China's National Reimbursement Drug List (NRDL) Negotiation: Value Considerations and Key Factors Influencing Payment Standards

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INTRODUCTION AND OBJECTIVES

- Since 2017, the National Healthcare Security Administration (NHSA) in China has implemented a systematic and value-based drug evaluation mechanism to assess innovative therapies seeking inclusion in the National Reimbursement Drug List (NRDL). As part of this government-led framework, the NHSA conducts annual price negotiations with pharmaceutical companies to secure reasonable payment standard for exclusive or high-value drugs covered by public healthcare.
- The payment standards for NRDL drugs are determined through a structured process that carefully balances clinical value and health economics value alongside market competition and the comparative pricing of similar drugs.
- This study reviews the latest NRDL updates and highlights key factors in setting payment standards.

METHODS

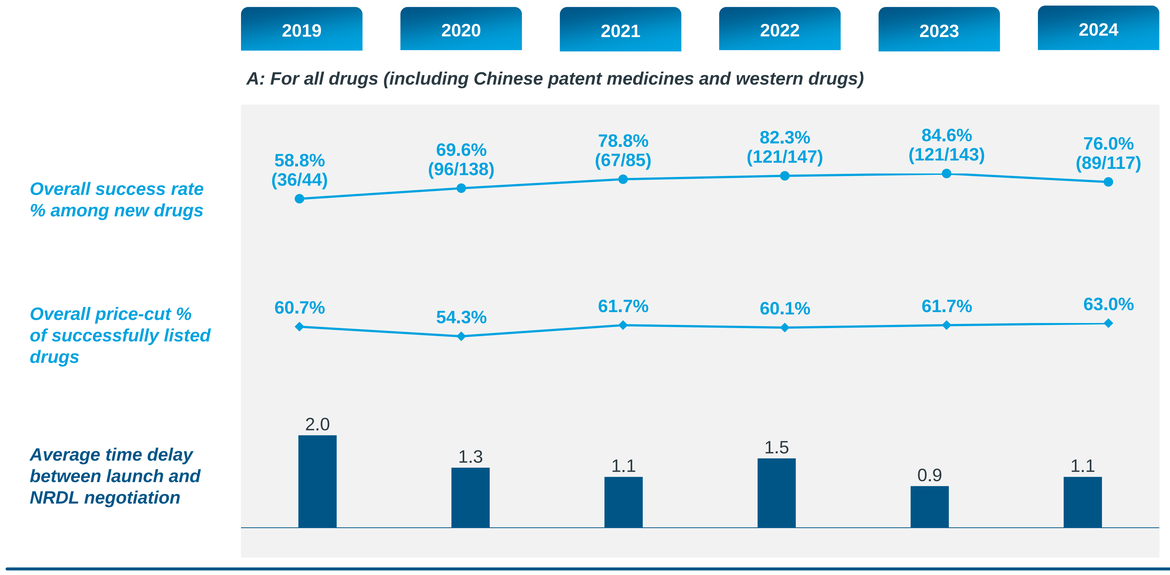
- A comprehensive literature review was conducted to identify relevant studies including peer-reviewed publications indexed in PubMed, CNKI, and Wanfang, in addition to policy documents available on government official website.
- Quantitative analyses were conducted, using the best available prices and product data before and after NRDL negotiations from 2017 to 2024.
- Descriptive statistics was used to summarize the NRDL negotiation outcomes.

RESULTS

❖NRDL results overview

- A total of 871 drugs were added to the NRDL through 2017-2024, the average price-cut of NRDL negotiated drugs has remained relatively stable at around 60% since 2019. (**Figure 1)**
- In 2024, among 249 unlisted candidates, 117(47%) participated in the price negotiation, with 89(76%) successfully listed. These 89 drugs had an average price reduction of 63% and were listed within a median time of 1.1 years after approval.
- Of note, the negotiation success rate for innovative drugs (first launched globally in China) was over 90%.

