

Selective uptake of medicines outside China's National Reimbursement Drug List by commercial specialty-drug rosters: a multi-product audit of the 2020–2025 negotiation cohorts

Yuehua Liu

Wuhan University

Yuzhe Zhang

Shenyang Pharmaceutical University

Yongliang Mu

Wuhan University

Yulong Li

Wuhan University

Yuanhao Wan

Wuhan University

Jian Wang

wang.jian993@whu.edu.cn

Wuhan University

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Abstract

Background.

China's 2025 NRDL cycle opened a parallel commercial health insurance (CHI) innovation-drug track; whether commercial specialty-drug rosters include medicines not covered by basic medical insurance (BMI) is undocumented.

Methods.

All 1,394 ingredients in the 2020–2025 formal-review pools were verified against the complete 2025 NRDL, yielding 578 never-listed ingredients (main pool), 701 listed comparators, and 115 with a listed component but an applied dosage form still unlisted at endpoint. Roster listing was audited on 14 commercial products—11 with enumerable rosters for drug-by-drug matching; two open-formulary products reported separately; attributes on encoded subsets.

Results.

Of 578 main-pool ingredients not in the NRDL, 74 (12.8%; 95% CI 10.3–15.8) appeared on an enumerated roster—67 on five city universal (huimin bao) and 55 on six high-limit commercial rosters—versus 168/701 (24.0%; 95% CI 21.0–27.3) NRDL-listed comparators. Listing was 55/555 (9.9%; 95% CI 7.7–12.7) among BMI applicants not listed and 19/23 (82.6%; 95% CI 62.9–93.0) among commercial-track-only sponsors; listing was higher among ingredients with repeated formal-review applications than among single-cycle applicants (no formal-review record 0/9; one application 21/423, 5.0%; two 16/55, 29.1%; ≥ 3 18/68, 26.5%; the gradient is non-monotonic across the two-and- ≥ 3 strata; Cochran–Armitage $z = 6.84$, $p < 0.001$). Encoded-subset gradients were steep: first-in-class 26/27 (96.3%) vs low-innovation 3/61 (4.9%); E1 RCT with hard endpoints 22/36 (61.1%); annual cost > 500,000 yuan 31/33 (93.9%) vs < 50,000 yuan 2/100 (2.0%); ATC L 46/55 (83.6%) vs anti-infectives 0/16. Patterns reproduced in the 2025 entrant cohort ($n = 88$). Of 8 orderable ingredients with BMI applications, 1 listing predated any application, 1 was same-year, and 6 followed outcome publication.

Conclusions.

Enumerable commercial rosters list 12.8% of ingredients not included in the NRDL versus 24.0% of listed comparators, concentrated in high-price, high-innovativeness antineoplastic therapies; roster composition differs across channels, price tiers, and therapeutic areas. This is a roster listing rate, not total commercial coverage; open formularies and general out-of-catalog benefits are not name-matchable.

1. Background

China's basic medical insurance (BMI) covers over 95% of the population, but its National Reimbursement Drug List (NRDL) cannot absorb every approved innovative drug at launch prices [4, 5]. A multi-level medical security system is therefore explicit national policy: the "Opinions on Deepening Reform of the Medical Security System" (2020) calls for commercial health insurance to complement basic insurance, and the 2025 NRDL cycle for the first time opened a parallel commercial health insurance (CHI) innovation-drug track—141 commercial-track filings alongside 311 basic-track applicants, of which 19 ingredients were recommended for inclusion in the inaugural commercial innovation-drug catalogue [1–3].

Two commercial product categories dominate retail distribution. *City universal insurance* ("huimin bao", HMB) is a government-guided, low-premium (typically 69–200 yuan/year), near-universally accessible supplementary insurance co-branded with local healthcare-security administrations; by 2024 over 300 city products covered hundreds of millions of enrollees [6]. *High-limit commercial medical insurance* ("baiwan xian yiliao") is a commercial, age/health-underwritten product (premiums roughly 200–2,000 yuan/year by age) sold directly by insurers, with high deductibles and unlimited or million-level caps. Both categories publish explicit "specialty-drug rosters" (teyao mulu)—closed or semi-closed drug lists that determine reimbursement.

Whether these rosters list drugs that BMI does not is an empirical question with policy stakes. Domestic commentary asserts that commercial products "pick up" innovative drugs not included in the NRDL, but published evidence is sparse: existing literature documents HMB's low claims ratios and roster erosion, and high-limit products' hospital-pharmacy fulfilment gaps, but no study maps commercial rosters against the *universe* of drugs that sought but did not obtain NRDL listing. Internationally, complementary private

insurance in universal systems (US Medigap, French contrats responsables, Australian PHI) typically covers cost-sharing rather than excluded drugs, making China's roster-based model distinctive.

Three questions follow. First, *how much* of the medicine space not included in the NRDL do commercial rosters actually list? Second, *which* drugs are listed—does selection track price, innovativeness, therapeutic area, or evidence? Third, *when* does commercial listing occur relative to the BMI negotiation sequence—before application (genuine parallel), during uncertainty, or only after BMI negotiation outcomes are published? This paper answers all three using a component-level cohort of 1,394 ingredients that entered the 2020–2025 NRDL formal-review pools, linked to the audited specialty-drug rosters of 14 commercial products.

2. Methods

2.1 Data sources

NRDL negotiation universe. The formal-review ("xing shen") pools for negotiation years 2020–2025 were compiled from the National Healthcare Security Administration (NHSA) official published lists [11–17], yielding 2,825 drug-year records covering 1,612 generic-name entries and 1,394 unique ingredients (active moiety / component level; see section 2.2 and Additional file 2, Appendix A1). Official annual admission outcomes—successful listing via negotiation, bidding, or direct inclusion—were taken from NHSA announcements and the official structured lists of newly listed drugs (2016–2025) [1–3]. The 2025 dual-track counts (311 basic-track applicants; 141 commercial-track filings; 121 passing commercial-track review, including 79 dual-track filings; 19 ingredients recommended for inclusion in the inaugural commercial catalogue) are from NHSA's 2025 cycle communiqué [3].

Complete 2025 NRDL reconciliation. To verify that "never listed" is not confounded by historical NRDL inclusions we missed, the complete 2025 NRDL (National Healthcare Security Administration Document [2025] No. 33, 202 pages, 3,253 items: 1,446 western + 1,335 Chinese patent medicines including 95 ethnic + 472 negotiation-phase drugs) was transcribed using a layout-preserving column-extraction pipeline (pdftotext -layout, with numbering regex at column-coordinate-anchored positions; each section's identified count matches the official subtotal within rounding). After cross-referencing with historical annual panels, every ingredient in the analysis cohort was classified as "NRDL-listed" if and only if it had at least one record meeting any of: (i) terminal-status field indicating listing; (ii) annual outcome containing "newly listed"; or (iii) name-level match to the official 2025 newly-listed list of 114 drugs. As a reverse check, the NRDL-listed comparator ingredients (2.2; n = 701 at final reconciliation) were re-matched against the 2025 complete directory and every non-direct match was adjudicated in a mutually exclusive drug-by-drug audit ledger: 630 of 701 (89.9%) were directly name-matched in the current directory (including 11 ingredients reclassified from the dosage-form candidate list after endpoint verification, 2.2). The remaining 71 were resolved as: 40 fixed-dose combinations and compounded preparations (e.g. drug–saline/glucose combination infusions, parenteral-nutrition multi-chamber bags, peritoneal-dialysis and haemofiltration replacement fluids) for which the directory was re-checked preparation by preparation—38 are themselves listed in the 2025 directory under their preparation name (including antibiotic–solvent combination packs listed as such, multi-chamber nutrition bags, and preparations whose dosage form is captured within a bracketed entry, e.g. compound danshen dripping pills within the "compound danshen tablets (pills, capsules, granules, dripping pills)" entry); the remaining 2 (compound amino acid injection (17AA-III) and compound polyethylene glycol (3350) electrolyte oral solution—the directory lists the same active components under other amino-acid formulations and as the (3350) electrolyte powder, but not these specific preparation/dosage-form products) have listed components without the specific fixed-dose product itself being enumerated; 21 ingredients present in the 2025 directory under parsing/naming variants (including one ingredient with a successful 2025 renewal, agreement period 2026–2027); and 10 ingredients historically listed and subsequently removed (8 removed at end-2025 with reimbursement ceasing 2026-07, one removed in 2024, one removed in early 2025; historical listing confirmed in the 2016–2025 panel and NHSA removal notices). We therefore distinguish "preparation itself listed" from "components listed but the specific fixed-dose product not enumerated": 699 of the 701 comparators have the preparation or ingredient itself listed, and the 2 component-only preparations are reported separately and excluded in a sensitivity analysis (their commercial listing is 0, and the comparator listing rate is unchanged at 24.0%); the full ledger is in Additional file 2, Appendix A1.

