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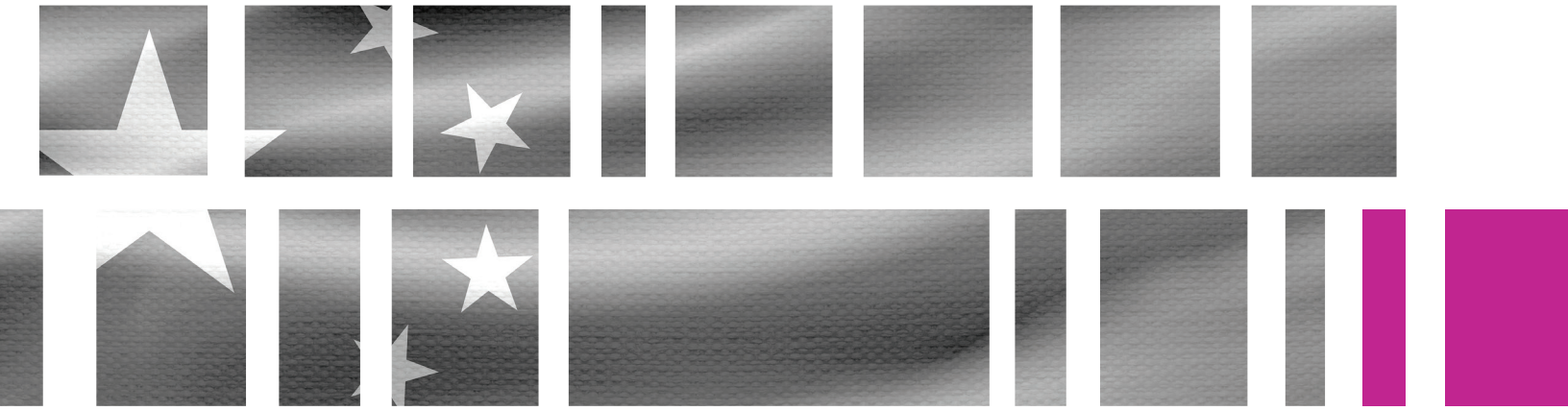

A WHITEPAPER FROM INSTITUTE@PRECISION

China Market Access After NRDL Maturity: What Comes After the Price Reset?

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Executive Summary

For years, inclusion in the National Reimbursement Drug List (NRDL) was seen as the golden ticket for gaining entry to China's vast pharmaceutical market. Western pharmaceutical companies regarded this as the ultimate prize in securing national coverage, rapid patient access, and a commercial inflection point for their innovative medicines.

