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Differentiated Access under China's National Reimbursement Drug Negotiation: A Comparative Case Study of Three Innovative Pharmaceuticals

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Abstract: China's National Reimbursement Drug Negotiation (NRDN) mechanism is the primary pathway for innovative drugs to enter the national reimbursement list. However, different drug categories may follow distinct institutional pathways and yield different pricing outcomes. This study preliminarily explores how three categories of innovative pharmaceuticals—competitive biologics, breakthrough high-cost therapies, and rare disease drugs—navigate China's reimbursement system, and examines differentiated pricing dynamics and affordability outcomes. A multiple-case comparative design was used, focusing on sintilimab (PD-1 inhibitor), axicabtagene ciloleucel (CAR-T therapy), and risdiplam (SMA oral drug). Data were collected from Drugdataexpy, corporate annual reports, and policy documents (through April 2026). Sintilimab followed conventional negotiation with tiered price reductions (86% cumulative reduction). Axicabtagene ciloleucel (1.2 million CNY) has not entered basic insurance but gained early access via the newly established Commercial Health Insurance Innovative Drug Catalog (December 2025). Risdiplam took a rare disease priority pathway with a pre-negotiation voluntary price cut (94% cumulative reduction). These three cases suggest a possible trend toward stratified governance within China's drug access system. However, the commercial catalog's effectiveness remains unverified due to short implementation time. Causal inferences are limited by data availability and case study design.

Keywords: National Reimbursement Drug Negotiation; Innovative pharmaceuticals; Case study; Stratified access; Early-stage policy analysis

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1. Introduction

The rapid expansion of China's innovative pharmaceutical market has been accompanied by the institutionalization of the National Reimbursement Drug Negotiation (NRDN) mechanism. According to the National Healthcare Security Administration's December 2025 notice on the National Drug Catalog and related

reports, eight negotiation rounds since 2016 have achieved average price reductions exceeding 50% [1]. In 2025, the system introduced the Commercial Health Insurance Innovative Drug Catalog—a "dual-catalog" system creating a parallel reimbursement pathway for high-cost therapies that exceed basic medical insurance capacity, as stipulated in the joint notice issued by the National Healthcare Security Administration and the Ministry of Human Resources and Social Security (Medical Insurance Issuance [2025] No. 33).

Existing research predominantly uses quantitative methods to assess aggregate policy effects [2–6]. While valuable, these studies cannot capture the heterogeneous institutional pathways faced by different drug categories. A PD-1 inhibitor facing multiple competitors, a million-yuan CAR-T therapy, and an orphan drug for a rare disease each confront fundamentally different negotiation dynamics. China's reimbursement system differentiates among these categories through distinct institutional channels, and divergent pricing outcomes may be explained by differences in market competition, budget impact, and disease rarity. These mechanisms remain underexplored in the current literature.

This study addresses the gap through a multiple-case comparative analysis of three paradigmatic drugs: sintilimab, axicabtagene ciloleucel, and risdiplam. By tracing their access pathways, pricing trajectories, and affordability indicators, this study preliminarily explores the possible institutional logic underlying China's evolving reimbursement system.

2. Institutional background

2.1. Evolution of China's reimbursement system

China's NRDN is a centralized, value-based pricing system where the National Healthcare Security Administration (NHSA) negotiates directly with manufacturers. Successful negotiation yields a nationally uniform reimbursement price [7]. The State Council's April 2026 *Opinions on Improving the Drug Price Formation Mechanism* articulated that drugs with high innovation and substantial clinical value may maintain relatively stable initial prices.

2.2. The dual-catalog reform of 2025

In December 2025, the inaugural Commercial Health Insurance Innovative Drug Catalog was published by the NHSA and the Ministry of Human Resources and Social Security. It covers drugs with "high innovation, substantial clinical value, and significant patient benefit that exceeds basic insurance coverage." These drugs are not reimbursed by basic insurance funds and are exempt from hospital cost-containment metrics. As of this study's completion (April 2026), the catalog had been operational for less than four months; therefore, this analysis focuses on its institutional design and early access conditions rather than long-term effects.

2.3. Institutional provisions for different drug categories

The system incorporates multiple channels: reference pricing for competitive drugs, priority review for rare diseases/pediatrics, and flexible pricing for breakthrough therapies. These form the institutional substrate for the three cases.