Commercial rosters. Fourteen products were selected to represent the two dominant categories across first-tier and second-tier cities and national distribution:

- - *City universal (huimin bao)*, 8 products: Beijing Puhui Jiankang Bao 2026 (Beijing), Shanghai Huhui Bao 2026 (Shanghai), Shenzhen Huimin Bao 2025/2026 (Shenzhen), Suzhou Suhui Bao 2026 (Suzhou), Chengdu Huirong Bao 2026 (Chengdu), Nanjing Ninghui Bao phases III–VI (Nanjing, 2023–2026 benefit years), Dongguan Guanjiafu 2025 (Dongguan), Guangzhou Suisuikang 2025/2026 (Guangzhou).

- - *High-limit commercial medical insurance, 6 products*: ZhongAn Zunxiang e-Sheng 2026, PICC Hao Yibao (Youzhenbao / long-term medical) 2025/2026, Ping An e-Sheng Bao 2026 flagship edition, CPIC Lan Yibao (Yixiang Wuyou) edition E 2025/2026, CPIC add-on specialty-drug medical insurance edition B (filed 2025), Taikang Online inpatient expense medical insurance 2025 edition K (roster code YWTY020).

Every roster was obtained from an official source—insurer official websites, official WeChat articles, government (healthcare-security administration or municipal government) pages, or official claim-settlement notices—and each source was independently accessed and verified (Additional file 1, Table S1). Products fall into three evidentiary tiers. (i) **Five city products with complete enumerated rosters** (Beijing, Shanghai, Shenzhen, Suzhou, Chengdu) and **six high-limit products with complete current rosters** (2025–2026 versions): these 11 products form the drug-by-drug matching basis. (ii) **One product with partially collected rosters** (Nanjing): all successive annual rosters (phases III–VI) and their diffs are published and contribute to temporal/diff analysis; it adds no drug-level match beyond the 11-product union. (iii) **Two open-formulary products** (Dongguan Guanjiafu and Guangzhou Suisuikang): official statements explicitly state they maintain no dedicated specialty-drug roster and cover all compliant drugs above the deductible. Because no enumerable roster exists, they cannot be drug-by-drug matched; they are reported as a distinct product type (open formularies) in Table 1 and Additional file 1, Table S1 and are not counted in listing-rate denominators.

Table 1
The 14 audited commercial products and their benefit responsibilities (A/B/C/D classification)

#	Product (benefit year used)	Type	A: enumerated domestic specialty roster	C: overseas / Boao roster	B: general out-of-NRDL compliant-drug benefit	D: negative-list / no-roster out-of-hospital	Drug-by-drug matching basis
1	Beijing Puhui Jiankang Bao (2026)	HMB	Yes—176 drugs (71 domestic + 65 overseas + 40 tier-2)	Yes	Yes—out-of-catalog inpatient self-pay; 70%/35% coinsurance; deductible 15,000–20,000 yuan; cap 1m yuan	No (B limited to inpatient)	A + C rosters
2	Shanghai Huhui Bao (2026)	HMB	Yes—50 domestic high-cost drugs; 5 CAR-T	Yes—24 overseas	Yes—specific inpatient self-pay; 70%/30% tiers	No (B limited to inpatient)	A + C rosters
3	Shenzhen Huimin Bao (2026)	HMB	Yes—rare-disease 14 drugs	Yes—HK/Macao 22 items	Yes, open-structured—tiers 2/3 in/out-catalog compliant drug cost (negative-list design; 70%/50%; per-drug annual cap 500k)	B itself negative-list	Tier-4 rare-disease 14-drug roster (A)
4	Suzhou Suhui Bao (2026)	HMB	Yes—48 domestic + 5 CAR-T	Yes—75 overseas	Yes—liability 2 inpatient self-pay after BMI; deductible 20,000 yuan; 50% (20–100k)/70% (> 100k); unit price of self-paid drugs capped at 5,000 yuan	No (B inpatient + price cap)	A + C rosters
5	Chengdu Huirong Bao (2026)	HMB	Yes—58 domestic	Yes—18 overseas	Yes—liability 2 "out-of-BMI-scope individual self-pay" (inpatient/specialist outpatient; up to 50%)	No	A + C rosters
6	Nanjing Ninghui Bao (phases III–VI)	HMB	Yes—50 (28→36→45→50 by phase; 4 CAR-T)	Within roster	Yes since phase II (out-of-catalog inpatient self-pay)	No	A roster (diff/temporal only; adds no drug beyond 11-product union)
7	Dongguan Guanjiayu (2025/2026)	HMB	No roster—official: no dedicated specialty roster; all compliant costs above deductible	No	Yes—open compliant-cost benefit after deductible	Fully open (no roster)	Not enumerable—non-listing ≠ no coverage
8	Guangzhou Suisuikang (2026)	HMB	No roster—official "four no-limits", all NMPA-approved drugs	No	Yes—open (180 yuan/year; 2.45m cap)	Fully open (no roster)	Not enumerable—non-listing ≠ no coverage
HMB = city universal insurance (huimin bao); MMI = high-limit commercial medical insurance. Full provenance—product full name, underwriter, version, effective date, official URL, source type—is in Additional file 1, Table S1; all URLs accessed 2026-09-08 and verified to contain the roster, terms clause, or policy statement quoted. Key structural finding: no product is a "pure roster" product—10 of the 11 enumerable products also carry a standalone B-type general out-of-NRDL benefit (product 13, the CPIC add-on specialty-drug rider, has no standalone general liability and attaches to a CPIC main policy); 4 high-limit products (9–12) additionally carry a D-type negative-list out-of-hospital responsibility; products 7–8 are open-formulary by design. The unit of analysis is the product-level enumerable specialty-drug (A/C) roster responsibility, whether borne by a main policy or an add-on rider.							

#	Product (benefit year used)	Type	A: enumerated domestic specialty roster	C: overseas / Boao roster	B: general out-of-NRDL compliant-drug benefit	D: negative-list / no-roster out-of-hospital	Drug-by-drug matching basis
9	ZhongAn Zunxiang e-Sheng (2026)	MMI	Yes—270 oncology + 31 rare-disease + 30 imported + 7 CAR-T	Yes—15 Boao	Yes—general medical 3m (inpatient/specialist outpatient; 100% after social insurance)	Yes—"out-of-hospital drug & device expense" (no roster, no disease restriction)	A roster PDF
10	PICC Hao Yibao · Youzhenbao/long-term medical (2025)	MMI	Yes—307 oncology specialty (0 deductible, 100%, cap 2m)	Optional Japan oncology	Yes—general inpatient 2m / serious-illness 4m	Yes—general & serious-illness out-of-hospital drug & device (1m each)	A roster
11	Ping An e-Sheng Bao, flagship edition (2026)	MMI	Yes—298 oncology out-of-hospital (incl. 7 CAR-T)	Yes—85 urgent-imported	Yes—general/serious-illness inpatient (6m cap)	Yes—out-of-hospital drug & device "no disease restriction"; 0 deductible; cap raised 50k→1m for 2026	A roster
12	CPIC Lan Yibao, edition E (2026)	MMI	Yes—276 specialty	Yes—64 Boao (0-deductible edition)	Yes—long-term medical main inpatient liability (20-year guaranteed renewal)	Yes, official terms: out-of-hospital drug/device directory = "NMPA-approved drugs and devices through 2025-12-31, excluding contract-excluded items" (negative list)	A roster (276); D not enumerable
13	CPIC add-on specialty drug, edition B (2026)	MMI	Yes—200 + oncology specialty (name/manufacture/field itemised) + CAR-T	No	No standalone general medical liability (add-on to CPIC long-term main policy)	No	A roster (entire matching basis)
14	Taikang YWTY020 (2025 edition K)	MMI	Yes—oncology out-of-hospital specialty list (YWTY020)	No	Yes—main inpatient medical liability (standard million-limit structure)	No	A roster (YWTY020 PDF)
HMB = city universal insurance (huimin bao); MMI = high-limit commercial medical insurance. Full provenance—product full name, underwriter, version, effective date, official URL, source type—is in Additional file 1, Table S1; all URLs accessed 2026-09-08 and verified to contain the roster, terms clause, or policy statement quoted. Key structural finding: no product is a "pure roster" product—10 of the 11 enumerable products also carry a standalone B-type general out-of-NRDL benefit (product 13, the CPIC add-on specialty-drug rider, has no standalone general liability and attaches to a CPIC main policy); 4 high-limit products (9–12) additionally carry a D-type negative-list out-of-hospital responsibility; products 7–8 are open-formulary by design. The unit of analysis is the product-level enumerable specialty-drug (A/C) roster responsibility, whether borne by a main policy or an add-on rider.							

Roster extraction. Each roster's drug list was transcribed to a long table (2,204 product–drug entries across the 12 closed-formulary products). Product matching used the **original printed name stem as the primary key**; standardised names were used only as a

supplementary union, and one confirmed erroneous standardisation mapping (camrelizumab for injection recorded as the rilzabrelumab injection name, affecting six high-limit product entries for camrelizumab, an NRDL-listed PD-1) was excluded.

