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## BACKGROUND

China's National Reimbursement Drug List (NRDL) undergoes annual adjustments, incorporating a value assessment and price negotiation mechanism to evaluate innovative drugs for reimbursement. Unlike regions that rely extensively on Health Technology Assessment (HTA) and pharmacoeconomic evaluations to inform reimbursement decisions, in China, payer considers annual treatment cost as a key component of its economic value assessment for NRDL inclusion. Historical NRDL outcomes reveal that drugs with annual treatment costs above 300,000 RMB are more likely to fail in negotiations, effectively establishing an "informal ceiling" on the pricing of innovative drugs.

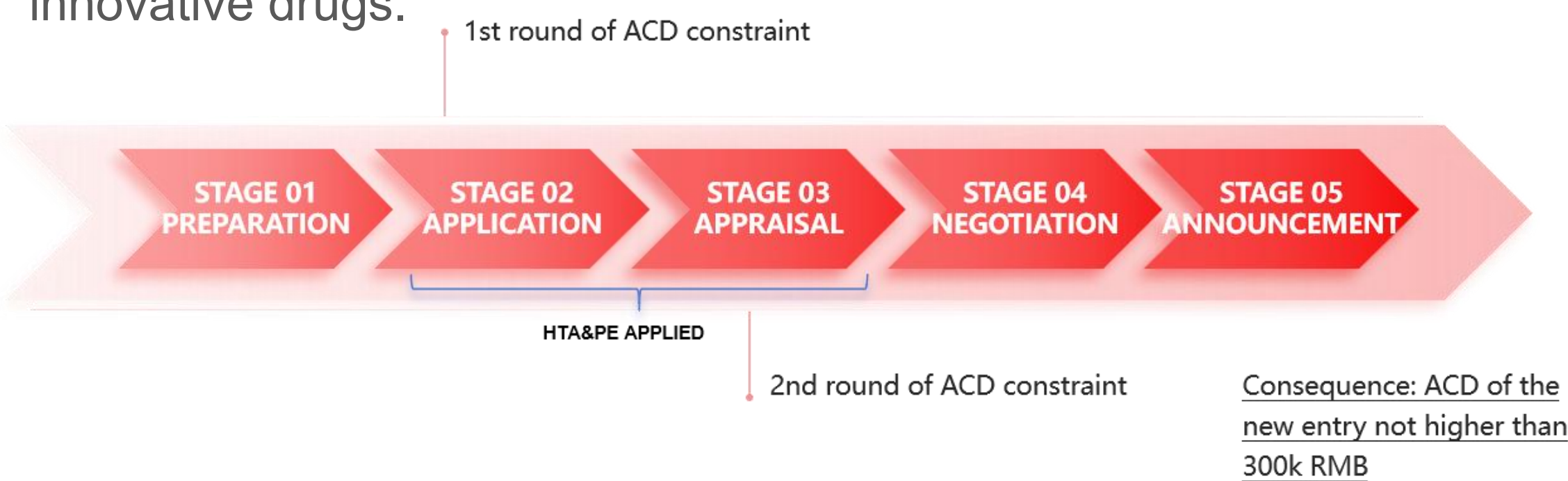


Figure 1 China's NRDL yearly adjustment process and the consideration of Annual Cost of the Drug

## OBJECTIVES

This study aims to examine and enhance the annual cost threshold practices for NRDL entry, with the following objectives:

