

Beyond Indication Expansion: Aligning Evidence, Reimbursement, and Access in Multi-Indication Oncology Drugs [Letter]

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Dear editor

We read with interest the article by Chen et al, “Indication Expansion Dynamics and Trial Characteristics of Novel Multi-Indication Anti-Cancer Drugs in China (2000–2024): A Cross-Sectional Study”. The authors provide a useful cross-sectional analysis of 74 novel multi-indication anti-cancer drugs approved by the National Medical Products Administration (NMPA), covering 265 indications from 2000 to 2024. Their study is valuable because it maps approval sequences, pivotal trial characteristics, and National Reimbursement Drug List (NRDL) inclusion within China’s evolving oncology drug regulatory landscape. Building on their finding that NRDL inclusion has not kept pace with market approval, this Letter argues that indication expansion should be assessed not only by the number of approved indications, but also by evidence maturity, reimbursement status, and real-world access.¹

This distinction matters because drug approval, NRDL inclusion, indication-level reimbursement, and actual patient access are related but not identical. NMPA approval authorizes a drug or indication for market use. NRDL inclusion reflects whether a medicine is listed for national reimbursement. Indication-level reimbursement concerns whether each approved use of the same drug is covered in practice. Actual patient access depends further on affordability, availability, utilization, and regional implementation. Chen et al show significant differences across indication approval sequences in treatment type, NMPA approval type, trial arms, trial design, and endpoints in single-arm studies.¹ These findings would have greater clinical and policy value if they were connected more explicitly to the maturity of evidence and the level at which reimbursement applies.

Recent literature supports the need to interpret approval sequences through evidence maturity. Zhang et al found that among cancer drug indications approved in China between 2005 and 2020, a substantial proportion had no documented overall survival benefit or had immature survival evidence.² Maeda et al similarly showed that many oncology drug approvals in Japan relied on surrogate endpoints, while confirmatory studies using overall survival were not consistently conducted after approval.³ These findings do not diminish the importance of timely oncology innovation. Rather, they suggest that approval expansion should be interpreted alongside endpoint hierarchy. For multi-indication drugs, evidence supporting one indication may not be equivalent to evidence supporting another, particularly across tumor types, treatment lines, and biomarker-defined populations.

The reimbursement dimension is also central. Lawlor et al noted that oncology medicines with multiple indications pose distinct market access challenges because clinical value, pricing, and reimbursement expectations may differ across indications.⁴ Pan et al further showed that the relationship between anticancer drug prices and clinical value varies across China, Japan, and South Korea, reinforcing the need to connect value assessment with coverage decisions.⁵ Therefore, the gap between NMPA approval and NRDL inclusion should not be treated merely as an administrative delay. It raises a broader question about whether regulatory authorization is being translated into reimbursed and accessible care for each approved indication.

The proposed approval-evidence-reimbursement-access framework adds to the findings of Chen et al by converting their descriptive mapping into a more evaluative approach. First, it would measure the interval between NMPA approval and NRDL inclusion for each drug-indication pair. Second, it would classify pivotal evidence according to endpoint maturity, including overall survival, progression-free survival, objective response rate, and other surrogate endpoints. Third, it would distinguish drug-level NRDL inclusion from indication-level reimbursement coverage. Fourth, where data permit, it would incorporate real-world access indicators such as affordability, utilization, regional availability, and post-reimbursement uptake. This framework would help determine not only how rapidly indications expand, but whether such expansion produces clinical and public value. Chen et al provide an important empirical foundation; applying this framework would further strengthen future assessments of multi-indication oncology drug development in China and beyond.

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