Attribute coding. Drug attributes were coded by two trained coders with adjudication, using NMPA registration classification (Class 1 innovative / Class 5.1 imported originator / Class 2 modified / Class 3 domestic generic of an overseas-marketed originator / generic / ATMP; see § 3.4 and the note to Additional file 2, Table S5 for definitions) [8, 18]; innovativeness class (first-in-class [FIC], fast-follow [FAST], me-better [MEB], modified [MOD], low-innovation [LOW], traditional Chinese medicine [TCM]); evidence tier defined by study design and endpoint type (E1 = RCT + hard clinical endpoint; E2 = RCT + surrogate endpoint; E3 = single-arm + hard endpoint; E4 = single-arm + surrogate endpoint; BE = bioequivalence); ATC class; orphan/rare-disease status [9, 10]; annual treatment cost; and registration class. Coding sources included NMPA labels, guidelines, and the published "353-out-of-list high-frequency 91 specialty ingredients" reference table. Because that table was itself assembled from commercially visible specialty drugs, we report all attribute analyses on the **encoded subset** with **attribute-specific encoded denominators** (see 2.4) and non-encoded ingredients shown as a separate stratum; we replicate the key comparisons in the **2025 single-year entrant cohort** (2.5).

2.2 Cohort construction

The analysis cohort is at **ingredient (active moiety) level**, because commercial rosters list ingredients rather than specific dosage forms. The 2,825 drug-year formal-review records were normalised to 1,612 generic-name entries and then to 1,394 unique ingredients (148 stems merged 366 variant names).

After reconciliation against the 2025 complete NRDL (§ 2.1), an ingredient was classified as **NRDL-listed** if any record met any of the three listing criteria; ingredients with no listing record in any year were classified as **not included during the observation period** (the "not-included pool"). This yielded **701 NRDL-listed and 578 not-included ingredients** at the component level. A separate group of **115 dosage-form gap** ingredients (2.2 below) was identified from the same formal-review universe; the final component-level cohort of 1,394 ingredients comprises the 578 main pool, the 701 listed comparator, and the 115 dosage-form gap group.

Within the not-included pool, we further separate:

- **Main pool (n = 578):** the *component itself* has never appeared on any NRDL inclusion list across any year.
- **Dosage-form gap group (n = 115):** the *component* is listed in some dosage form, but endpoint verification against the 2025 directory confirmed the specific dosage form applied for remains unlisted at the observation endpoint (2025 directory; status re-verified, not inferred from any single failed cycle). These are "old ingredient, new dosage form" applicants. A further 11 candidates initially flagged here were re-adjudicated at endpoint: both component and applied dosage form were already in the 2025 directory (parsing false-positives), so they were moved to the comparator pool (630 direct matches). Of these 11, only temozolomide for injection is itself enumerated on a commercial roster and is counted within the comparator's 24.0% listing rate; rosters enumerate ingredients by name rather than by dosage form. Per-drug lists are in Additional file 2, Appendix A2.

This separation is required because "component never listed" and "component listed but applied dosage form not listed" answer different commercial questions: commercial rosters list ingredients (i.e. components), so the dosage-form gap group tests whether a *new dosage form* of an already-listed component can be captured by a commercial roster, rather than whether an unlisted component is captured. The main pool of 578 is the basis for all primary analyses of roster listing rate; the 115 dosage-form gap ingredients are reported as a separate supplementary analysis (3.7); the 701 listed ingredients form the comparator.

2.3 Commercial coverage variables and benefit responsibility

For each ingredient, drug-by-drug roster listing was coded on the **11 complete-roster products** (5 city products with complete enumerated rosters; 6 high-limit products) using the audited roster long table. Two binary indicators were defined on the 11-product basis: HMB-listed (on any of the 5 complete city rosters) and MMI-listed (on any of the 6 high-limit rosters), with "commercially listed" = either. Roster listing of the 701 comparator ingredients was coded identically.

Benefit responsibility classification. To distinguish what is measurable by drug-by-drug matching from what is not, every product was classified by its benefit responsibilities:

- **A** = enumerated domestic specialty-drug roster (drugs listed individually by name)
- **C** = overseas / Hainan Boao / GBA Macao-Hengqin listed drugs (drugs listed individually by name)

- - **B** = general out-of-NRDL compliant drug cost benefit for inpatient/outpatient care, reimbursed from eligible expenses after the deductible at the coinsurance rate rather than from an enumerated drug list
- - **D** = negative-list / no-roster out-of-hospital drug & device benefit (no enumerated positive list; only exclusions are specified)

Of the 14 products, **10 of the 11 enumerated-roster products also carry a standalone B-type responsibility** (i.e. they reimburse non-roster compliant drugs above a deductible); the eleventh (the CPIC add-on specialty-drug policy, product 13) is a pure add-on rider with no standalone general medical liability of its own and must attach to a CPIC long-term main policy. The unit of analysis is the product-level enumerable specialty-drug (A/C) roster responsibility, whether borne by a main policy or an add-on rider. **Four high-limit products** (ZhongAn Zunxiang e-Sheng 2026, PICC Hao Yibao Youzhenbao, Ping An e-Sheng Bao 2026, and CPIC Lan Yibao edition E) additionally carry a D-type negative-list out-of-hospital responsibility (CPIC Lan Yibao edition E's official terms explicitly define out-of-hospital drugs as "consistent with NMPA-approved drugs through 2025-12-31, excluding contract-excluded items"—a negative-list formulation). The two open-formulary products (Dongguan Guanjiayu and Guangzhou Suisuikang) have **no enumerable roster at all**; their B-type benefit is their entire design, and they are reported separately throughout. Because B- and D-type benefits do not enumerate drugs by name, drug-by-drug matching is methodologically inapplicable to them: "not listed on the A/C roster" does not imply "not reimbursed by this product". The rate we report is therefore the **roster listing rate against the enumerated A/C lists of 11 products**, not a measure of total commercial coverage.

2.4 Attribute variables and per-attribute encoded denominators

Because attribute coding coverage is not uniform, we report each attribute analysis on its **attribute-specific encoded subset**:

- - Innovativeness (inn): 176 of 578 main-pool ingredients (30.4%)
- - Evidence tier (evi): 127 of 578 (21.9%)
- - Rarity (rare): 176 of 578 (30.4%)
- - Annual price (price): 170 of 578 (29.4%)
- - Registration class (reg): 208 of 578 (36.0%)
- - ATC class (atc): 176 of 578 (30.4%)

Non-encoded ingredients are retained as a separate stratum ("Uncoded") in every table and figure. All within-attribute gradients are reported as observed descriptive patterns in the encoded subset; no multivariable adjustment is performed.

2.5 Temporal analysis

For each commercially listed main-pool ingredient, we reconstructed the year of first appearance on each commercial roster where version history was recoverable. Four city products have archived successive annual rosters permitting year-level reconstruction (Beijing, Shanghai, Suzhou, Chengdu); Nanjing successive editions (phases III–VI) are archived and enter the diff analysis; the Shenzhen editions were not fully archived; and the six high-limit products are current cross-sections whose carriers confirmed no historical roster versions are publicly retrievable. These latter sources contribute no temporal ordering.

Temporal ordering is reported only for main-pool ingredients that have (i) a **basic-track (BMI) application date on record** and (ii) a **reconstructible HMB first-listing year**. Ingredients that applied **only** through the commercial track without ever filing for basic-track listing are reported as a separate "commercial-track-only" group and are not orderable relative to a basic-track sequence. Ingredients without a reconstructible HMB first-listing year are reported as "date not reconstructible" and excluded from temporal ordering.

Each orderable listed ingredient was assigned to one of three mutually exclusive categories: (T1) commercial listing **before first BMI application**; (T2) **same year** as a BMI application (month-level order not recoverable); (T3) **after BMI outcomes were published** (i.e. following a known failed cycle).

2.6 Annual funnel and policy-event analysis

Year-by-year funnels (formal review → negotiation/bidding entry → success → newly listed; renewals separately) were reconstructed from NHTSA official communiqués. The 2021 denominator follows the NHTSA official interpretation: 174 applicants for the 2021 negotiation cycle, of whom 74 were newly listed (67 via negotiation plus 7 direct inclusions), a 42.5% listing rate [12, 24]. Roster-change events across products 2021–2026 were taken from the annual diff ledger (246 product-year events total: 201 drug-level add/remove events plus 45 non-drug-level events).

2.7 Statistical analysis

All analyses are descriptive. Coverage proportions are reported with Wilson binomial 95% confidence intervals (CIs) to display the sampling uncertainty around each observed proportion, not for between-group inference beyond the reported trend and χ^2 tests; χ^2 or Fisher's exact tests are used as appropriate, with two-sided $p < 0.05$ nominal. No multivariable regression or causal adjustment is used; the paper's structural claims are explicitly labelled as observed correlates. Analyses used Python 3.11 (pandas, scipy); all figures and tables are generated from locked analysis datasets (audit scripts P31–P35, final datasets P41, available on request).