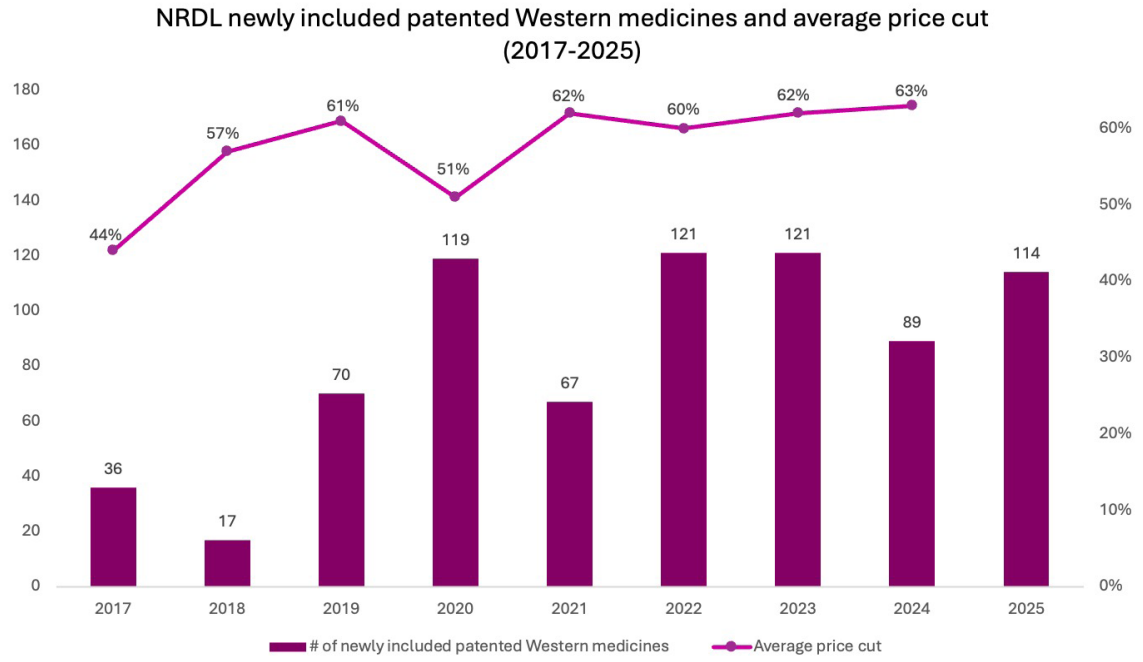

Figure 1. NRDL newly included patented Western medicines and average price cut (2017-2025)
Source: www.nhsa.gov.cn

That perception is no longer accurate. In practice, the market access challenges in China only really begin after manufacturers accept the negotiated price and secure NRDL inclusion. Despite listing, manufacturers may still face unresolved patient affordability issues and slow, limited uptake across local hospitals.

In today's China, a successful lifecycle management is increasingly shaped by events after NRDL inclusion: whether policy access translates into sustained real-world utilization, whether patients can afford residual out-of-pocket (OOP) cost post-NRDL reimbursement, and whether a product's value is preserved and supported by real-world evidence (RWE). In other words, NRDL is no longer the finish line. It is just the start of a more complex post-NRDL stage that requires a more sustainable access strategy.

What does this mean for manufacturers?

In China's mature NRDL era, success is no longer defined by national reimbursement alone. Manufacturers need to treat NRDL inclusion as the beginning of an execution phase that requires:

1. Translating policy access into operational access through provincial platform updates, channel readiness, and hospital listing
2. Mitigating residual patient OOP burden to enable initiation and persistence
3. Building an RWE engine that can defend value at NRDL renewal while supporting hospital and clinician adoption

A credible market access strategy therefore needs an integrated post-NRDL plan, not just a negotiation plan.

Post-NRDL provider access is neither immediate nor unlimited

Why this matters: *Even with policy access secured through NRDL, operational access can be delayed, and utilization will not materialize until channels and providers are activated.*

A common presumption among manufacturers seeking China market access is that NRDL inclusion should naturally lead to rapid volume growth that can compensate for the price concession made during negotiation. In reality, volume uptake needs time and can be constrained by multiple factors. NRDL listing creates the potential for national rollout, but actual uptake depends heavily on regional execution and individual hospital access. After NRDL inclusion, manufacturers must update product reimbursement eligibility and NRDL pricing across multiple provincial registration platforms. These updates are administratively burdensome, unevenly paced across provinces, and often a prerequisite for hospital and pharmacy activation, thus creating material time lags before prescriptions can flow. In parallel, dual-channel pharmacy formulary requirements introduce additional friction: Companies must first engage in regional government affairs to secure eligibility under local dual-channel policies, then conduct one-by-one engagement with designated retail pharmacies to enable listing, stocking, pricing alignment, and pharmacist readiness. Together, these operational and channel complexities mean that national NRDL inclusion does not immediately translate into broad, on-the-ground access, dampening early-phase volume realization despite formal reimbursement gains.

Individual hospital listing is another critical step for drug access. Multiple stakeholders may be involved, such as the hospital head, pharmacy department, clinical department, and health security department.

Stakeholders typically conduct clinical and economic assessment for new drugs, particularly as Diagnosis-Related Group (DRG) and Diagnosis-Intervention Packet (DIP) increases financial pressure on NRDL fund utilization. The evaluation process may take months to a year. As a result, active engagement from multiple manufacturer field teams is critical to ensure seamless and timely hospital listing.

