

ISPOR Asia Pacific 2018

Dynamic Adjustment Mechanism For National Drug Formulary

Chair: Prof Shu-Chun Li, University of Newcastle

Speakers: Dr Hao Hu, China National Health Development Research Centre

Dr Fei-Li Zhao, University of Newcastle

Dr Lan Gao, University of Deakin



Dynamic Adjustment Mechanism for National Drug Formulary: China case

Dr. Hu Hao/Prof. Zhao Kun

Division of Policy Evaluation and Health Technology Assessment
China National Health Development Research Center (CNHDRC)

11th September

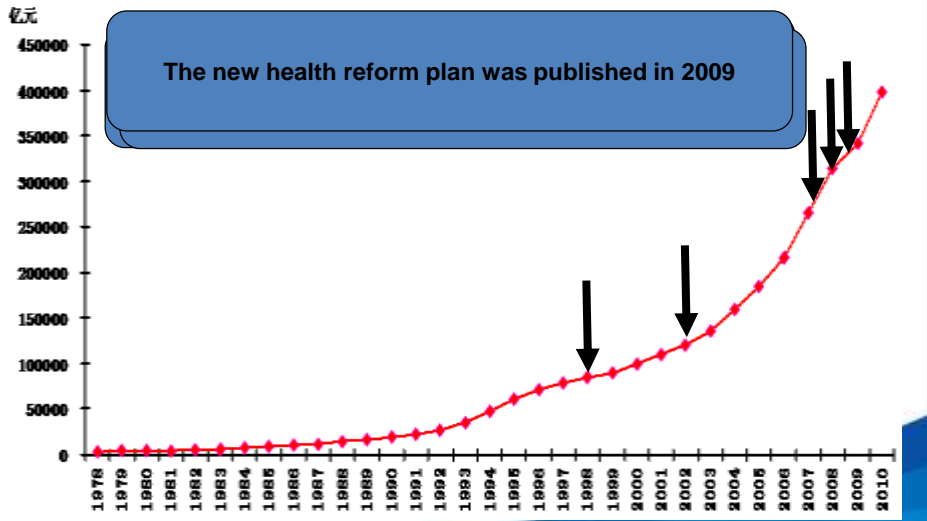
Tokyo, Japan

China National Health Development Research Center

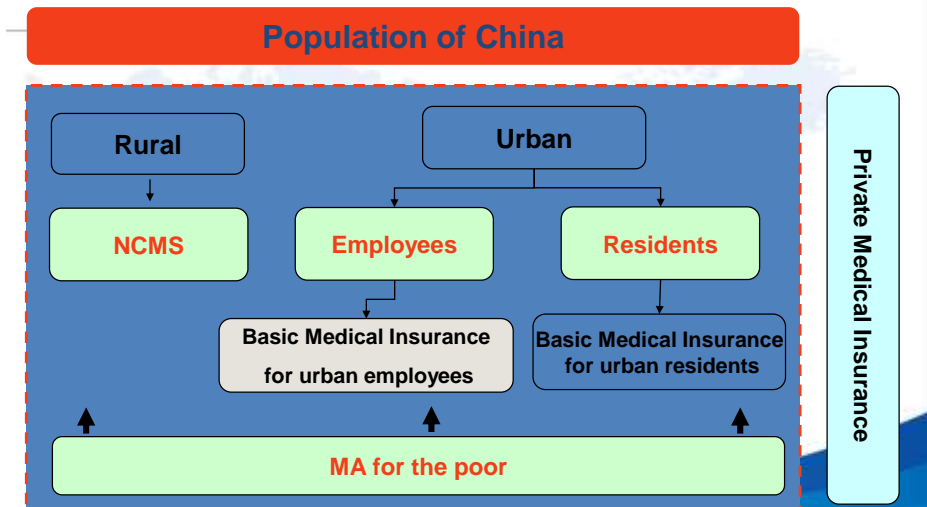
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Major National Healthcare Insurance Schemes



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





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---NHFPCC---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 rear 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 NEDL was at 2012
 - Updating 2018—Issued soon