3. Results

3.1 The NRDL negotiation funnel, 2020–2025

Figure 1. National NRDL negotiation funnel, 2020–2025. (A) Outside-list drugs passing formal review, inside-list (renewal-pool) drugs, and successful new additions/renewals by cycle. (B) Outside-list conversion rate (newly added / outside-list passed formal review). 2020 uses the broader preliminary scope; 2025 renewals are the official aggregate (148 simple renewals + 30 re-negotiated = 178) because drug-level renewal names are not published.

Figure 1 presents the year-by-year funnel.

Additional file 1, Table S3 reports the annual funnels. Among drugs entering formal review, the annual newly-listed counts and rates were: 2020, 119 listed (16.9% of the 704-drug review pool under the then broader scopet); 2021, 74 newly listed out of 174 negotiation-cycle applicants (42.5%; 67 via negotiation plus 7 direct inclusions, per the NHTA official interpretation [24]); 2022, 108/199 (54.3%); 2023, 126/226 (55.8%); 2024, 91/249 (36.5%) [16]; 2025, 114/311 (36.7%) [17]. The 2025 basic track proceeded as 311 formal-review drugs → 127 entering negotiation/bidding plus 2 direct inclusions → 112 successes (88.2% of entrants: 105 negotiation successes and 7 bidding successes) → 114 newly listed, including 50 Class-1 innovative drugs. The 2025 renewal track processed 224 drugs through formal review, with 178 successes (148 simple renewals including 15 with average price reductions of 8.4%, and 30 renegotiations with average reductions of 13.8%), 8 failures (4.3% failure rate), and 21 routine removals, totalling 29 exits. The inaugural commercial track received 141 filings, passed 121 through formal review (79 dual-track filings that also applied to the basic track), and recommended 19 ingredients for inclusion in the first commercial innovation-drug catalogue.

The funnel describes a system in which the share of formal-review entrants reaching the list has varied between 36.5% and 55.8% since 2022, with the 2021 rate (42.5%) lower than the 2022–2023 peaks and the 2024–2025 rates around 37%. The annual pool of drugs that applied and were not listed in that cycle is therefore structurally persistent rather than exceptional; across 2020–2025 these cumulative not-included ingredients form the cohort analysed below: the main pool of 578 (component never listed), reported against 701 NRDL-listed comparators, plus a supplementary dosage-form gap group of 115 (component listed, applied dosage form not listed at endpoint). We make no claim that BMI listing capacity is a single "binding constraint" on access—applicant composition, evidence maturity, and price negotiations all vary by year—but the funnel establishes that non-listing after application is a common, recurring outcome.

† The 2020 formal-review pool was compiled under a broader scope (704 entries including catalogue-category adjustments); rates from 2021 onward use the NHTA negotiation-cycle denominators.

3.2 Roster listing rate of the main pool: 12.8%

Figure 2. Roster listing of NRDL-not-included and NRDL-listed ingredients on the 11 complete-roster commercial products (2026 cross-section). (A) Main pool ($n = 578$, never NRDL-listed) versus comparator ($n = 701$, NRDL-listed): any commercial listing, city huiminbao rosters (5 products), and high-limit commercial rosters (6 products). (B) Main-pool listing by application track: basic-track only (487), dual-track (68), and commercial-track-only sponsors who never filed for BMI (23). Listing = ingredient name enumerated on an audited A/C specialty-drug roster; open-formulary products and B/D-type general benefits are not name-matchable.

Figure 2 summarises listing rates on the 11 complete-roster products and the application-track decomposition.

Of the 578 main-pool ingredients whose component was never listed on the NRDL during 2020–2025, **74 (12.8%; 95% CI 10.3–15.8) appeared on at least one of the 11 complete-roster commercial products**; 504 (87.2%) were not found on any collected complete roster (Table 2). By channel, 67 (11.6%) appeared on the five complete city universal (HMB) rosters and 55 (9.5%) on the six high-limit (MMI) rosters. The partially collected Nanjing rosters added no drug beyond this union; the two open-formulary products have no enumerable roster and are reported separately.

Table 2
Roster listing rate of the main pool and the comparator (drug-by-drug matching on 11 complete-roster products)

Cohort	n	Listed on any commercial roster (5 HMB ∪ 6 MMI)	HMB (5 complete city rosters)	MMI (6 high-limit rosters)
Main pool (component never NRDL-listed)	578	74 (12.8%; 95% CI 10.3–15.8)	67 (11.6%; 9.2–14.5)	55 (9.5%; 7.4–12.2)
– Main analysis queue (applied BMI ≥ 1, not listed)	555	55 (9.9%; 95% CI 7.7–12.7)	–	–
– – basic-track only	487	21 (4.3%; 95% CI 2.8–6.5)	–	–
– – dual-track	68	34 (50.0%; 95% CI 38.4–61.6)	–	–
– Commercial-track-only supplementary queue (never filed BMI)	23	19 (82.6%; 95% CI 62.9–93.0)	–	–
Dosage-form gap group (component listed, applied form unlisted at endpoint; separate analysis)	115	6 (5.2%; 95% CI 2.4–10.9)	2	5
Comparator (NRDL-listed)	701	168 (24.0%; 95% CI 21.0–27.3)	40 (5.7%; 4.2–7.7)	163 (23.3%; 20.3–26.5)
Main analysis queue (555 BMI applicants) by formal-review appearances (years on NHSA-published formal-review-passed lists, 2020–2025): no formal-review record*	9	0 (0%; 95% CI 0.0–29.9)		
1 appearance	423	21 (5.0%; 95% CI 3.3–7.5)		
2 appearances	55	16 (29.1%; 95% CI 18.8–42.1)		
≥ 3 appearances	68	18 (26.5%; 95% CI 17.4–38.0)		

Percentages are of the row n. Values in parentheses after a percentage are binomial Wilson 95% CIs (shown without repeating "95% CI" in the HMB/MMI and gradient columns for compactness); CIs describe sampling uncertainty around each observed proportion and are not used for between-group inference. The 11-product matching basis comprises the five city products with complete enumerated rosters and the six high-limit products. The partially collected Nanjing product adds no drug beyond this union; the two open-formulary products (Dongguan, Guangzhou) have no enumerable roster and are excluded from drug-by-drug matching. The dosage-form gap group (115) is excluded from the main-pool denominator by design and reported in § 3.7; 11 further endpoint-adjudicated candidates were reclassified into the comparator. Listing is measured against enumerated A/C rosters; B-type general benefits and D-type negative-list responsibilities are not measurable by drug-by-drug matching. *Counts are appearances on the NHSA published formal-review ("xing shen") passed lists for negotiation years 2020–2025; NHSA does not publish a separate list of drugs that entered negotiation/bidding but were not admitted, so formal-review appearances cannot be equated with negotiation rounds entered. Nine older ingredients (generics or Chinese patent medicines) filed for the basic track but leave no formal-review-passed record in 2020–2025 and are shown separately as "no formal-review record" (not as zero negotiation rounds). The gradient excludes the 23 commercial-track-only ingredients, which by construction never filed for BMI and have no formal-review appearances (their listing rate, 19/23 = 82.6%, is reported separately). Listing is higher among repeated (2 or ≥ 3) formal-review applicants than among single-cycle applicants, but the two-cycle (29.1%) and ≥ 3-cycle (26.5%) rates are not monotonically ordered. Gradient test: Cochran–Armitage $z = 6.84$, $p < 0.001$ ($\chi^2 = 46.8$).

Two analytical sub-queues must be distinguished. Within the 578 main pool, the filing track composition is:

- - **Basic-track only** (applied to BMI only): 487 ingredients; 21 listed (4.3%)
- - **Dual-track** (applied to both BMI and the commercial track): 68 ingredients; 34 listed (50.0%)
- - **Commercial-track only** (never filed for BMI): 23 ingredients; 19 listed (82.6%)

We therefore report two primary listing rates:

- - **Main analysis queue** (applied for BMI at least once but not listed): **555 ingredients, 55 listed (9.9%; 95% CI 7.7–12.7)** = the basic-track-only 487 (21 listed) plus the dual-track 68 (34 listed).
- - **Commercial-track-only supplementary queue** (never filed for BMI): **23 ingredients, 19 listed (82.6%; 95% CI 62.9–93.0)**.

The 19 ingredients recommended for the inaugural CHI catalogue (Additional file 1, Table S2) all appeared on commercial rosters; however, only 5 of them (elranatamab, talquetamab, zanidatamab, velaglucerase β , lurbinectedin) had never filed for basic-track listing, while 14 (including the four covered CAR-T products, ipilimumab, the two anti-amyloid antibodies, and teduglutide) had also applied to the basic track in the same or earlier cycles and thus fall in the main analysis queue.

