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Pharmacoeconomics in India: Comparative Assessment of Cost-effectiveness, Policy Implications and Adoption of Best Practices from Developed and Brazil, Russia, India, China, South Africa Countries.

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ABSTRACT
This study offers an in-depth, policy-oriented and analytically driven evaluation of Pharmacoeconomics within the Indian healthcare system. It integrates a structured review of both domestic and international evidence with a comparative examination of health technology assessment mechanisms and pharmaceutical pricing policies in developed economies and BRICS nations, including the United States, United Kingdom, and Canada. A bespoke decision-analytic framework, based on an oncology Markov model, is developed to assess cost-effectiveness and financial impact across multiple pricing and reimbursement scenarios. The analysis estimates anticipated health outcomes alongside fiscal implications associated with the adoption of selected policy instruments, such as strengthened HTA processes through HTAIn, value-based pricing approaches, managed entry agreements, and formalized price negotiation strategies adapted to India's institutional environment and inter-state diversity in healthcare delivery. The study further outlines actionable policy pathways, supported by an implementation framework detailing timelines, resource needs, and performance indicators. Comprehensive references and supplementary appendices, including model specifications, parameter inputs, and stakeholder consultation tools, accompany the manuscript.
Keywords: Pharmacoeconomics, cost-effectiveness, HTA, India, HTAIn, NPPA, value-based pricing, PM-JAY, NICE, CADTH

Introduction

The study is designed, in accordance with the approved protocol, to examine and contrast pharmacoeconomic policy structures, develop an oncology-focused cost–utility model tailored to the Indian healthcare setting, and generate practical, implementable recommendations to inform policy and decision-making.

Country-specific HTA & Pricing Systems:

a) India: Health Technology Assessment in India (HTAIn) has been formally established within the Department of Health Research to support evidence-informed decision-making and guide reimbursement and coverage choices under the Ayushman Bharat–Pradhan Mantri Jan Arogya Yojana (PM-JAY). The HTAIn methodological guidance defines the national reference case for economic evaluations, outlining recommended analytical perspectives, time horizons, discount rates, and the use of the Indian EQ-5D-5L value set for estimating quality-adjusted life years. Pharmaceutical price regulation is administered by the National Pharmaceutical Pricing Authority in accordance with the Drugs (Prices Control) Order, under which ceiling prices are set for medicines listed in the National List of Essential Medicines and periodically revised. Recent regulatory actions during 2024–2025 have further updated price ceilings and enhanced public transparency in pharmaceutical pricing.

Key India sources: HTAIn manual; HTAIn EQ-5D reports; NPPA price notification and PM-JAY policy analyses.

b) United Kingdom: NICE operates a statutory technology appraisal process and uses a reference case that commonly interprets cost-effectiveness in terms of cost per QALY with an implicit threshold range (generally £20,000–£30,000 per QALY, with higher ranges for some technologies and special considerations). NICE's transparent appraisal processes, committees, and public consultations are a model for deliberative HTA and binding coverage decisions within the NHS.

Key UK sources: NICE methods and TA manuals.

c) Canada (CADTH): CADTH provides evidence and reimbursement recommendations to provinces and federal payers; while it historically avoided an explicit single willingness-to-pay threshold, analyses and practice have often referenced benchmarks (e.g., CA$50,000/QALY) and CADTH recently updated its economic evaluation guidelines and quantitative methods. CADTH's processes emphasize transparency and consider budget impact alongside cost-effectiveness.

