The aim for health reform in 2008 is to achieve Healthy China Strategy in 2020.
- The new health reform plan was published in 2009.

Healthcare Insurance (3 + 1 Insurance Scheme, April, 2009)

Population of China

- Rural
  - NCMS
- Urban
  - Employees
  - Residents
    - Basic Medical Insurance for urban employees
    - Basic Medical Insurance for urban residents
  - MA for the poor

Private Medical Insurance
Governance Reform (Recent)

- **13th National People’s Congress--5th March, 2018**
  - New Payer: National Healthcare Security Administration (NHSA)
    - Reimbursement access
    - Pricing (drug, lab test and service)
    - Procurement (working with NHC)
  - New Scheme:
    - Merging all Medical Insurance Schemes into One
    - Covering 97% of Chinese Population
  - New MoH:
    - MoH---NHFPC---NHC (National Health Commission)

Dynamic adjustment mechanism in NRDL & NEDL

- **National Reimbursement Drug List (NRDL)**
  - first round of drug price negotiation for 44 costly drugs in 2017: The price of 36 drugs dropped by 40-60% and got into NMRL: 31 medicine+5 TCM, target cancer drug, NCD, and rare disease etc.
  - The second round of drug price negotiation for 18 cancer drugs (end of Sep 2018 next slide)

- **National Essential Drug List (NEDL)**
  - Last version of NEML was at 2012
  - Updating 2018—Issued soon
### 2018 NRDL Price Negotiation on Cancer Drug

<table>
<thead>
<tr>
<th>Brand/manufacturer</th>
<th>Generic name</th>
<th>TA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hematology (6)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 Jakavi/NVS</td>
<td>Ruxolitinib</td>
<td>MF(Mycobacterium)骨髓杆菌椎体炎</td>
</tr>
<tr>
<td>2 Idelalisib/Takeda</td>
<td>Ibrutinib</td>
<td>CLL, MCL</td>
</tr>
<tr>
<td>3 Immunocore</td>
<td>Ibrutinib</td>
<td>CLL, MCL</td>
</tr>
<tr>
<td>4 Tafibutcit/NVS</td>
<td>Ibrutinib</td>
<td>CLL, MCL</td>
</tr>
<tr>
<td>5 Vizag/Beigene</td>
<td>Ibrutinib</td>
<td>CLL, MCL</td>
</tr>
<tr>
<td>6 Aryl/Pfizer</td>
<td>Pegaspargase</td>
<td>ALL, 急性淋巴细胞白血病</td>
</tr>
<tr>
<td><strong>Solid Tumor (12)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7 Tagrisso/AZ</td>
<td>Osimertinib</td>
<td>NSCLC 非小细胞肺癌</td>
</tr>
<tr>
<td>8 Zykadia/NVS</td>
<td>Eribinib</td>
<td>NSCLC 非小细胞肺癌</td>
</tr>
<tr>
<td>9 Gilotinibi</td>
<td>Afatinib</td>
<td>NSCLC 非小细胞肺癌</td>
</tr>
<tr>
<td>10 Xalkori/Pfizer</td>
<td>Crizotinib</td>
<td>NSCLC 非小细胞肺癌</td>
</tr>
<tr>
<td>11 福可维/正大天晴</td>
<td>Anlotinib</td>
<td>NSCLC 非小细胞肺癌</td>
</tr>
<tr>
<td>12 Zelboral/Roche</td>
<td>Venuramibun</td>
<td>MM(malignant melanoma) 黑色素瘤</td>
</tr>
<tr>
<td>13 Ebirim/Merck</td>
<td>Cetuximab</td>
<td>CRC 结直肠癌</td>
</tr>
<tr>
<td>14 Silvarga/Bayer</td>
<td>Regorafenib</td>
<td>HCC-2L, 肝细胞癌二线，CRC-3L, 结直肠癌三线</td>
</tr>
<tr>
<td>15 Votripte/NVS</td>
<td>Pazopanib</td>
<td>RCC 肾细胞癌</td>
</tr>
<tr>
<td>16 Sutent/Pfizer</td>
<td>Sunitinib</td>
<td>RCC 肾细胞癌</td>
</tr>
<tr>
<td>17 Inlyta/Pfizer</td>
<td>Axitinib</td>
<td>RCC 肾细胞癌</td>
</tr>
<tr>
<td>18 Sandostatin.LAR/NVS</td>
<td>Octreotide Microspheres</td>
<td>NET 神经内分泌肿瘤</td>
</tr>
</tbody>
</table>

### HTA Dossier for 2nd drug price negotiation

- **Two Component:**
  - General Information
    - Letter of Commitment
    - Power of Attorney
    - Self-Assessment Report
    - list of Product Information
  - Topic Specific Information
    - Pharmacoeconomics
    - Clinical efficacy
    - Market Information
Specific information needed in dossier

- **Basic Product Info**
- **Clinical Efficacy information**
  - Reference Drug Information
  - Registration, Reimbursement
  - Comparative
  - OS, PFS
- **Pharmacoeconomic Information**
  - Mainland China
  - Producing Country
- **Product Price Information**
  - China Price
  - Product Price Information
  - Country, Recommended Country
  - Country Specific Price, Negotiation
- **Production Market Information**
  - Mainland China Market Information
  - Sales, Budget Impact Analysis Key
  - Market Information of Producing
- **Drug Negotiation Intention Payment Standard**

Updated National Essential Drug List

- From 520 (2012) to 685(2018) items
  - Medicine 417 items, TCM 268 items
- Disinvested 22
- Newly Added:
  - Focus on Cancer (i.e. Antineoplastic Drug-12 items, innovative cancer drug)
  - Pediatric (i.e. High-Demanding -22items)
  - NCD
  - Pan-genotype Hep-C
- Rules in Priority setting
  - Burden of Diseases
  - Clinical Needs and Preferable
  - Clinical Effectiveness
  - Cost Effectiveness
- Consistency Evaluation for Generic Drug
Dimensions of Value Judgement

- Cost-effectiveness
- Clinical effectiveness
- Uncertainty Degree & Scope
- Innovation
- Law and Policy
- Social, Ethical, Equity and Human Right
- Application Setting Requirement

Thank you!!!

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