The comparator tells a different story: of the 701 NRDL-listed ingredients, 168 (24.0%; 95% CI 21.0–27.3) appeared on at least one of the same 11 products—40 (5.7%) on the five complete HMB rosters and 163 (23.3%) on the six MMI rosters. High-limit products thus list NRDL-listed drugs at roughly 2.5 times the rate at which they list main-pool ingredients (23.3% vs 9.5%), while HMB products show the reverse tilt (11.6% vs 5.7%).

Figure 3 shows the gradient. Within the main analysis queue of 555 BMI applicants, roster listing was higher among ingredients with repeated formal-review applications than among single-cycle applicants. Our count variable is the number of appearances on the NHTA published formal-review ("xing shen") passed lists for negotiation years 2020–2025 (filing), which is the most granular stage for which NHTA publishes a drug-level list; NHTA does not separately publish the set of drugs that entered negotiation or bidding after passing formal review, so formal-review appearances cannot be equated with negotiation rounds entered. Nine older ingredients (generics or Chinese patent medicines) appear in basic-track application records but on no published formal-review-passed list during 2020–2025; they are reported separately as "no formal-review record" (0 listed) rather than as zero negotiation rounds. Among ingredients with one formal-review appearance, 21/423 (5.0%) were listed; two appearances, 16/55 (29.1%); three or more, 18/68 (26.5%) (Cochran–Armitage trend test $z = 6.84$, $p < 0.001$). The two-appearance (29.1%) and ≥ 3 -appearance (26.5%) rates are not monotonically ordered; the defensible reading is that repeat applicants are listed more often than single-cycle applicants, not that listing rises with each successive round. The 23 commercial-track-only ingredients have no basic-track formal-review record by construction and are excluded from this gradient (their listing rate is 82.6%, reported separately above). Commercially listed main-analysis-queue ingredients are disproportionately repeat formal-review applicants rather than single-cycle applicants.

3.3 Listing gradients by attribute

Figure S1 (Additional file 1) charts the gradients; Additional file 2, Table S5 gives exact denominators and rates. Within the encoded subsets (each attribute on its own encoded denominator; see 2.4), listing showed strong unadjusted associations with every attribute examined (Additional file 2, Table S5). Gradients are descriptive; no multivariable adjustment is made.

Innovativeness (encoded 176 of 578; 402 non-encoded). FIC 26/27 (96.3%); FAST 35/62 (56.5%); MEB 1/3 (33.3%); MOD 0/7; LOW 3/61 (4.9%); TCM 0/16. The non-encoded stratum (402 ingredients) had 9 listed (2.2%).

Evidence tier (encoded 127 of 578; 451 non-encoded). E1 (RCT + hard endpoint) 22/36 (61.1%); E2 (RCT + surrogate) 11/46 (23.9%); E3 (single-arm + hard) 5/6 (83.3%); E4 (single-arm + surrogate) 24/32 (75.0%); BE 2/7 (28.6%). The non-encoded stratum (451 ingredients) had 10 listed (2.2%). The high listing of E3 and E4 ingredients reflects that many recently approved specialty oncology drugs obtained approval on single-arm trial evidence; commercial rosters commonly list precisely such drugs, whereas the NRDL negotiation process has conventionally favoured drugs with randomised-trial evidence of hard outcomes [7].

Rarity (encoded 176 of 578; 402 non-encoded). Orphan/rare-disease ingredients 22/35 (62.9%) vs non-rare 43/141 (30.5%). The non-encoded stratum (402 ingredients) had 9 listed (2.2%).

ATC class (encoded 176 of 578; 402 non-encoded). L (antineoplastic & immunomodulating) 46/55 (83.6%); A (alimentary/metabolism) 8/22 (36.4%); N (nervous) 4/21 (19.0%); M (musculoskeletal) 2/8 (25.0%); B (blood) 2/12 (16.7%); V (various) 2/9 (22.2%); H (systemic hormones) 1/4 (25.0%); J (systemic anti-infectives) 0/16; C (cardiovascular) 0/9; R (respiratory) 0/9. The non-encoded stratum (402 ingredients) had 9 listed (2.2%).

Annual treatment cost (encoded 170 of 578; 408 non-encoded). >500,000 yuan 31/33 (93.9%); 200,000–500,000 18/20 (90.0%); 50,000–200,000 9/17 (52.9%); <50,000 2/100 (2.0%). The non-encoded stratum (408 ingredients) had 14 listed (3.4%).

Registration class (encoded 208 of 578; 370 non-encoded). ATMP (cell/gene therapy) 6/6 (100%); Class 1 innovative (chemical/biological) 57/87 (65.5%); Class 1 innovative (one subclass) 1/4 (25.0%); Class 5.1 imported innovative 1/7 (14.3%); Class 2 modified 0/9; Class 3 (domestic copy of an imported originator) 1/39 (2.6%); generic 1/29 (3.4%); Class 4 0/3; TCM 0/16; other 0/8. The non-encoded stratum (370 ingredients) had 7 listed (1.9%). Western medicines overall 74/430 (17.2%) vs TCM overall 0/148.

The 9 listed ingredients outside the encoded subset (Additional file 2, Appendix A3) are mostly long-marketed specialty drugs absent from recent innovation coding frames—imiglucerase, elosulfase alfa, liposomal doxorubicin, interferon α -2b gel, laronidase, pralatrexate, mobocertinib, agalsidase beta, alglucosidase alfa—consistent with roster listing of established high-cost specialty drugs rather than only new molecular entities.

3.4 Within-ATC-area comparisons: gradients are not purely area composition

Because ATC L dominates listing, we examined whether innovativeness/evidence gradients persist *within* therapeutic areas (Additional file 2, Table S6). Within ATC L (n = 55, 46 listed, 83.6%): FIC 21/21 (100%), FAST 24/28 (85.7%), LOW 0/4 (0%), MEB 1/2 (50.0%); E1 19/19 (100%), E4 21/23 (91.3%), E2 4/7 (57.1%), E3 2/3 (66.7%). Within L, FIC/FAST and E1/E4 are nearly universal and cannot be statistically separated from each other—listing in this cell is near ceiling.

Within A (n = 22, 8 listed, 36.4%): FAST 5/9 (55.6%) vs LOW 2/8 (25.0%); E4 3/5 (60.0%) vs E2 1/7 (14.3%). The evidence-tier difference in A (E4 60.0% vs E2 14.3%) is directionally large but rests on a small cell and does not reach nominal significance; we report it as an observed pattern, not evidence of an independent effect.

Within N (n = 21, 4 listed, 19.0%): FAST 3/9 (33.3%), FIC 1/1 (100%), LOW 0/10 (0%); E2 3/16 (18.8%), E1 1/3 (33.3%). Within J (n = 16, **0 listed**): FAST 0/7, LOW 0/8; E1 0/5, E2 0/2, E4 0/1—systemic anti-infectives show zero listing across innovativeness, evidence, and encoding strata, so within-J factors cannot be discriminated.

3.5 2025 single-year entrant cohort: gradients reproduced

Among the 88 main-pool ingredients whose first formal-review entry was in 2025 (encoding near-complete for this cohort), listing was 34/88 (38.6%). The principal gradients reproduce: innovativeness FIC 15/15 (100%), FAST 18/36 (50.0%), MEB 1/3 (33.3%), MOD 0/3 (0%), LOW 0/19 (0%), TCM 0/12 (0%); evidence tier E1 10/15 (66.7%), E2 8/28 (28.6%), E3 4/4 (100%), E4 12/16 (75.0%), BE 0/1; ATC L 25/28 (89.3%), A 2/8, N 3/12, J 0/9; price > 500,000 yuan 15/16 (93.8%), 200–500,000 10/11 (90.9%), 50–200,000 5/7 (71.4%), < 50,000 0/50. The innovativeness and area gradients are therefore not artefacts of pooling across years.

3.6 Temporal ordering: commercial listing relative to NRDL application

Of the 74 listed main-pool ingredients, 19 had reconstructible HMB first-listing years permitting temporal classification (high-limit commercial rosters contribute no temporal ordering because no historical versions are publicly retrievable). Of these 19:

– **8 had a basic-track application on record** and are orderable:

- **T1, commercial listing before first BMI application (1 drug):** dinutuximab beta (HMB 2022 vs first basic-track application 2023).
- **T2, same year as a BMI application, month-level order unrecoverable (1 drug):** socazolimab (BMI application 2024, HMB listing 2024).
- **T3, after BMI outcomes were published (6 drugs):** tazemetostat, tosylamide, talazoparib, benmelstobart (applied to BMI 2025, listed on HMB 2026 after 2025 outcomes published); ipilimumab (first BMI application 2021, listed HMB 2022); inotuzumab ozogamicin (first BMI application 2022, listed HMB 2023).