3. Methods

3.1. Multiple-case comparative design

This study employs a multiple-case comparative design following Yin's case study methodology [8]. Three cases

were purposively selected to represent distinct categories of innovative pharmaceuticals and their corresponding institutional pathways (**Table 1**).

Table 1. Overview of selected cases

Case	Pharmaceutical type	Institutional pathway	Selection rationale
Sintilimab	Competitive PD-1 inhibitor	Conventional NRDN with renewal	Represents competitive biologics facing tiered price reductions
Axicabtagene ciloleucel	Breakthrough CAR-T therapy	Non-inclusion in NRDN → Commercial insurance pathway	Represents high-cost therapies exceeding basic insurance capacity
Risdiplam	Rare disease SMA drug	Priority review → Accelerated NRDN with pre-negotiation voluntary price reduction	Represents rare disease drugs utilizing dedicated review and reimbursement pathways

3.2. Analytical framework

Four dimensions: (1) access pathway, (2) pricing trajectory, (3) affordability impact, (4) institutional mechanism.

3.3. Data sources

Data triangulated from the Drugdataexpy database (Yaozh, https://www.yaozh.com), corporate annual reports (2020–2025), NHSA and NMPA policy documents, and drug labels. Retrieval date: April 1, 2026.

4. Case 1: Sintilimab – Tiered price reductions for competitive biologics

4.1. Access pathway

Sintilimab (Tyvyt®), a fully human anti-PD-1 antibody co-developed by Innovent and Eli Lilly, received conditional approval in December 2018. According to Innovent's 2025 annual results announcement, it had nine approved indications in China as of 2025, with eight included in the NRDL. It entered the 2019 negotiation cycle and was included effective January 2020, with subsequent renewals adding new indications.

4.2. Pricing trajectory

Launch price: 7,838 CNY per 100 mg vial. The 2019 negotiation yielded a reimbursement price of 2,843 CNY (64% reduction). By 2024–2025, following multiple renewals, the price further decreased to 1,080 CNY—a cumulative reduction of 86% from launch.

4.3. Affordability impact

Volume gains appear to have substantially offset price reductions. According to Innovent's 2025 annual report, total product revenue reached 11.9 billion CNY, a 44.6% year-over-year increase, with sintilimab identified as a primary driver (single-drug sales not disclosed). This observation is consistent with the "volume-for-price" mechanism, but the company's total revenue growth cannot be exclusively attributed to sintilimab. The drug has cumulatively benefited over two million oncology patients since launch.

4.4. Institutional mechanism

Sintilimab's case illustrates the core logic of NRDN for competitive categories: the NHSA uses its monopsony power to extract substantial discounts while offering manufacturers predictable volume. Renewal rules allow

Class 1 innovative drugs to renegotiate rather than accept automatic stepwise reductions, providing some pricing stability.

5. Case 2: Axicabtagene ciloleucel—Commercial insurance breakthrough for high-cost therapy

5.1. Access pathway

Axicabtagene ciloleucel (Yescarta®), a CD19-directed CAR-T therapy, received conditional approval in June 2021 as China's first approved cell therapy. According to Fosun Pharma's 2025 annual report, it never entered the basic insurance catalog. The 2024 NRDL preliminary review notably excluded it. In December 2025, it was included in the inaugural Commercial Health Insurance Innovative Drug Catalog, effective January 2026.

5.2. Pricing trajectory

The drug launched at 1.2 million CNY per infusion. Critically, this price has remained unchanged from 2021 through 2026 across all provincial procurement records. The price stability reflects both the absence of direct therapeutic alternatives and the fundamental incompatibility of this price level with basic insurance's implicit "red line" (industry observers suggest drugs exceeding 500,000 CNY annual cost are effectively excluded from basic NRDN).

5.3. Affordability impact

Despite exclusion from basic insurance, the drug achieved partial patient access through multi-channel financing. Fosun Pharma's 2025 annual report indicates that by 2025, it was covered by over 110 provincial "Huiminbao" programs and more than 90 commercial insurance products, with the treatment center network expanding to over 210 centers across 29 provinces. The product's 2025 sales reached the 500 million to 1 billion CNY range with growth exceeding 30%. The cumulative number of treated patients surpassed 1,000 by 2025. However, these figures reflect access through supplementary insurance, not the new commercial catalog; the catalog's incremental contribution cannot be isolated from these data.

