Developing A Value Assessment Framework for Modified New Drugs in China

HTA85

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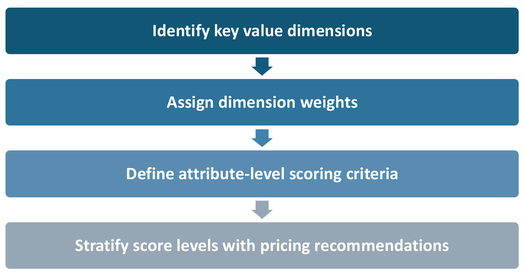
BACKGROUND

- In China, **~20%** of newly reimbursed National Reimbursement Drug List (NRDL) drugs (2022–2023) were **modified new drugs,** with **~40%** involving **dosage form changes**.
- **All new drugs follow a unified reimbursement access pathway**, without differentiation by innovation level.
- **Due to reliance on non-inferiority or bioequivalence trials**, most modified drugs lack robust evidence for cost-effectiveness analysis (CEA).
- Cost-minimization analysis (**CMA**) is commonly used, **potentially undervaluing** modified drugs.

OBJECTIVES

- To develop a **fit-for-purpose value assessment framework** for modified new drugs in China, using dosage form innovations as a pilot.
- To provide **evidence-based support** under existing access routes, especially when **health economic data is lacking**.

METHODS



- We analyzed **24 modified dosage form drugs** included in NRDL during 2022–2023, comparing their costs with **existing formulations.** Key value attributes were extracted.
- Core value dimensions and weights were identified using standardized regression.
- The framework was refined using China's **official pricing assessment tool** from the *Pricing Classification Guidelines for Newly Launched Chemical Drugs* **to ensure policy alignment.**

RESULTS

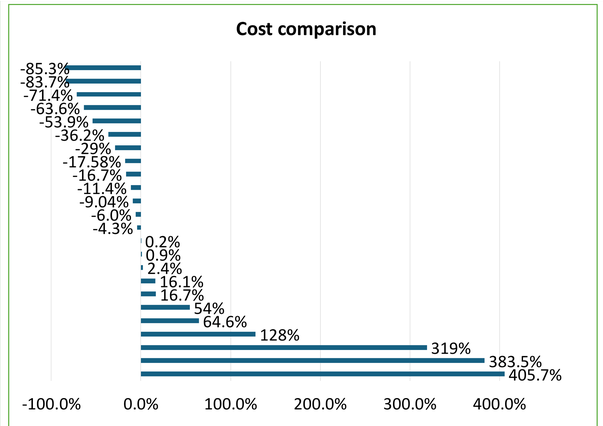


Figure1: Cost comparison of Modified Dosage Form Drugs (2022–2023,NRDL)

- 45.83% of modified drugs granted premium pricing.
- Inhalation formulations (e.g., solutions, sprays) achieved the highest premium levels, potentially driven by **device-associated innovation and improved patient usability**.

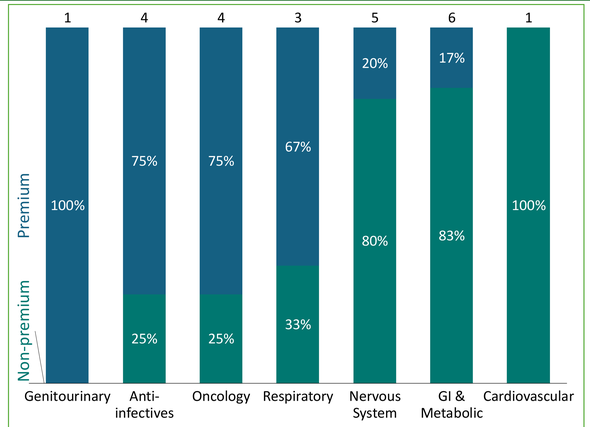


Figure2: Negotiated Pricing Outcomes by Therapeutic Area (n=24)

- **Premium pricing** was more commonly granted in **anti-infectives**, **oncology**, and **respiratory** drugs..
- These areas often involve **high clinical urgency** or require **device-based delivery**, supporting higher perceived value.

Table 1: **Value Assessment Framework — Dimensions, Weights, and Scoring Criteria**

Dimension Category	Key Dimension	Weight	Scoring Criteria
1. Pharmaceutical Value	1.1 Type of modification	10%	Route-changing & breakthrough: 3 pts Route-changing & general: 1 pt Non-route change but major release/form change: 2 pts Minor change: 0 pt
2.Clinical Value	2.1 Targets severe subpopulations	5%	Yes: 1 pt / No: 0 pt
	2.2 Improves administration: convenience/safety	20%	Yes: 1 pt / No: 0 pt
	2.3 Priority review eligibility		
	2.3.1 Indication listed in *Rare Disease Catalog*	10%	Yes: 1.5 pts / No: 0 pt
	2.3.2 Listed in *Urgent Shortage Clinical Drugs*		Yes: 1 pt / No: 0 pt
	2.3.3 Drugs for Class A and B infectious diseases		Yes: 1 pt / No: 0 pt
	2.4 National policy support		
	2.4.1 Listed in *National Major Drug Innovation Project*	10%	Yes: 1 pt / No: 0 pt
	2.4.2 Listed in *Encouraged Generic Directory*		Yes: 0.5 pt / No: 0 pt
	2.4.3 Domestic innovation		Yes: 0.5 pt / No: 0 pt
	2.5 Pediatric formulation	5%	Pediatric-specific: 1 pt Pediatric-adapted: 0.5 pt Non-pediatric: 0 pt
	2.6 Clinical priority	5%	Preferred treatment option: 1 pt / Not preferred: 0 pt
3.Evidence Support	3.1 Guideline recommendation	15%	Authoritative guideline: 1.5 pts General guideline/consensus: 0.5 pt Not recommended: 0 pt
	3.2 Key clinical trial	15%	Conducted: 1 pt / Not conducted: 0 pt

- The value score ranges from 0 to 1.725, composed of **pharmaceutical value** (0.3, 10%), **clinical value** (1.125, 65%), and **evidence support** (0.3, 25%).
- Based on quartile thresholds, drugs are stratified into four value tiers—**low, medium, high, and top**—corresponding to increasing levels of assessed value.

Application : Pricing

- Ideally, specific price ranges would be suggested based on each value tier.
- However, due to the limited number of comparable drug samples, the current framework only supports **directional pricing guidance**, as summarized below:

Table 2: **Value Tier–Based Pricing Recommendations**

Tier Level	Score Range	Pricing Recommendation
Top Tier	1.350 – 1.725	Not lower than existing dosage form; **premium is encouraged**
High Tier	0.900 – 1.325	Not lower than existing dosage form
Medium Tier	0.450 – 0.875	Not higher than existing dosage form
Low Tier	0.000 – 0.425	**Price reduction is recommended**

CONCLUSION

- Due to their clinical and regulatory characteristics, most modified drugs are **not suitable for full health technology assessment (HTA)**, and lack sufficient evidence for traditional pharmacoeconomic pricing.
- This framework **quantifies drug value** and addresses the limits of cost-minimization analysis by incorporating **pharmaceutical, clinical, and evidence dimensions**.
- The framework provides quantified value scores and tier-based pricing recommendations, offering a **practical too**l to support simplified access and inform reimbursement decisions.
- This approach may inform future policy design for **differentiated evaluation and pricing mechanisms** in China's NRDL access pathways.

REFERENCE

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