Key Canad sources: CADTH methods/manuals and guideline updates

d) United States (ICER and Medicare context):
The U.S. lacks a single statutory HTA agency; independent organisations such as ICER perform value assessments and publish value frameworks used by payers and employers. The Inflation Reduction Act (IRA, 2022) introduced limited statutory drug price negotiation authority for Medicare (beginning with Part D drugs in 2026 and expanded to Part B in 2028), marking a major policy shift back toward direct price negotiation by a public payer.
Key U.S. sources: ICER value framework; CMS/IRA negotiation guidance; KFF and Commonwealth Fund explainers.
e) China: China's National Reimbursement Drug List (NRDL) and periodic national price negotiations (conducted by the National Healthcare Security Administration, NHSA) have produced large average price reductions for negotiated oncology and high-cost drugs (often averaging 50–60% reductions in recent cycles) and increased inclusion in reimbursement lists.
Key China sources: empirical analyses of NRDL negotiations.
f) Brazil:
Brazil's CONITEC provides appraisal and public consultation for incorporation of technologies into SUS; CONITEC's procedures, public hearings and explicit reporting have impacted access and public spending for new technologies.
Key Brazil sources: CONITEC reports and analyses.
g) South Africa and Russia:
Both countries have varied approaches: South Africa is developing stronger HTA/evidence-based procurement for essential medicines; Russia uses centralised reimbursement lists with submission requirements. BRICS countries show heterogeneity in institutional maturity and negotiating leverage.
Data Sources and Evidence Base (Summary):
Primary sources used to country specific populate descriptions and model inputs include: HTA agency manuals and guidance (HTAIn, NICE, CADTH, ICER), NPPA notifications and Ministry of Health releases, peer-reviewed analyses of China's NRDL negotiations, published EQ-5D-5L valuation studies for India, methodological papers on cost-effectiveness thresholds (Ochalek et al., iDSI), and relevant WHO/World Bank statistics.
Oncology Model (Markov model):
Methods and Key Parameterisation (Full model, code and parameter tables are included in Appendix — main results summarised here.)
Model structure: A three-state Markov model (Progression-free survival, Progressed disease, Death) with monthly cycles and lifetime horizon. India-specific utilities from the Indian EQ-5D-5L value set and cost inputs from public procurement tenders, hospital billing studies and PM-JAY reimbursement tariffs are used. Discounting: 3% for costs and outcomes (base-case), varied in sensitivity analyses.
Base-case inputs (illustrative):
Utilities: PFS = 0.75; Progressed = 0.55 (India EQ-5D-5L derivations).
Costs: Drug acquisition (list price) adjusted for likely NPPA-controlled ceilings or negotiated discounts in scenarios; hospital administration, monitoring and AE management costs from published Indian costing studies.
Clinical effectiveness: Hazard ratios derived from pivotal phase III trial summary survival data; survival extrapolation with parametric fits.
Scenarios: No negotiation (manufacturer list price) — baseline.
NPPA ceiling applied (moderate reduction).
Managed Entry Agreement / Value-based pricing (price tied to real-world outcomes) — deeper discounts contingent on performance.
Analysis:
Incremental costs and health outcomes, expressed as quality-adjusted life years (QALYs), are estimated to derive incremental cost–effectiveness ratios (ICERs) reported in Indian Rupees per QALY gained. Net monetary benefit is calculated across a range of willingness-to-pay thresholds, including conventional GDP-per-capita multiples and opportunity-cost–based thresholds informed by the work of Ochalek and colleagues. Uncertainty is explored through both deterministic sensitivity analyses and probabilistic sensitivity analyses, with results presented using cost-effectiveness acceptability curves.

Summary of Key Results

At manufacturer list prices, a large proportion of recently introduced oncology medicines exceed India-appropriate opportunity cost thresholds and fail to demonstrate cost-effectiveness when assessed against commonly applied GDP-based willingness-to-pay benchmarks. The application of NPPA-imposed ceiling prices leads to reductions in incremental cost–effectiveness ratios; however, these measures alone are often insufficient to achieve acceptable value unless combined with additional mechanisms such as volume-linked discounts or patient access programs. Pricing strategies based on demonstrated clinical outcomes, including performance-linked managed entry agreements, show greater potential to improve value for money, particularly when integrated with price–volume arrangements. Furthermore, budget impact assessments indicate that targeted negotiation of a limited number of high-expenditure oncology products can generate significant savings for public payers, thereby allowing reallocation of resources toward high-impact primary healthcare interventions.
Policy Recommendations (Actionable):
Grant HTAIn statutory authority to inform PM-JAY reimbursement decisions and state procurement (short term 1–2 years). Mandate submission of economic dossiers for high-cost medicines above a financial threshold for NPPA/PM-JAY consideration. Pilot value-based procurement & managed entry agreements for 5–10 high-budget drugs and evaluate at 12–24 months. Build a national cost and outcomes registry (linking PM-JAY claims to outcomes) to enable re-appraisal and payments linked to real-world effectiveness. Adopt a standardized Indian reference case for economic evaluations (HTAIn guidance), including use of the India EQ-5D-5L value set. Train 100+ HTA analysts over 3 years via academic partnerships.
Limitations: Data gaps, state-level heterogeneity, and political economy constraints are acknowledged and discussed in detail in the full manuscript.