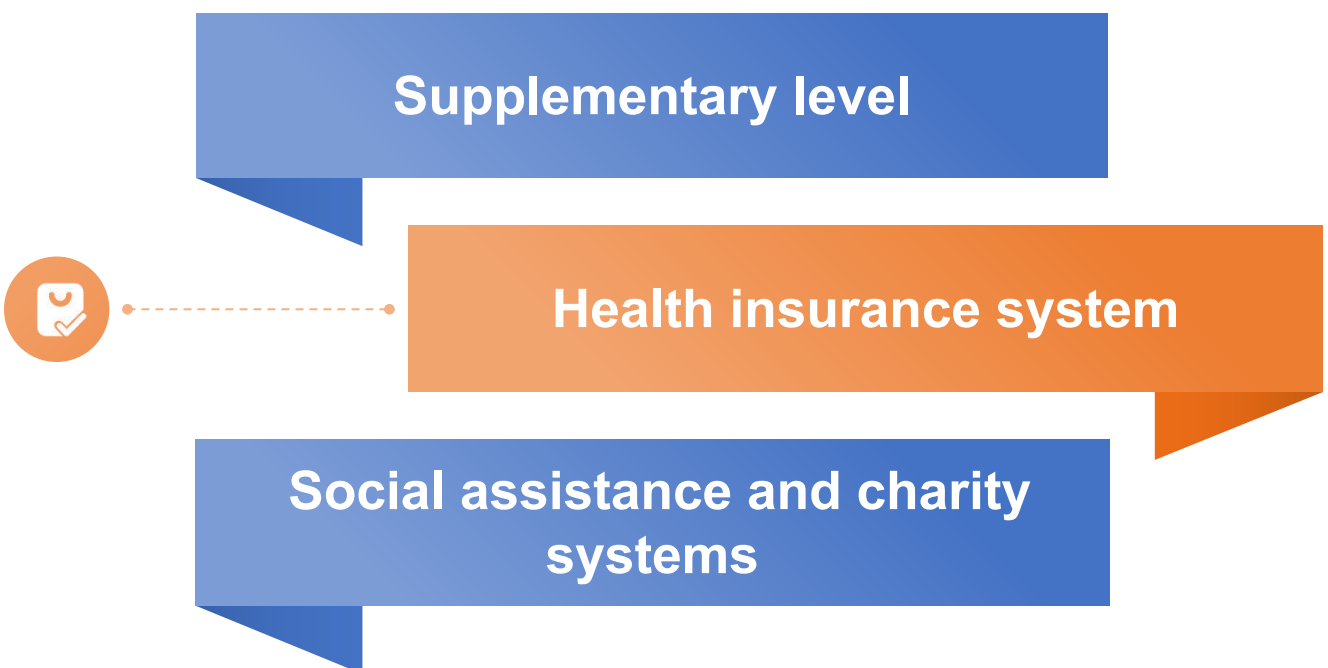
- Compare China's approach to annual cost thresholds in NRDL negotiations with those of international systems that utilize HTA and structured pharmacoeconomic assessments.
- Assess the rationale behind China's annual cost thresholds and explore the integration of these thresholds within broader NRDL policies.
- Propose optimization strategies for setting annual cost thresholds in NRDL negotiations to better support innovative drug reimbursement, providing theoretical backing for annual cost threshold implementation.

## METHOD

- Case Analysis  
Analyze price/cost levels of case-study drugs in selected reference regions.
- Policy Comparison  
Study the healthcare systems and access pathways in these regions for insight into reimbursement mechanisms.
- Quantitative Analysis  
Employ logistic regression analysis to investigate the impact of annual treatment cost levels on the likelihood of catastrophic health expenditure in Chinese households under the current NRDL benefit levels.

## RESULTS

China's healthcare security system primarily includes diverse sections, with basic medical insurance (BMI) as its core component. Key factors defining insurance benefit standards include the reimbursement rate, deductible, and cap of reimbursement payment.



In the selected reference regions\*, the annual cost of case study drugs after reimbursement ranged from 2 to 14 times the per capita GDP, with an average of 6.1 times (median 5.2 times) per capita GDP. Most of these drugs were covered by medical insurance across the selected regions, with annual costs generally exceeding 3.5 times the local per capita GDP. Many of these drugs were reimbursed or granted access through managed entry agreements, outcome-based payment models, and discount agreements. These diverse payment models have significantly improved patient access to high-cost drugs.

Compared to the selected reference regions, China has a higher out-of-pocket expenditure share within its total healthcare expenses. Given the disparities in reimbursement benefits and the absence of an out-of-pocket ceiling mechanism in China, increases in annual treatment costs place a greater financial burden on Chinese patients relative to those in the reference regions.