5.4. Institutional mechanism and a note on outcome evaluation

Axicabtagene ciloleucel's access pathway differs fundamentally from sintilimab's conventional NRDN process. The commercial catalog represents an institutional innovation designed for pharmaceuticals whose price points exceed the fiscal capacity of basic medical insurance. The catalog's design features—exemption from hospital cost-containment metrics, recommendation for commercial insurance and mutual aid coverage, and nationally uniform listing—provide an alternative channel that bypasses the implicit budget constraints of basic insurance.

However, a careful note on evaluation is warranted. The Commercial Health Insurance Innovative Drug Catalog was first published in December 2025. As of April 2026, the policy had been operational for less than four months. Therefore, this case primarily analyzes the catalog's institutional design logic and early access conditions, rather than its quantitative implementation effects. Whether this channel meaningfully improves patient access, reduces out-of-pocket burdens, or influences manufacturer pricing strategies remains an open empirical question.

What this case currently shows is that the catalog provides an alternative institutional pathway for high-cost innovative therapies that exceed basic insurance capacity. The inclusion of axicabtagene ciloleucel

suggests that manufacturers are willing to participate. Nevertheless, the catalog's actual effectiveness cannot be determined from available early-stage data. In addition, access to CAR-T therapy depends on factors beyond reimbursement. The drug's safety profile—cytokine release syndrome incidence of 90–100% and neurologic toxicity of 42–87%—requires specialized institutional capacity. The expansion to over 210 certified treatment centers across 29 provinces represents necessary infrastructure development as critical to patient access as the financing mechanism itself.

6. Case 3: Risdiplam – Rare disease acceleration and pre-negotiation price signaling

6.1. Access pathway

Risdiplam (Evrysdi®), the first oral treatment for spinal muscular atrophy (SMA), was approved in China in June 2021 through priority review channels for pediatric and rare disease pharmaceuticals, as documented in Roche's 2025 annual report. It benefited from multiple accelerators: rare disease designation, pediatric indication, and clinical urgent need status. It successfully entered the NRDL in the 2022 negotiation cycle, effective early 2023. A tablet formulation approved in 2025 eliminated cold-chain requirements and simplified administration.

6.2. Pricing trajectory

Risdiplam's pricing trajectory contains a distinctive feature: a pre-negotiation voluntary price reduction. Launch price: 63,800 CNY per bottle (60 mg). In June 2022—coinciding with the NRDN application window—Roche voluntarily reduced the price to 14,500 CNY (77% reduction). Following negotiation, the reimbursement price was set at 3,780 CNY, a cumulative reduction of 94% from launch. This pre-negotiation reduction may reflect strategic price signaling: manufacturers anticipating NRDN's downward pricing pressure may adjust launch prices preemptively to improve negotiation positioning.

6.3. Affordability impact

Roche's 2025 finance report shows that Evrysdi achieved global sales of 1.757 billion CHF, a 13% increase (at constant exchange rates) from 1.631 billion CHF in 2024. Sales in the International region (including China) increased from 378 million CHF to 439 million CHF, a growth rate of 25%, higher than the United States (+10%) and Europe (+9%). Roche attributed the International region's growth to strong Chinese market demand for multiple innovative pharmaceuticals, noting that Evrysdi benefited from NRDL coverage and priority review policies. A limitation: Roche's report did not disclose Evrysdi's specific Chinese sales revenue or patient numbers; the 25% growth reflects multiple markets and cannot be directly equated with China's performance. The tablet formulation further enhanced accessibility by removing cold-chain requirements.

6.4. Institutional mechanism

Risdiplam's case illustrates preferential treatment for rare disease pharmaceuticals: accelerated approval timeline (approximately 18 months from global to China approval), priority review designation, and successful negotiation despite a relatively high post-negotiation price. The pre-negotiation voluntary price reduction suggests NRDN's influence may extend upstream, shaping manufacturer pricing strategies before formal negotiation. This possible "deterrence effect" implies that total savings attributable to NRDN could exceed those captured in negotiation outcomes alone, though this interpretation remains speculative without direct evidence.

