SHOULD VOLUME-BASED PROCUREMENT PRICE OF COMPARATOR BE REFERENCED FOR INNOVATIVE DRUGS IN NATIONAL REIMBURSEMENT DRUG LIST NEGOTIATION IN CHINA?

Jing Wu[1], Jun Liu[2], Jian Ming[3], Shuli Qu[3], Tian Wei[3], Lanqing Zhu[2], Jing Chen[2]

1. School of Pharmaceutical Science and Technology, Tianjin University, Tianjin, China; 2. IQVIA, Beijing, China; 3. IQVIA, Shanghai, China

Background and Objectives

- **Innovative drugs** bring **outstanding clinical benefits** to patients by improving treatment adherence in rare diseases, significantly reducing related medical expenses, and thereby reducing the economic burden of patients and healthcare system
- In current China's National Reimbursement Drug List (NRDL) negotiation, when submitting **cost-effectiveness analysis evidence**, **Volume-based Procurement (VBP)** price is referenced for comparator if comparator is **off-patent drug with generics**.
- Lower price may become the main concern for pharmaceutical manufacturers to invest R&D and launch in China, which will affect patient access to innovative drugs

- **Objective**: This study aims to explore whether it is reasonable to **reference VBP price** of comparator in **innovative drugs NRDL negotiation** through two simulated case studies on hypothetical **oncology** innovative drug X and **chronic disease** innovative drug Y

Methods

Oncology Case

- From the **health care system** perspective, a **partitioned survival model** was constructed for innovative drug X in treatment of **metastatic castration-resistant prostate cancer (mCRPC).**
- The model adopted **life-time horizon.** Quality-adjusted life year (QALY) and costs were discounted at an annual rate of **5%.**
- The efficacy and safety data of The hypothetical drug X is combined from **two innovative mCRPC drugs**. Cost and utility inputs were retrieved from **published literature**. **Abiraterone** was selected as comparator as itis **widely used** among mCRPC patients in China.
- We compared the negotiation prices of drug X at given willingness-to-pay threshold using **branded price** (before VBP) and **VBP price of Abiraterone.**
- The **trend of market growth** and overall **sales forecast** for drug X **under different willingness-to-pay thresholds** were estimated to evaluate its **long-term return.**

Chronic Disease Case

- From the **healthcare system** perspective, IQVIA **CORE diabetes model** was used to simulate for innovative drug Y in treatment of **Type 2 diabetes (T2D).**
- The model adopted **life-time horizon.** Quality-adjusted life year (QALY) and costs were discounted at an annual rate of **5%.**
- The efficacy and safety data of The hypothetical drug Y is combined from **multiple innovative GLP-1 agonists in global pipelines**. Cost and utility inputs were retrieved from **published literature**. **Basal Insulin Degludec** was selected as comparator as it is **widely used** among T2D patients in China.
- The **trend of market growth** and overall **sales forecast** for drug Y **under different willingness-to-pay thresholds** were estimated to evaluate its **long-term return.**

Results: Oncology Case

Table 1. CEA Model results

Comparator	Willingness-to-pay threshold	Δ QALY	Reference Price	Monthly costs of comparator	Innovative drugs X's CEA-based monthly cost
Abiraterone	¥64,781/QALY	0.323	Branded price	¥ 16,231	**¥ 24,590**
			VBP price	¥ 4,009	**¥ 4,071**

- Drug X achieved **0.323 QALY gain** compared with Abiraterone.
- Assuming a willingness-to-pay threshold of **0.8 times GDP per capita (CNY 64,781)**, the **monthly cost** calculated with negotiation prices of drug X were **CNY 24,590 and CNY 4,071** respectively, using branded price and VBP price of Abiraterone.
- The **price difference** of inverting innovative drugs is **more than 6 times**. Monthly cost of CNY 4,071 is **75% lower** than branded Abiraterone before VBP (CNY 16,231) and is close to abiraterone VBP price (CNY 4,009).