\*Reference regions include the U.S., the U.K., German, Japan, Taiwan China. The criteria for selecting reference regions include: a relatively high economic level, the inclusion of both Asian and non-Asian regions, with representative healthcare insurance/security system

A logistic model was constructed to examine whether drug expenditures result in catastrophic spending for households with an average income level. The dependent variable is catastrophic expenditure, while independent variables include annual cost of drug and factors related to reimbursement benefits, such as reimbursement rate and cap. The range of annual cost of drug was determined based on the reference region's listing price for the case-study drug, identifying the highest level of annual cost (price) accepted in the reference regions as a benchmark. For the insurance benefit variables, higher-tier reimbursement rules were applied, specifically the urban employee medical insurance reimbursement (UEBMI) policies in the capital cities of each province.

$$\text{Logit}(P(\text{Cata}=1))=\ln(P(\text{Cata}=1)/(1-P(\text{Cata}=1)))=\beta_0+\beta_{\text{AnnualCost}}\cdot\text{AnnualCost}+\beta_{\text{Bcap}}\cdot\text{Bcap}+\beta_{\text{Acap}}\cdot\text{Acap}+\beta_{\text{Brank}}\cdot\text{Brank}+\beta_{\text{Arank}}\cdot\text{Arank}$$

*N=93*

The results revealed that annual costs between 320,000 and 340,000 RMB had the highest marginal effect on inducing catastrophic health expenditure. When annual costs range from 350,000 to 400,000 RMB, the probability of catastrophic expenditure exceeded 50%, based on the UEBMI benefit rules and average level of disposable income of households, indicating the upper limit of threshold from the perspective of patient affordability.

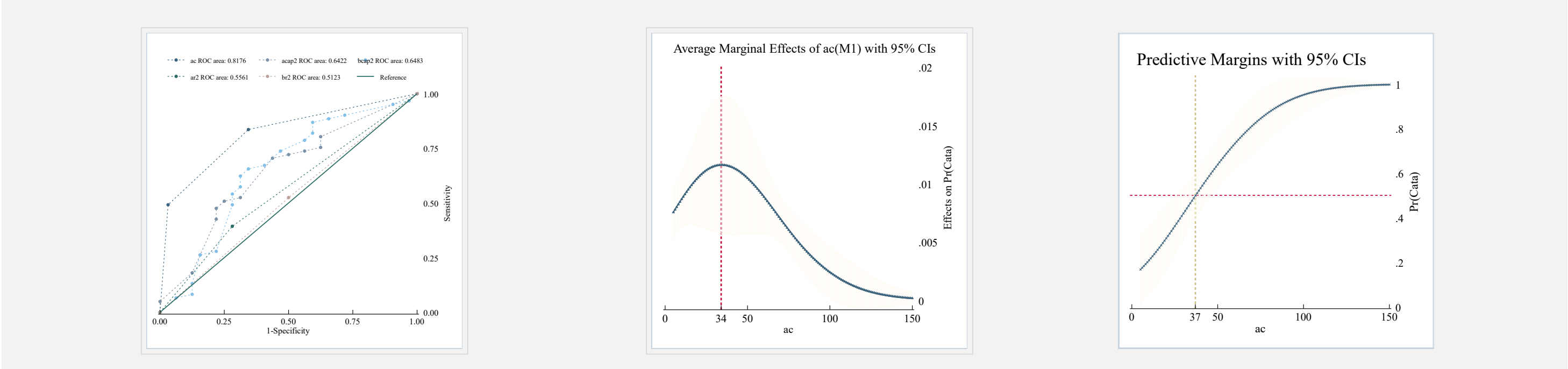


Figure 2-4 ROC curve, AME of annual cost of drug variable, Predictive Margins of annual cost of drug variable

## CONCLUSIONS

- In comparison to the reference regions, China's healthcare security system exhibits distinct characteristics. Given the current regulatory framework, the implementation of annual cost threshold in NRDL adjustment process is rationale and essential.
- The Urban Employee Basic Medical Insurance (UEBMI) offers higher benefits compared to the Urban Resident Basic Medical Insurance (URBMI). In our analysis, the upper limit of the threshold was estimated based on regions with higher UEBMI benefit levels. If URBMI benefits were used, the estimated cost threshold would be lower due to the reduced benefit levels in URBMI.
- It is suggested that the annual cost threshold in the application stage could be moderately relaxed to allow more high-value innovative drugs to be considered in appraisal and price negotiation stages. In the future, this threshold should be periodically adjusted in line with improvements in national economic conditions, income levels, and the coordination and enhancement of benefit levels within the healthcare system.

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