– **11 were commercial-track-only** (never filed for BMI, so the BMI-sequence ordering is inapplicable): elranatamab, talquetamab, lurbinectedin, gilteritinib, radium-223 dichloride, mogamulizumab, avelumab, puzosicimab, teclistamab, amivantamab, and enfortumab vedotin (these cannot be ordered relative to a basic-track sequence and are reported separately).

– The remaining **55 listed main-pool ingredients lacked reconstructible HMB first-listing years** (listed on current cross-section high-limit rosters, or on city rosters without recoverable version history) and are excluded from temporal ordering.

Among the 19 HMB-dated listed main-pool ingredients, the approval-to-listing interval (first HMB roster year minus NMPA approval year) had a median of 1 year (distribution: 0 years $\times$ 1, 1 year $\times$ 10, 2 years $\times$ 6, 3 years $\times$ 1, 4 years $\times$ 1). This median describes how quickly rosters absorb newly approved specialty drugs; it is not an approval-to-coverage or rejection-to-listing interval.

The temporal evidence is deliberately narrow. Of all 74 listed main-pool ingredients, only 8 are orderable relative to a basic-track sequence: 1 was listed before any BMI application, 1 in the same year (month order unrecoverable), and 6 only after BMI outcomes were published. Among the 19 commercial-track-only listed ingredients, 11 appear on the archived rosters of the four city products with version history (Beijing, Shanghai, Suzhou, Chengdu) and so have a reconstructible first-HMB-listing year (reported above); the other 8 appear only on the Shenzhen roster (no archived editions) or on high-limit current cross-sections and have no reconstructible date. This

commercial-track-only group used the commercial channel as a first-choice route, but its timing cannot be ordered against a basic-track sequence that never occurred. Commercial-track application dates therefore do not substitute for basic-track dates.

3.7 Dosage-form gap group (n = 115): 6 listed

Endpoint verification against the complete 2025 NRDL confirmed 115 ingredients whose component is listed in some dosage form but whose *applied* dosage form remained unlisted at the observation endpoint ("old ingredient, new dosage form" cases; Additional file 2, Appendix A2). Verification was applied to the endpoint status of each applied form, not inferred from any single failed application year. Of these 115, **6 had the specific gap dosage form itself enumerated on a commercial roster**: edaravone sublingual tablet and triptorelin pamoate injection (MMI), baclofen oral solution (HMB), palonosetron capsules (MMI), melphalan hydrochloride for injection (HMB + MMI), and bendamustine injection (MMI)—2 on HMB rosters and 5 on MMI rosters. A further 11 candidates initially flagged as dosage-form gaps were re-adjudicated at endpoint: both component and applied dosage form were already in the 2025 directory (parsing false-positives), and they were moved to the comparator pool. One of these 11, temozolomide for injection, is itself enumerated on a commercial roster and, being already in the 2025 NRDL, belongs to the comparator pool (701)—consistent with rosters listing ingredients by name rather than by dosage form. Commercial rosters are ingredient-level in their listing, so the 6 true-gap entries above demonstrate that a new dosage form of an already-listed component can occasionally be captured by name. The 115 ingredients are excluded from the main-pool denominator by design; this supplementary group answers whether the *new-form* channel reaches commercial rosters (6/115, 5.2%), distinct from the main question about never-listed components.

3.8 Roster dynamics: expansions, exits, and renewal failures

Across the five city products with archived successive rosters (Suzhou, Shanghai, Beijing, Chengdu, Nanjing), the diff ledger records 201 drug-level additions/removals for benefit years 2021–2026 plus 45 non-drug-level events (multi-drug scope expansions counted as single events, indication adjustments, cap changes; Additional file 2, Table S7, note). Drug-level additions/removals by benefit year were: 2021, 1 added/8 removed; 2022, 41/16; 2023, 29/23; 2024, 10/11; 2025, 10/9; 2026, 23/20.

Three commercial exit events were documented: idursulfase beta removed from the Suzhou product in 2022; agalsidase beta removed from the Shanghai product in 2026 following reported cumulative claims of about 45 million yuan; and axicabtagene ciloleucel removed from the Shanghai product in 2026, the same benefit year in which that product added a fully domestic CD19 CAR-T (approved 30 July 2025, priced at 899,000 yuan). Exits thus track claims burden or lower-priced domestic alternatives, without implying causation.

Of the 8 drugs that failed NRDL renewal in the 2025 cycle (beinaglutide, danoprevir, ravidasvir, alirocumab, duvelisib, octafluoropropane lipid microspheres, sodium oligomannate, linperlisib—all NRDL-listed comparator ingredients, not main-pool ingredients), duvelisib and linperlisib remain listed on the current (2025–2026) rosters of four high-limit products. Because only current cross-sections are available for these products, we report this as continued presence on collected rosters; we cannot establish whether listing began before or after the renewal failure, and make no "post-failure adoption" claim.

4. Discussion

4.1 Principal findings

Across 1,394 ingredients that entered the 2020–2025 NRDL formal-review pools, and after verifying every ingredient against the complete 2025 NRDL, the 578 main-pool ingredients whose component has never been listed on the NRDL show a roster listing rate of **12.8% (74/578)** on the 11 complete-roster audited products: 67 (11.6%) on the five complete city universal rosters and 55 (9.5%) on the six high-limit commercial rosters, against 24.0% (168/701) of NRDL-listed comparators on the same products. Listing is not random. Within the encoded subsets it concentrates in high-price, high-innovativeness antineoplastic and immunomodulating ingredients—FIC 96.3%, ATMP 100%, annual cost > 500,000 yuan 93.9%, ATC L 83.6%—while systemic anti-infectives, cardiovascular drugs, respiratory drugs, and Chinese patent medicines show zero or near-zero listing. These gradients survive within-area comparison and reproduce in the 2025 entrant cohort; they are unadjusted descriptive associations in encoded subsets, not causal drivers.

The two-track decomposition is informative: among the **555 main-analysis-queue ingredients that applied for BMI at least once but were not listed**, only 55 (9.9%) are listed; whereas among the **23 commercial-track-only ingredients that never filed for BMI**, 19 (82.6%) are listed. The latter segment differs in composition rather than in payer logic: its sponsors pursued commercial listing without filing for BMI. This describes how the channels differ in the drugs they carry; a reform-driven expansion this study can report but not causally attribute. B- and D-type responsibilities may extend payment beyond what is name-matchable (4.5).

Temporal evidence is deliberately narrow. Only 8 listed main-pool ingredients are orderable relative to a basic-track sequence: 1 was listed before any BMI application, 1 in the application year (month order unrecoverable), and 6 only after BMI outcomes were published. We make no "rejection-backfill" claim beyond these 6; commercial-track-only ingredients cannot be ordered against a basic-track sequence that never occurred. The 19 ingredients recommended for the inaugural CHI catalogue include 5 whose sponsors never filed for basic-track listing (elranatamab, talquetamab, zanidatamab, velaglucerase β , and lurbinectedin); the other 14 CHI admissions had also applied to the basic track.

What the 12.8% measures. It is the fraction of main-pool ingredients enumerated on the 11 products' specialty-drug rosters (A/C-type enumerated lists), not the fraction of NRDL-not-included drugs that commercial insurance pays for. Ten products also carry a B-type general out-of-NRDL benefit and four a D-type negative-list out-of-hospital responsibility (neither name-matchable), and two products (Dongguan, Guangzhou) are open-formulary designs with no enumerable roster (Table 1).

4.2 Interpretation: roster composition across channels

The observed rosters are concentrated on a narrow high-value segment rather than spread across the full NRDL-not-included universe. Three descriptive features accompany this concentration; we report them without attributing them to payer decisions we cannot observe. First, the near-monotonic price gradient and the zero listing of TCM and anti-infectives are consistent with the economics of high-deductible, low-premium products, where ultra-high-cost therapies with small treated populations (CAR-T at 1–1.2 million yuan per course, rare-disease enzyme replacement) can be carried through reinsurance and stop-loss because prevalence is low, whereas high-volume, moderately priced drugs would bear more heavily on premiums. Second, the two product types carry different drug mixes: HMB rosters tilt toward main-pool ingredients (11.6% vs 5.7% for listed comparators) and high-limit rosters toward listed drugs (23.3% vs 9.5%), a difference in roster composition across channels rather than evidence of opposing payer selection logic. Third, rosters change over time: documented exits followed either large cumulative claims (agalsidase beta, ~45 million yuan on one Shanghai product) or domestic-substitute entry (axicabtagene ciloleucel exited as a domestic CAR-T priced at 899,000 yuan arrived).

Read alongside the policy record, the 2025 commercial track formalised a channel that city products had already used, and the 19 inaugural catalogue recommendations show that enumerated coverage can be delivered for products such as cell therapies, rare-disease biologics, and Alzheimer's antibodies that are difficult to absorb into basic insurance at launch prices [21]. A hypothesis consistent with, though not tested by, our data is that the channel's measurable value lies in breadth of channel choice for a narrow high-value segment (82.6% of commercial-track-only sponsors obtained roster listing), not in population-level closure of the NRDL-not-included gap: 87.2% of main-pool ingredients are absent from every audited enumerated roster, and payment through B-type general and D-type negative-list benefits is not measurable from rosters alone.

