



Immunotherapy for Cancer in India: Navigating the Access–Efficacy Chasm

Barnini Ghosh¹ Aju Mathew² Sujith Kumar Mullapally³

¹Department of Medical Oncology, Ruby General Hospital, Kolkata, West Bengal, India

²Department of Medical Oncology, MOSC Medical College, Ernakulam, Kerala, India

³Department of Medical Oncology, Apollo Proton Cancer Center, Chennai, Tamil Nadu, India

Address for correspondence Barnini Ghosh, MBBS, MD, DrNB (Medical Oncology), PDCR, Department of Medical Oncology, Ruby General Hospital, Kolkata 700107, West Bengal, India (e-mail: barninig@gmail.com).

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Abstract

Keywords

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The advent of immune checkpoint inhibitors (ICIs) has transformed oncology practice, yet their penetration in India remains under 5%, mainly due to prohibitive financial toxicity. This commentary explores the “access–efficacy chasm” in the Indian health care landscape. While incorporating ICIs into the National List of Essential Medicines is a necessary step for price rationalization, regulators must balance price ceilings against the risk of compromising manufacturing quality and disrupting the supply chain. To democratize access, Indian oncologists have pioneered scientifically adaptive low-dose protocols. However, the recent introduction of affordable indigenous biosimilars and the potential influx of novel Asian molecules are fundamentally altering the financial justification for these ultra-low doses. Pragmatic price policies, academic validation of affordable regimens, and robust legal safeguards for off-label dosing are advocated.

Introduction

The Landscape: A Tale of Two Worlds

The advent of immune checkpoint inhibitors (ICIs) has undeniably revolutionized modern oncology, fracturing the survival glass ceiling in malignancies ranging from melanoma to non-small cell lung cancer. In the West, immunotherapy has seamlessly transitioned from a salvage option to a backbone of standard of care, rapidly moving into adjuvant and neoadjuvant settings. However, the Indian landscape presents a stark, polarizing dichotomy. While India bears a massive burden of highly immuno-responsive cancers—particularly tobacco-induced head and neck squamous cell carcinomas (HNSCCs) and lung cancers—the penetration of ICIs in routine Indian practice is estimated to be dismal, likely under 3 to 5% of eligible patients.¹ This disparity is not due to lack of clinical indication, but due to economic infeasibility. While Western guidelines debate the

nuances of triplet combinations, the average Indian oncologist is often forced to debate the feasibility of a single dose of immunotherapy.

The WHO EML Paradox

In a landmark recognition of their clinical value, PD-1/PD-L1 inhibitors were added to the World Health Organization (WHO) Model List of Essential Medicines (EML).² Theoretically, this categorizes them as minimum medicine needs for a basic health care system. Yet, in low- and middle-income countries like India, “essential” does not translate to “accessible.” Despite the WHO endorsement, the financial toxicity associated with these molecules—costing lakhs of rupees per cycle—remains a prohibitive barrier for a population largely dependent on out-of-pocket expenditure. The disconnect between global policy and local affordability has created an ethical crisis where the “standard of care” seems as if it is a luxury.

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Issues and Challenges

The NLEM Imperative

The most immediate regulatory step is the inclusion of practically accessible immunotherapy agents in the National List of Essential Medicines (NLEM) of India. Inclusion in the NLEM is not merely symbolic; it is the gateway to price capping under the Drug Price Control Order (DPCO). Bringing them under the NLEM umbrella is a necessary catalyst to enforce trade margin rationalization, thereby reducing the maximum retail price and facilitating bulk procurement by government health schemes, which currently restrict ICI usage to very specific, often unattainable, clauses that create practical hurdles in the initiation of immunotherapy for eligible patients with cancer.

However, aggressively driving down prices through the NLEM and DPCO is a double-edged sword. The manufacturing of monoclonal antibodies (mAbs) is expensive and complex. While certain mAbs like Trastuzumab have been included in the NLEM, imposing rock-bottom price ceilings on such biologics risks making their production financially unsustainable. Therefore, while price rationalization is necessary for access, regulators must strike a delicate balance to ensure that manufacturers can maintain stringent quality standards without disrupting the supply chain.

The Quagmire of Low-Dose Therapy

Necessity is the mother of invention, and in Indian oncology, financial challenges have created several low-dose immunotherapy protocols. Although termed low dose in comparison to the approved doses, the concept of low-dose immunotherapy is based on the pharmacological principle that PD-1 receptor occupancy is saturated at doses far lower than the Food and Drug Administration (FDA)-approved labels—for example, Nivolumab achieves saturation at 0.3 mg/kg body weight, whereas the FDA- and Drugs Controller General of India (DCGI)-approved dose is at 2 mg/kg body weight. Indian researchers have pioneered the use of metronomic or low-dose regimens (e.g., Nivolumab 20 mg or 40 mg flat dose) in randomized trials that confirmed clinical efficacy with a much-reduced impact on financial toxicity.^{3,4} Recent clinical trials and systematic reviews^{5,6} validate the efficacy of low-dose nivolumab across diverse indications, notably for relapsed/refractory solid tumors including HNSCC. Furthermore, it is being investigated to downstage locally advanced, unresectable HNSCC to facilitate definitive surgery.