Figure 1. Innovative drug X's 10-year market growth forecast

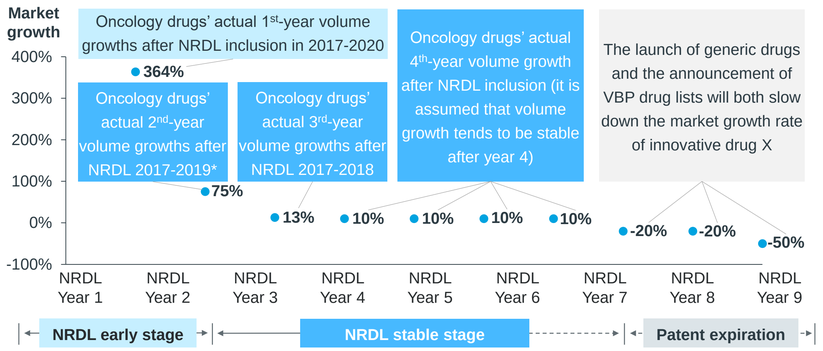
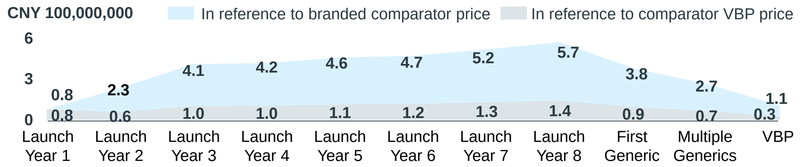


Figure 2. Innovative drug X's 10-year sales revenue forecast



- In the long-term sale forecast simulation, the estimated revenue of innovative drug X would be **80% lower** than average of **other prostate cancer drugs listed in NRDL**.

Results: Chronic Disease Case

Table 2. IQVIA CORE diabetes model results

Comparator	Willingness-to-pay threshold	Δ QALY	Reference Price	Annual costs of comparator	Innovative drugs X's CEA-based annual cost
Basal Insulin	¥80,976/QALY	0.183	Branded price	¥ 8,552	**¥ 10,309**
			VBP price	¥ 3,041	**¥ 5,017**

- Drug Y achieved **0.183 QALY gain** compared with basal insulin.
- Assuming a willingness-to-pay threshold of **1 times GDP per capita (CNY 80,976)**, the **annual cost** calculated with negotiation prices of drug Y were **CNY 10,309 and CNY 5,017** respectively, using branded price and VBP price of basal insulin.
- CNY 5,017 is **lower** than the latest annual costs of all available branded GLP-1 drugs (ranged from CNY 6,503 to CNY 12,387); and is **lower** than all available branded basal insulins in China (ranged from CNY 6,704 to 8,552).

Figure 3. Innovative drug Y's 10-year market growth forecast

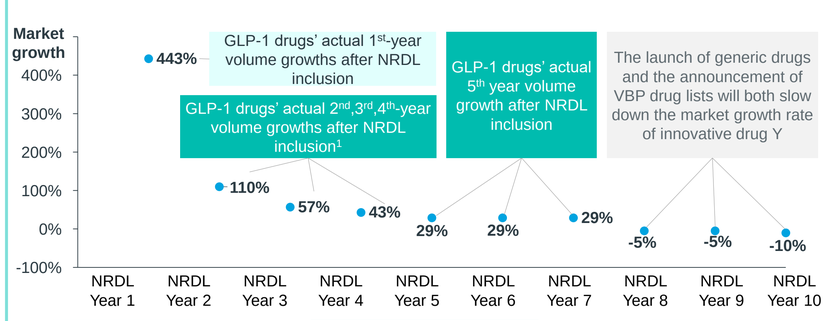
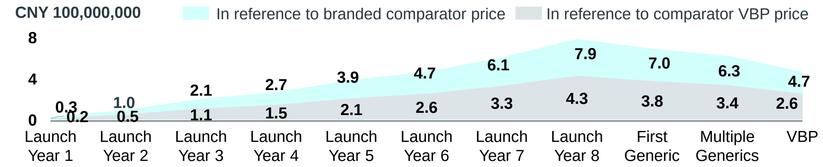


Figure 4. Innovative drug Y's 10-year sales revenue forecast



- If referenced to VBP price, the estimated sales of innovative drug Y would be **too low to support R&D and access of innovative GLP-1 drugs into China market.**

Discussion & Policy Advocacy

- To ensure long-term clinical benefits and local & foreign innovative drug access to Chinese patients, government support plays a crucial role in optimizing the decision-making process. There are several issues to considered to ensure a healthy market access environment in China:
  - When selecting reference drug for NRDL negotiation, it is recommended to select drugs with similar level of innovation, to pair with the clinical value of the innovative drugs.
  - Consider to distinguish the pricing mechanism for innovative drugs from generics. Originator's price before VBP is more appropriate to be referenced for innovative drugs' NRDL negotiation, to pair with its greater investment and higher innovation value.
  - Conducting value-based pricing for innovative drugs and granting reasonable return to innovative drugs are crucial for expanding the innovative drug options for Chinese patients.

CONTACT

Jing Wu, Ph.D., School of Pharmaceutical Science and Technology, Tianjin University, Room 209-4, Tianjin, 12, 300072, China; Email: jingwu@tju.edu.cn

DISCLOSURE

No potential conflict of interest was reported by the authors.