4.3 Comparison with prior literature

The result complements existing Chinese evidence that HMB rosters erode over time and concentrate on a few high-profile oncology drugs [19, 22], and that high-limit products face hospital-pharmacy fulfilment constraints [20]. We add the denominator-side finding that even the union of 11 complete-roster products lists only 12.8% of the main-pool universe of ingredients not included in the NRDL, while listing 24.0% of NRDL-listed comparators on the same products. Internationally, the Chinese model differs from Medigap-style complementary insurance (which covers cost-sharing for Medicare-covered services) and from French *contrats responsables* (which supplement statutory cost-sharing): Chinese enumerated rosters substitute for, rather than supplement, basic coverage for the drugs they list, making roster composition itself the coverage decision. We make no comparative claim about selection under mandated health-technology-assessment systems elsewhere [23]: no comparable selection data were collected from other settings.

4.4 Policy implications (measured)

First, the dual-track architecture is best evaluated on channel-specific outcomes (time-to-listing for commercial-track drugs, roster stability, claims experience) rather than on the volume of drugs absorbed: 9.9% of the main analysis queue versus 82.6% of the commercial-track-only queue are listed, consistent with the channel serving sponsors who choose it rather than backfilling after BMI non-listing; a reform effect would require pre/post comparison. Second, roster provenance is scattered across insurer PDFs and municipal pages, historical high-limit rosters are largely unavailable, and reconciling our cohort against the complete 2025 NRDL required layout-preserving extraction; public, versioned, machine-readable rosters with effective dates would make the commercial layer auditable and support the division-of-labour and hand-off evaluations our findings motivate (Additional file 1, Table S1). Third, whether the B-type general out-of-catalog benefits and D-type negative-list out-of-hospital responsibilities of four high-limit products can pay for medium-prevalence chronic-disease drugs outside the NRDL remains an open question for claims-based studies; their high deductibles and segmented coinsurance suggest roster listing may remain the binding channel for high-value drugs.

4.5 Limitations

First, the 14 products are a purposive, non-probability sample of leading city and national products, and drug-by-drug matching rests on 11 complete-roster products (5 city + 6 high-limit). "Not listed on collected enumerated rosters" is not equivalent to "no commercial coverage anywhere in China": two open-formulary products (Dongguan, Guangzhou) reimburse all compliant drugs without enumerating them, and B/D-type responsibilities are not enumerable; the true market-wide *payment* coverage could be broader, and our 12.8% is strictly a roster listing rate. Second, attribute coding covers between 127 and 208 of 578 main-pool ingredients (evidence tier 127, 21.9%; price 170; innovativeness/ATC/rarity 176; registration class 208, 36.0%); each attribute is reported on its own encoded denominator, no multivariable adjustment is attempted, and the 2025 entrant cohort ($n = 88$, near-complete encoding) mitigates but cannot eliminate selection bias; structural gradients are descriptive. Third, temporal analysis rests on 8 orderable listed main-pool ingredients plus 11 commercial-track-only ingredients with a reconstructible first-listing year that cannot be ordered against a BMI sequence; high-limit products publish only current cross-sections, and the approval-to-listing median is not a non-listing-to-listing interval. Fourth, the cohort is ingredient-level by design: 115 endpoint-verified "old ingredient, new dosage form" cases form the dosage-form gap group (section 3.7; Additional file 2, Appendix A2); 11 further candidates were re-adjudicated at endpoint as already listed and moved to the comparator (only temozolomide for injection is itself roster-enumerated and counted in the comparator rate; Additional file 2, Appendix A3); findings are not dosage-form-specific beyond the 6 gap cases documented. Fifth, roster transcription was audited against original printed names, correcting one standardisation error (camrelizumab mis-mapped to ravulizumab across six products) and one overseas-drug listing (Additional file 1, Table S2). Sixth, we measure *roster listing*, not utilisation or claims payment; actual point-of-care reimbursement and what B/D-type benefits pay for non-enumerated drugs are the subject of separate claims-based work. Seventh, the reverse check of the 701 comparator ingredients achieved direct name-level matches for 630 in the 2025 complete directory; the remaining 71 were adjudicated in a drug-by-drug ledger as 40 fixed-dose/compounded preparations (38 themselves listed under their preparation name; 2 with listed components but the preparation itself not enumerated, excluded in a sensitivity analysis that leaves the comparator rate unchanged), 21 naming variants, and 10 historically listed drugs subsequently removed (Additional file 2, Appendix A1). Name-level matching across formatting variants cannot be fully automated and may retain residual error in both directions.

4.6 Conclusion

Among the 14 observed commercial products, the 11 with enumerable specialty-drug rosters list 12.8% of the 578 main-pool ingredients whose component was never included in the NRDL during 2020–2025, versus 24.0% of NRDL-listed comparators; listed drugs are concentrated in high-price, high-innovativeness antineoplastic and immunomodulating therapies, and roster composition differs across channels, price tiers, and therapeutic areas. Roster listing was 9.9% in the main analysis queue (sponsors that filed for BMI and were not listed) and 82.6% in the commercial-track-only queue (sponsors that never filed for BMI), with repeat formal-review applicants listed more often than single-cycle applicants. These are roster listing rates against enumerated lists, not estimates of total commercial payment or access: enumerated rosters together with the products' general medical-benefit and negative-list responsibilities define each product's coverage scope, and actual reimbursement and access at the point of care require claims data that this study does not have. By documenting what the enumerated rosters do and do not contain, the study provides descriptive evidence for identifying the division of labour across payment tiers and the measurement boundaries between roster listing, coverage scope, and realised access; whether the 2025 dual-track reform changes what is listed or paid requires pre/post comparison and claims-based evaluation.

Declarations

Ethics approval and consent to participate. Not applicable. This study used only publicly available administrative rosters, regulatory records and insurer-published policy documents, with no human participants or personal data; ethics committee approval and informed consent were not required.

Consent for publication. Not applicable.

Availability of data and materials. The datasets supporting the conclusions of this article are included within the article and its additional files. The cleaned drug-level master tables, audit logs, archived product rosters, the 2025 NRDL extraction and the full source-verification table are available from the corresponding author on reasonable request; all roster sources are public URLs with access dates (Additional file 1, Table S1).

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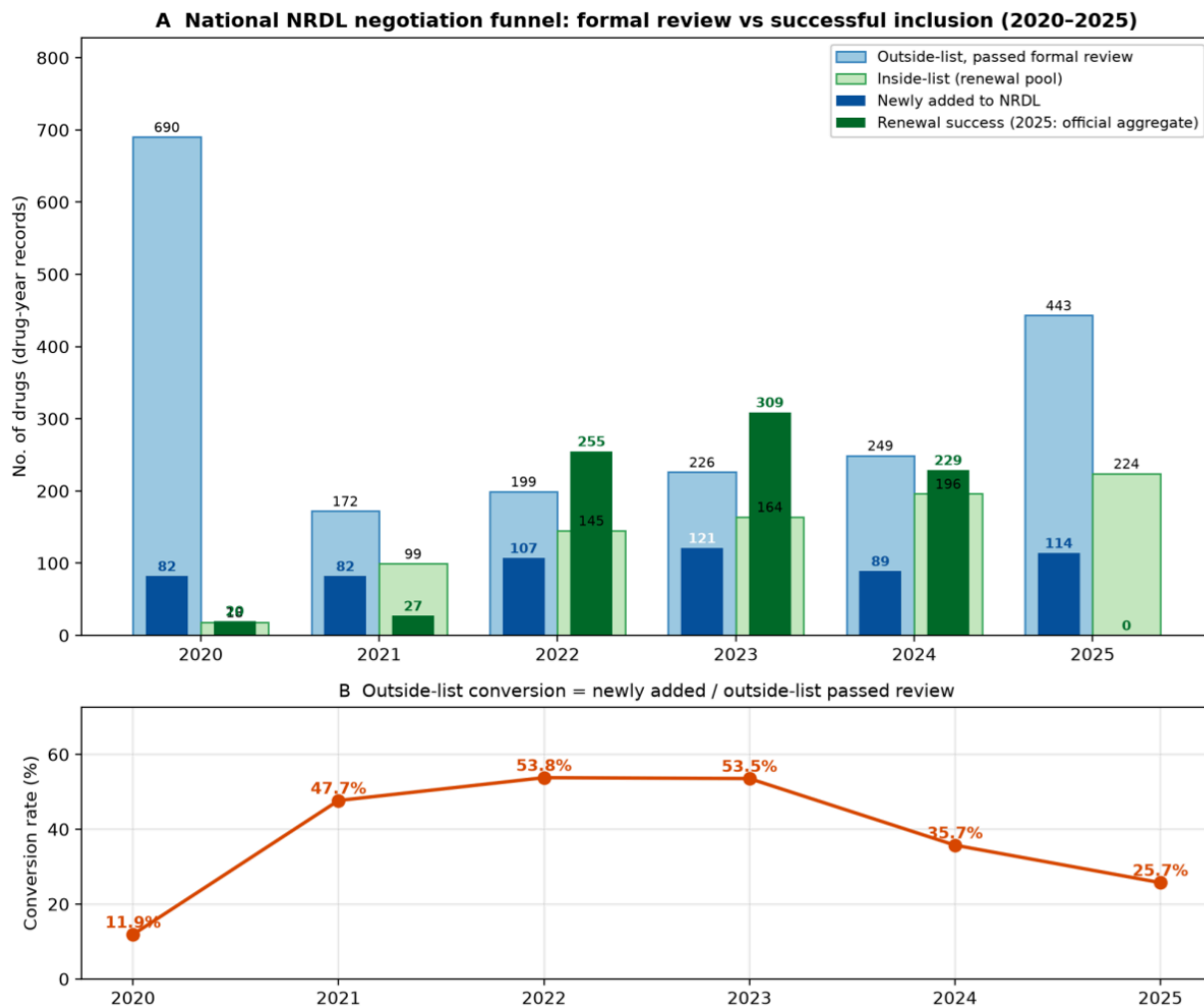
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Figures