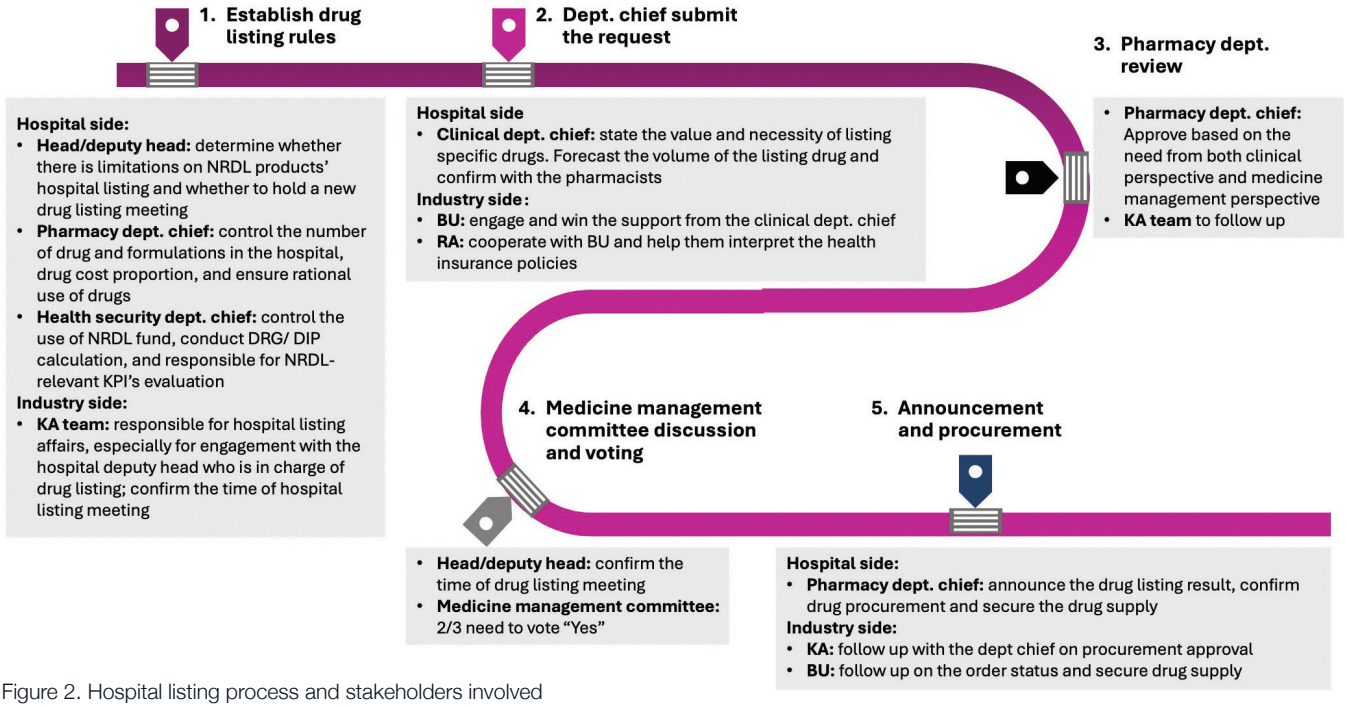

Figure 2. Hospital listing process and stakeholders involved

Manufacturers should therefore avoid treating NRDL inclusion as a guarantee of an immediate boost in clinical uptake. Post-NRDL, access strategy imperatives need to address the lag between NRDL execution announcement and provincial execution, provider activation, and hospital access. This requires holistic planning around regional government affairs, dual-channel pharmacy activation, hospital stakeholder engagement, coordination among field teams, and gradual, phase-by-phase volume expansion rather than immediate scale-up.

Affordability can still remain a barrier, even after NRDL inclusion

Why this matters: *Even when operational access is in place, residual OOP burden can prevent eligible patients from initiating or staying on therapy, limiting real-world utilization.*

Another hurdle that is often neglected during post-NRDL access strategy planning is that the price cut during negotiation and national reimbursement from public insurance do not automatically eliminate patient affordability challenge.

Despite full NRDL inclusion, patient out-of-pocket burden remains material as regional reimbursement rates typically range from 60% to 80%. This dynamic is particularly pronounced in high-cost therapeutic areas such as oncology and rare diseases, creating an underappreciated barrier to treatment initiation and persistence.