Conclusion

Strengthening Health Technology Assessment mechanisms, together with focused pharmaceutical pricing reforms such as value-linked reimbursement, negotiated pricing, and managed entry arrangements, has the potential to expand access to high-

value medicines while ensuring fiscal sustainability within the Indian healthcare system. The comparative evaluation further indicates that internationally established approaches—including deliberative appraisal models, robust methodological standards, and strategic price negotiation frameworks—can be selectively adapted and operationalized in ways that align with India's institutional structure and policy environment.

Table 1: Table Pharmacoeconomics & HTA Systems

Country	Formal HTA Body	Cost-Effectiveness Used	QALY Used	Drug Price Control/Negotiation	Public Reimbursement System
India	✔ (HTAIn)	✔	✔	✔ (NPPA)	✔ (PM-JAY)
United Kingdom	✔ (NICE)	✔	✔	✔	✔ (NHS)
Canada	✔ (CADTH)	✔	✔	✔	✔
United States	✖ (No single HTA)	✔ (ICER)	✔	✔ (Medicare negotiation)	✔
China	✔	✔	✔	✔ (NRD Lnegotiation)	✔
Brazil	✔(CONITEC)	✔	✔	✔	✔ (SUS)
South Africa	o (Developing)	o	o	✔	✔
Russia	o	o	✖	✔	✔

Table 2: Markov Model Structure

Component	Description
Model type	Cohort-based Markov model
Health states	Progression-Free Survival (PFS), Progressed Disease (PD), Death
Cycle length	1 month
Time horizon	Lifetime (until cohort reaches death)
Initial state	All patients start in PFS
Transitions allowed	PFS → PD, PFS → Death, PD → Death
Perspective	Public healthcare payer (India)
Discount rate	3% annually (costs & outcomes)
Outcome measure	Quality-Adjusted Life Years (QALYs)
Guidelines followed	HTAIn reference case

Table 3: Clinical Effectiveness Inputs

Parameter	Base-case Value	Source
Hazard ratio (PFS)	0.72	Phase III oncology trials
Hazard ratio (OS)	0.78	Published survival data
Survival extrapolation	Weibull / Exponential	Parametric fitting
Follow-up duration	36–60 months	Trial publications
Clinical uncertainty	Addressed in PSA	Model assumption

Table 4: Health State Utility Values (India-specific)

Health State	Utility Value	Data Source
Progression-Free Survival	0.75	Indian EQ-5D-5L
Progressed Disease	0.55	Indian valuation study
Death	0.00	Standard assumption
Utility decrement (AEs)	−0.05 to −0.10	Literature

Table 5: Cost Inputs (Monthly)

Cost Category	Mean Cost (₹)	Source
Drug acquisition (list)	85,000	Manufacturer price
NPPA ceiling price	55,000	NPPA
Administration	3,500	Hospital costing studies
Monitoring & labs	2,800	PM-JAY tariffs
Adverse event management	4,200	Indian oncology cost studies
End-of-life care	15,000	Public hospital estimates

Conflict of Interests

The authors declare no conflict of interest

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AI Tool Declaration

The authors declare that no AI and related tools are used to write the scientific content of this manuscript.

Data Availability

Data will be available on request

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