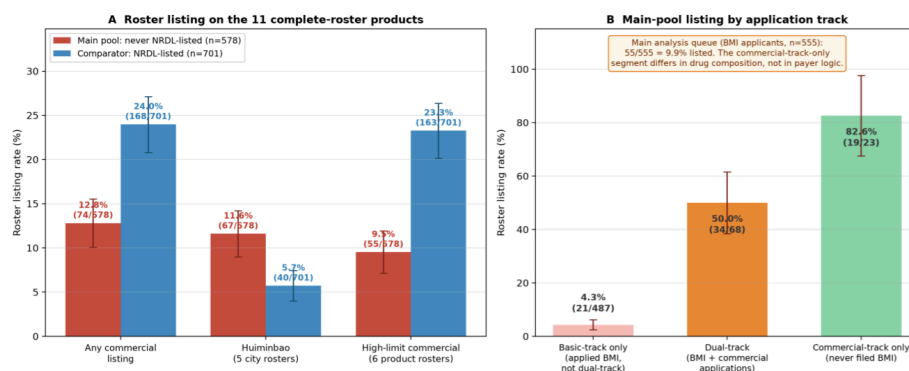


Note: 2020 formal-review roster = preliminary 751 / 708 dedup (official final 722; 704 outside-list). 2025 renewals = official aggregate (148 simplified + 30 re-negotiated = 178); drug-level renewal names are not published.

Figure 1

National NRDL negotiation funnel, 2020–2025. (A) Outside-list drugs passing formal review, inside-list (renewal-pool) drugs, and successful new additions/renewals by cycle. (B) Outside-list conversion rate (newly added / outside-list passed formal review). 2020 uses the broader preliminary scope; 2025 renewals are the official aggregate (148 simple renewals + 30 re-negotiated = 178) because drug-level renewal names are not published.

Commercial specialty-drug rosters: selective listing of NRDL-not-included ingredients (2026 cross-section; descriptive roster-listing rates, not coverage or payment estimates)



Listing = ingredient name enumerated on an audited specialty-drug roster (A/C lists) of 5 complete city universal products and 6 high-limit commercial products; open-formulary products and B/D-type general benefits are not name-matchable (see Methods). Whiskers show binomial Wilson 95% CIs (descriptive; no between-group inferential claim beyond the tests reported in the text).

Figure 2

Roster listing of NRDL-not-included and NRDL-listed ingredients on the 11 complete-roster commercial products (2026 cross-section). (A) Main pool (n=578, never NRDL-listed) versus comparator (n=701, NRDL-listed): any commercial listing, city huiminbao rosters (5 products), and high-limit commercial rosters (6 products). (B) Main-pool listing by application track: basic-track only (487), dual-track (68), and commercial-track-only sponsors who never filed for BMI (23). Listing = ingredient name enumerated on an audited A/C specialty-drug roster; open-formulary products and B/D-type general benefits are not name-matchable.

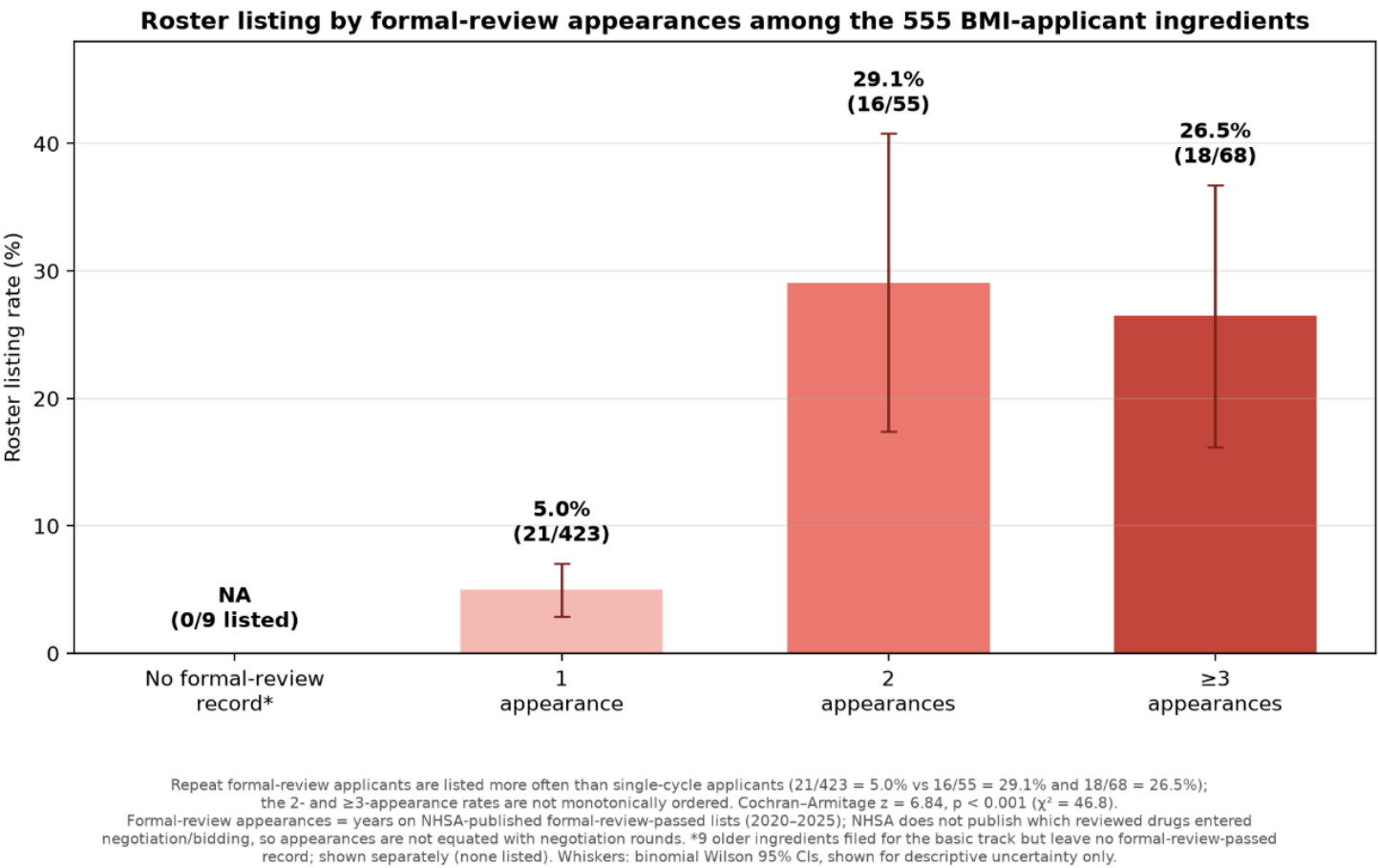


Figure 3

Roster listing by formal-review appearances within the main analysis queue (555 ingredients that filed for BMI at least once and were not listed). Formal-review appearances = number of years the ingredient appears on NHSA-published formal-review-passed lists for negotiation years 2020–2025. NHSA does not publish which reviewed drugs subsequently entered negotiation or bidding, so appearances are not equated with negotiation rounds. Nine older ingredients filed for the basic track but leave no formal-review-passed record and are shown separately (none listed). Repeat applicants are listed more often than single-cycle applicants; the 2-appearance (29.1%) and ≥3-appearance (26.5%) rates are not monotonically ordered. Cochran–Armitage $z = 6.84$, $p < 0.001$ ($\chi^2 = 46.8$).

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