While this approach has democratized access, it also places the oncologists in a methodological quagmire. Emerging evidence suggests efficacy, yet we lack robust, non-inferiority or near-equivalency trials against standard dosing. The trade-off is stark: is it better to offer a scientifically plausible adaptive therapy to a patient who can afford nothing else, or to deny treatment based on a rigid adherence to label guidelines? This efficacy versus adaptive debate is currently among the most contentious topics in Indian oncology.

The Patent Cliff and Biosimilars

The conversation around low-dose therapy may soon be rendered moot by market economics. The “patent cliff” is no longer a future prediction—it is our current reality. In January 2026, the Indian oncology landscape witnessed a watershed moment with the launch of the world’s first Nivolumab biosimilar (Tishtha, Zydus Lifesciences).⁷ Following a landmark Delhi High Court ruling that seemingly prioritized public interest over the final months of patent exclusivity, this molecule has entered the market at roughly one-fourth the cost of the innovator.

The price drop fundamentally alters the efficacy versus adaptive debate. With the cost of a standard-dose biosimilar now aligning with the cost of the previously utilized low-dose innovator regimens, the financial justification for ultra-low dosing (e.g., 20 mg flat) is being challenged in spite of robust supportive evidence for clinical use of lower dose immunotherapy. We are now at a pivotal junction: do we return to globally validated standard dosing using affordable biosimilars, or do we apply the low-dose strategy to these new biosimilars to drive costs down to truly grassroots levels? This question will not likely be answered in any clinical trial and will be a personal decision oncologists will have to make. The arrival of additional competitors will likely accelerate this race with further reduction in the pricing, creating better access and shifting the discussion toward the level of quality assurance between the various generics.

Emergence of Novel Immunotherapy Molecules

Simultaneously, the market is seeing an influx of PD-1 inhibitors from China (e.g., Toripalimab, Serplulimab, Tislelizumab), with robust efficacy data at a fraction of the cost of Western innovators.⁸ However, their regulatory journey is complex. The U.S. FDA’s recent rejection of applications based solely on Chinese population data highlights, among other reasons, the global demand for multi-ethnic trial diversity. For India, this raises the question: should the DCGI accept data from Asian cohorts to fast-track these affordable drugs, or must we insist on bridging trials, delaying access but ensuring efficacy and safety?

Off-Label Use and the Biomarker Maze

In the desperate bid to save lives, off-label use using unverified biomarkers is on the rise. However, the biomarker ecosystem in India is not yet standardized. PD-L1 testing is plagued by inter-observer variability, lack of standardization in antibody clones (22C3 vs. SP263 vs. 28–8), and the confusion between TPS (Tumor Proportion Score) and CPS (Combined Positive Score).

Legal and Consenting Dynamics

The Consumer Protection Act looms large over these adaptations. Administering 40 mg of Nivolumab when the package insert prescribes 240 or 480 mg constitutes off-label dosing. In the event of treatment failure or immune-related adverse events, the oncologists are legally vulnerable. We must advocate for a standardized, legally vetted informed

consent framework specifically for low-dose or off-label immunotherapy. This document must explicitly state that the chosen dose/protocol deviates from the manufacturer's label due to financial constraints, and that the patient accepts the potential for altered efficacy. While there is currently no landmark Supreme Court judgment directly penalizing the use of low-dose immunotherapy, the Indian judiciary evaluates medical negligence based on established precedents. Such a document, if developed and approved by national oncology bodies like the Indian Society of Medical and Pediatric Oncology (ISMPO), can be useful to protect oncologists if legal issues crop up on the use of lower than the regulator-approved dose of immunotherapy.

Local Factors: Research and the Microbiome

Finally, we cannot ignore the host's contribution toward the efficacy and toxicity of immunotherapy drugs. There are substantial regional variations in the gut microbiome, which is now considered a key mediator of immunotherapy response. The Indian diet—high in fiber and spices, and distinct fermentation patterns—may modulate the immune response differently than a Western diet. There is a critical need for indigenous research to understand the interaction of the microbiome in Indians with respect to response to ICIs.⁹ Additionally, the incorporation of immunotherapy in early-stage diseases needs to be prioritized, based on financial pragmatism. For instance, shifting our focus toward short, defined courses of neoadjuvant immunotherapy (often requiring just two to four cycles) for locally advanced cancers may be far more financially viable for an average Indian patient than committing to a full year of standard adjuvant therapy. By maximizing pathological responses upfront with a brief neoadjuvant course, we can potentially reduce overall drug exposure and financial toxicity while firmly maintaining curative intent.

Conclusion

The future of immunotherapy in India relies not just on drug discovery, but on improving access to care. We must create pathways that ensure each eligible patient gets the approved immunotherapy in an effective dose. We are at a crossroads where science meets socio-economics. To move forward, we need a tripartite approach: policy intervention to bring ICIs under price control (NLEM); academic commitment to formalize and validate low-dose protocols or bridging trials for cheaper biosimilars; and legal safeguards to protect the doctors navigating this gray zone. Oncologists in low- and

middle-income countries must stay open to adapting towards immunotherapy doses and schedules based on the regional socio-economic challenges that they face in the pursuit of cure and care of cancer patients.

Patient Consent

Patient consent not required.

Conflict of Interest

None declared.

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