Even when a therapy is recognized for its novel mechanism of action and strong clinical value—securing NRDL listing at the highest feasible price—residual OOP costs may continue to limit real-world uptake, warranting heightened attention from manufacturers of innovative, premium therapies.

As NRDL matures, manufacturers plan beyond reimbursement status itself and focus on truly resolving affordability issues for patients. This may require alternative access strategies, such as city-level supplementary medical insurance support or other mechanisms that help bridge the gap between national reimbursement and patient affordability.

CASE STUDY

Spinraza (nusinersen) is a treatment for spinal muscular atrophy. It participated in 2021 NRDL negotiation and has been included in the NRDL since 2022. Spinraza experienced a 94% price cut during negotiation, and its first-year annual treatment cost post NRDL was ~199K RMB (~29K USD), leaving patients with ~60,000 RMB (~8.8K USD) OOP after reimbursement. Meanwhile, average annual disposable household income in 2022 is only ~96,000 RMB (~14K USD). Despite the aggressive price cut, Spinraza's OOP expense remained burdensome for patients. In 2023, Spinraza was included in Zhenjiang's city supplementary insurance, which further reduced patient OOP cost by 45%.

Manufacturers must actively generate RWE post-NRDL inclusion

Following NRDL inclusion, manufacturers must operationalize RWE as a core access and lifecycle-management lever, with distinct use cases across pricing, access, and adoption.

RWE should be deployed to validate and defend budget impact assumptions at NRDL renewal. At each renewal cycle, products with actual budget impact exceeding initial estimates, anticipated future budget growth (e.g., from indication expansion that is listed in the NRDL), or significant shifts in the competitive landscape are more likely to face additional price pressure.

Real-world utilization, treatment duration, dosing patterns, and patient eligibility data can be used to explain deviations from initial projections, contextualize volume growth (e.g., epidemiology-driven vs. leakage), and argue for milder or zero price cuts. Outcomes and healthcare resource utilization data (including hospitalization avoidance or downstream cost offsets) can further reinforce the product's real-world value proposition during renewal.

Beyond price, RWE is critical to support hospital listing, maintain or strengthen NRDL positioning, and reduce administrative or clinical restrictions. Evidence demonstrating appropriate patient selection, real-world effectiveness, and alignment with guideline-recommended use can help address payer and hospital concerns around misuse or overutilization. RWE also enables manufacturers to push back against overly narrow reimbursement criteria and support broader, more flexible access at provincial and institutional levels.

RWE also plays a central role in driving uptake by building prescriber confidence and supporting broader clinical adoption. Data on real-world outcomes, treatment sequencing, persistence, and patient subpopulations can reinforce clinical relevance and product differentiation, particularly as competition evolves. In a mature NRDL environment, RWE increasingly becomes a prerequisite for sustained utilization growth rather than a "nice-to-have" evidence layer.

Other pathways are becoming increasingly relevant as part of the access scheme

As NRDL matures and remaining unmet needs become more visible, manufacturers must consider additional access pathways as part of a broader China market access strategy. This does not diminish NRDL's role as the foundational access mechanism in China. Rather, these emerging pathways should be viewed as complementary to NRDL, selectively deployed to supplement national reimbursement and enhance access outcomes, particularly for niche, innovative, or high-value therapies, where NRDL alone may not fully unlock their commercial potential across the portfolio.

- **Commercial insurance:**
  Commercial insurance has emerged as an increasingly important supplement to NRDL, with common access routes including high-limit medical insurance, critical illness insurance, and pay-for-performance arrangements. These pathways can help offset residual OOP costs for innovative, high-cost therapies and provide an additional access layer beyond the national reimbursement framework.

- **City supplementary medical insurance:**
  City supplementary medical insurance, commonly known as Huiminbao, is a city-level, commercial insurance designed to complement NRDL reimbursement. Supported by local governments, these plans aim to expand protection through broad eligibility criteria and affordable premiums. As a benefit to local residents, many Huiminbao programs allow enrollment for individuals with pre-existing conditions, albeit with restricted reimbursement criteria, further enhancing access where NRDL coverage alone may be insufficient.