2018 NRDL Price Negotiation on Cancer Drug

| | Brand/manufacturer | Generic name | TA |
|---------------------|----------------------|-------------------------------|------------------------------|
| Hematology (6) | 1 Imbruvica/Jassen | Ibrutinib 伊布替尼 | CLL, MCL |
| | 2 Jakavi/NVS | Ruxolitinib 芦可替尼 | MF(Myelofibrosis) 骨髓纤维化 |
| | 3 Ninlaro/Takeda | Ixazomib 伊沙佐米 | MM(Multiple myeloma) 多发性骨髓瘤 |
| | 4 Tassigna/NVS | Nilotinib 尼洛替尼 | CML 慢性粒细胞白血病 |
| | 5 Vidaza/Beigene | Azacitidine 阿扎胞苷 | MDS 骨髓增生异常综合症 |
| | 6 艾阳/恒瑞 | Pegaspargase 培门冬酶 | ALL 急性淋巴细胞白血病 |
| Solid Tumor (12) | 7 Tagrisso/AZ | Osimertinib 奥希替尼 | NSCLC 非小细胞肺癌 |
| | 8 Zykadia/NVS | Erlotinib 塞瑞替尼 | NSCLC 非小细胞肺癌 |
| | 9 Gilotrif/BI | Afatinib 阿法替尼 | NSCLC 非小细胞肺癌 |
| | 10 Xalkori/Pfizer | Crizotinib 克唑替尼 | NSCLC 非小细胞肺癌 |
| | 11 福可维/正大天晴 | Anlotinib 安罗替尼 | NSCLC 非小细胞肺癌 |
| | 12 Zelboraf/Roche | Vemurafenib 维莫非尼 | MM(malignant melanoma) 黑色素瘤 |
| | 13 Erbitux/Merck | Cetuximab 西妥昔单抗 | CRC 结直肠癌 |
| | 14 Stivarga/Bayer | Regorafenib 瑞戈非尼 | HCC-2L 肝细胞癌二线, CRC-3L 结直肠癌三线 |
| | 15 Votrient/NVS | Pazopanib 培唑帕尼 | RCC 肾细胞癌 |
| | 16 Sutent/Pfizer | Sunitinib 舒尼替尼 | RCC 肾细胞癌 |
| | 17 Inlyta/Pfizer | Axitinib 阿昔替尼 | RCC 肾细胞癌 |
| | 18 SandostatnLAR/NVS | Octreotide Microspheres 奥曲肽微球 | NET 神经内分泌肿瘤 |



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, ...
- **Pharmacoeconomics**
 - Mainland China
 - Producing Countries
- **Product Price**
 - China Price
 - Product Information
 - Country, Recommended Country
 - Country Specific Price, Negotiation
- **Production Market Information**
 - Mainland China Market Information
 - Sales, Budget Impact Analysis Key
 - Market Information of Producing Countries
 - Sales, Epi data, ...
- **Drug Negotiation Intention Payment Standard**

一、Basic Product Info

1. Generic name : _____ ; 2. English name : _____ ;

3. Brand name : _____ ; 4. specification : _____ ;

5. Formulation : _____ ; 6. ATC code : _____ ;

7. Indication (Fill in according to the instructions) : _____ ;

(2) Budget impact analysis key information

Epidemiological data in China (Year : _____) :

Incidence rate : _____ Prevalence : _____

mortality rate : _____ Five-year survival rate : _____

Forecast of drug market share in 2019-2020

(Calculated by negotiating intention payment standard) :

Forecast market share in 2019 : _____ Patient number : _____

Forecast market share in 2020 : _____ Patient number : _____

Forecast of drug costs in 2019-2020

(Calculated by negotiating intention payment standard) :

Forecast medical expenses in 2019 : _____

Forecast medical expenses in 2020 : _____

Remarks :

Submit relevant calculation basis according to the requirements of the attachment

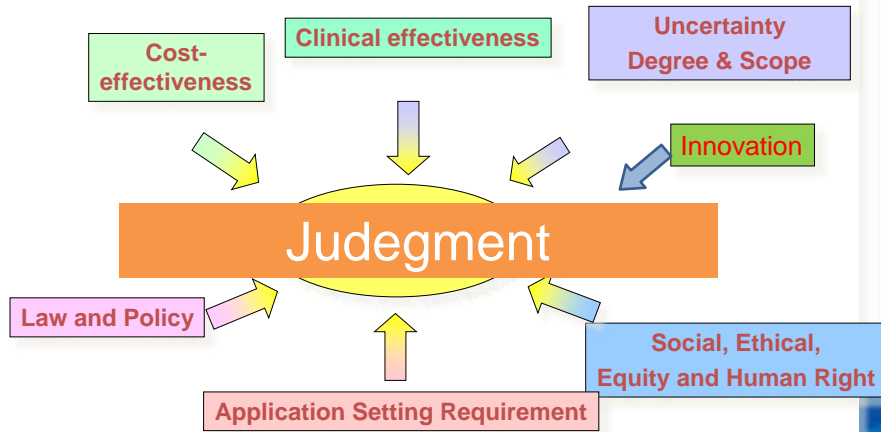


Updated National Essential Drug List

- 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



THANK YOU !!!

how.who@hotmail.com

zk317@yahoo.com