Figure 1: Overview of the NRDL negotiations for new drugs

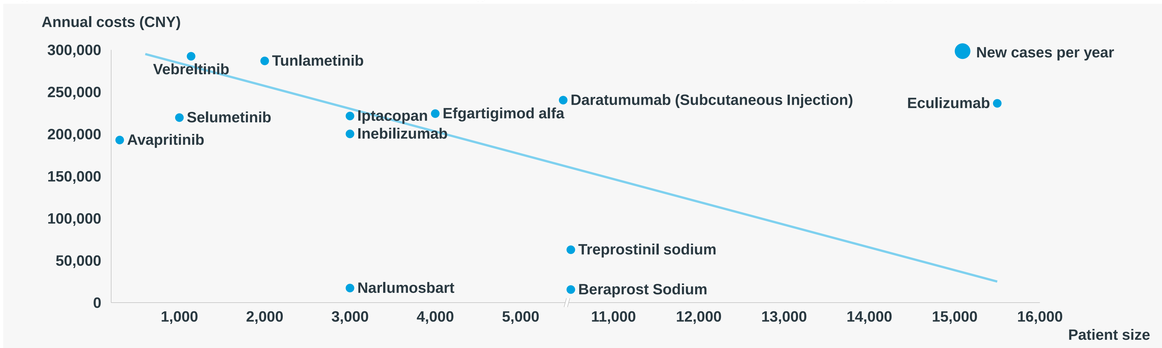


❖Key factors influencing payment standards

1) Budget impact

- Payment standards decrease with more targeted patients.
- Linear regression based on 12 rare disease drugs (cost: 15,505-292,365 CNY/year) estimated a cost reduction of 7,074 CNY for every 1,000 extra cases annually. (**Figure 2)**
- Analysis of 50 cancer drugs indicated that annual costs (range: 11,796CNY to 297,200CNY) were estimated to reduce by 1,369CNY for every 1,000 extra new cases per year. (**Figure 3**)

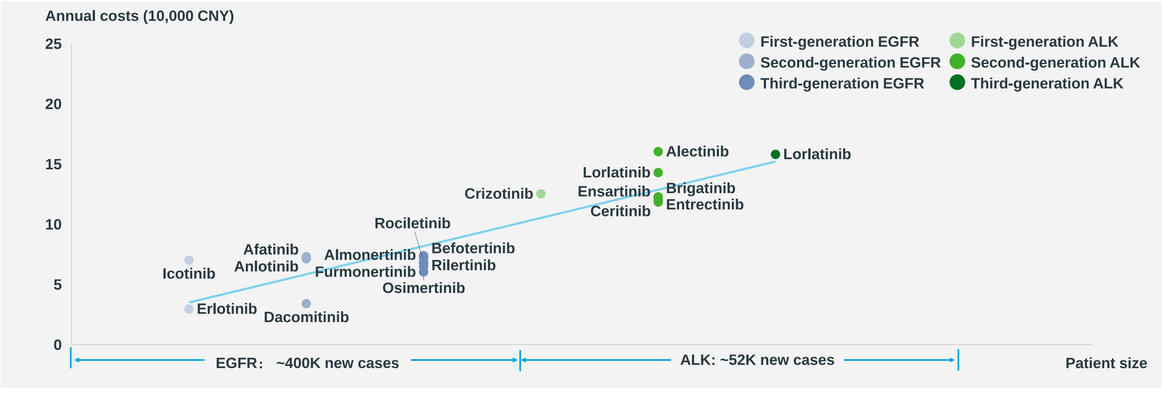
Figure 2: Trends in the annual costs of rare disease drugs with the number of targeted patients changing



2) Clinical value

- Later-generation products tend to achieve higher payment standards.
- Nineteen targeted therapies across three generations for treating NSCLC were analyzed. With each generational upgrade, annual costs for EGFR and ALK TKIs were estimated to increase by 8,995CNY and 16,394CNY, respectively.

Figure 3: Trends in the annual costs of NSCLC drugs across three generations



3) Other factors

- Whether a high-value new drug demonstrates cost-effectiveness within the given willingness-to-pay is another critical factor influencing its payment standard. Additionally, the price of alternative therapies already included in the NRDL will also be assessed to ensure fair reimbursement.

CONCLUSIONS

- Payment standard decisions of NRDL in China are complex, comprehensively considering factors such as clinical value, budget impact, and market competition, and showing an increasing trend of support for innovative drugs while ensuring affordability.

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