- **Commercial Innovative Drug List:**
  The newly launched Commercial Innovative Drug List is reviewed and assessed by National Healthcare Security Administration. It identifies innovative drugs with high clinical value and costs beyond the basic NRDL budget. China's first version was officially issued in December 2025, including 19 high-value, innovative drugs (i.e., CAR-T) indicated for oncology, rare disease, and Alzheimer's disease. Drugs on this list are expected to be reimbursed by commercial payers, but implementation has yet to be finalized. Cost for drugs on this list will also be excluded from DRG/DIP calculations, which may help reduce hurdles to hospital listing.

Bottom line:
RWE is not incremental. Rather, it is the bridge that sustains value and access after the initial reimbursement milestone.

Closing

China's NRDL remains a critical market access milestone, but it is no longer the finish line. In a mature reimbursement environment, the real determinants of success come after listing. This shifts the strategic question for manufacturers: It is no longer simply how to get listed, but how to build a sustainable post-NRDL model that preserves access, supports clinical utilization, and leverages evidence to manage value over time.

Manufacturers that continue to treat NRDL as the endpoint may secure initial reimbursement but fail to achieve commercial success. Manufacturers are optimally positioned to achieve post NRDL market access goals by strengthening regional and hospital access, addressing patient affordability, leveraging RWE for value communication, and selectively deploying alternative access pathways to complement NRDL and expand real world utilization. In China's mature NRDL era, competitive advantage no longer comes from reaching the reimbursement milestone alone. It comes from knowing how to sustain access and value after it.

About Precision AQ

Drawing on deep oncology and radiopharmaceutical expertise, Precision AQ partners with sponsors to support commercialization and market access with data-driven engagement and evidence strategies, enabling patients to access critical therapies.

Authors

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Ruby advises pharmaceutical and biotechnology companies on pricing and market access, with an expertise on China-specific strategies. Her experience spans policy analysis, NRDL strategy and negotiation, value message communication, alternative payment pathways, and early access and lifecycle planning. Prior to joining Precision AQ, she spent four years at IQVIA China supporting pricing and market access strategy as well as policy-driven decision-making. Ruby holds a Master of Public Administration degree in Health Services Management from New York University.

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Chloe specializes in global pricing and market access strategy with a strong focus on APAC markets. She advises pharmaceutical clients on pricing, reimbursement, and access decisions, translating cross-market insights into actionable strategies to support global launch and lifecycle management. Chloe has extensive experience across Japan, China, and broader APAC, as well as Europe and the Middle East, spanning oncology, cardiovascular, neurology, autoimmune, and rare diseases. Her work includes international reference pricing and launch sequencing, price modelling, evidence generation strategy, and value communication, as well as emerging areas such as AI-enabled payer engagement and MFN strategy. Chloe holds an MSc in International Health Management from Imperial College London and a BSc in Pharmaceutical Sciences from Tianjin University.

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Cherry advises pharmaceutical and biotechnology companies on commercial strategy and market access across therapeutic areas, including oncology, hematology, rare diseases, nephrology, autoimmune, respiratory, and cardiovascular conditions. Her experience spans the product lifecycle from clinical development through post-approval commercialization. She has supported initiatives including launch sequence optimization, pricing and market access strategy, value communication and messaging, payer and provider contracting, lifecycle and loss-of-exclusivity planning, innovative contracting models, and clinical advisory boards for strategic program planning.

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Based in London, **Alex** leads the International Pricing & Market Access Strategy practice, which he established in 2015. Alex brings over 20 years' consulting experience in the biopharmaceutical industry. He specializes in complex pricing strategies, including cross-indication strategy, launch-sequencing and international price referencing. He has worked across multiple therapy areas, including oncology, immunology, cardiovascular, orphan indications and cell & gene therapies. Prior to joining Precision, Alex was a Senior Director in the Pricing & Market Access practice for ICON plc (formerly PriceSpective). And before ICON, Alex was a Project Director at Apex Healthcare Consulting, a consultancy providing commercial and strategic evaluations for biopharmaceutical companies in specialty markets. Alex also worked at Wood Mackenzie, an Edinburgh-based advisory firm to the life sciences industry and started his career as a journalist at the Financial Times. Alex holds a BSc (Hons) degree in Biochemistry from the University of St Andrews.

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