7. Cross-case comparison

7.1. Divergent institutional pathways

The three cases exemplify fundamentally different institutional logics within China's reimbursement architecture (**Table 2**).

Table 2. Comparative summary of three cases

Dimension	Sintilimab	Axicabtagene ciloleucel	Risdiplam
Pharmaceutical category	Competitive biologic	Breakthrough cell therapy	Rare disease drug
Market context	Multiple competitors	Sole supplier, high barriers	Sole supplier, orphan designation
Launch price	7,838 CNY/10 0mg	1.2 million CNY/infusion	63,800 CNY/bottle
Access pathway	Conventional NRDN + renewals	Commercial catalog (early stage)	Priority review + accelerated NRDN
Price trajectory	Tiered reductions (86% cumulative)	Stable (unchanged)	Voluntary reduction + negotiation (94% cumulative)
Current reimbursement	Basic insurance (1,080 CNY)	Commercial catalog (1.2 million CNY)	Basic insurance (3,780 CNY)
Key institutional mechanism	Volume-for-price bargaining	Dual-catalog stratification (effectiveness unverified)	Rare disease preference + price signaling

Note: Sales data not directly comparable across cases due to different reporting scopes; see Sections 4.3, 5.3, 6.3 for limitations.

7.2. Stratified governance as an emerging institutional logic

The cross-case pattern suggests that China's pharmaceutical reimbursement system may be evolving from a uniform negotiation model toward a stratified governance framework. For drugs with therapeutic alternatives and larger patient populations, the system applies competitive pressure to achieve substantial cost savings. For drugs with transformative value but prohibitive budget impact, the commercial catalog provides an alternative channel—though its actual effectiveness remains unverified. For rare disease drugs with high unmet need, accelerated pathways and higher willingness-to-pay may facilitate timely access.

7.3. Alignment with international experience

China's stratified approach resonates with international practices, such as Germany's AMNOG system [9], France's ASMR rating [10], and Canada's PMPRB framework. China's dual-catalog innovation—creating a separate track for drugs exceeding basic insurance capacity—represents a distinctive contribution. Unlike Germany's benefit-based differentiation with years of implementation data, China's commercial catalog is in its infancy; its long-term performance relative to international models remains unknown.

8. Discussion

The three cases collectively suggest that NRDN's objective may have evolved beyond simple price reduction toward value-aligned pricing, consistent with Zhou *et al.* [4]. The sintilimab case reveals a possible association between competitor number and price reduction magnitude. The risdiplam case illuminates a possible "deterrence effect." The axicabtagene ciloleucel case highlights that access depends on factors beyond price—including

specialized infrastructure for CAR-T administration. The commercial catalog's early-stage design provides an alternative channel, but its actual impact cannot be assessed until the policy has been operational for a longer period.

Several policy considerations emerge: the dual-catalog system should be formally evaluated after two to three years of implementation; rare disease acceleration mechanisms have shown early promise; transparency in value assessment could further stabilize manufacturer expectations.

This study has several limitations. External validity is limited to the three studied categories. Some data rely on indirect indicators or corporate disclosures without independent verification. The commercial catalog had been operational for less than four months. Health outcomes were not assessed. Causal inference is not possible with a case study design. Therefore, conclusions should be understood as an exploratory description of institutional logic, not rigorous causal inference.

9. Conclusion

This multiple-case comparative analysis suggests that China's innovative pharmaceutical reimbursement system may be undergoing a transformation from uniform negotiation toward stratified governance: competitive biologics achieve deep price reductions through volume-based bargaining, breakthrough high-cost therapies access alternative payment channels through a commercial catalog whose effectiveness awaits future evaluation, and rare disease drugs benefit from accelerated pathways and preferential pricing consideration. The cases also reveal possible upstream effects on manufacturer pricing strategies and the importance of institutional capacity for complex therapies. Future research should evaluate the dual-catalog's impact after longer implementation, test the causal relationship between competitive intensity and price reductions using quantitative methods, and include additional drug types to validate the stratified governance framework.

Disclosure statement

The author declares no conflict of interest.

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