Review Article
ISSN: **3051-8830**
Journal homepage: https://www.harrisonacademicpress.com/index.php/IJHPEM
International Journal of Health Policy, Economics, and Management

Harrison Academic Press

Equity in Access to Novel Cancer Therapies Under National Health Insurance Schemes

Goossens T[1*], Potocnik J[2] and Papadopoulos I[3]

[1]*Department of Health Economics, Ghent University, Ghent, Belgium*
[2]*Department of Health Policy, University of Ljubljana, Ljubljana, Slovenia*
[3]*Department of Oncology, Aristotle University of Thessaloniki, Thessaloniki, Greece*

ABSTRACT

Background: Novel cancer therapies, including immune checkpoint inhibitors, chimeric antigen receptor T-cell (CAR-T) therapies, and molecularly targeted agents, have produced substantial survival gains but carry acquisition costs that strain the cost-effectiveness and budget-impact assessments national health insurance schemes use to decide reimbursement. Objective: To synthesize peer-reviewed evidence on how national health insurance and reimbursement architecture shapes equitable access to novel cancer therapies across countries and within insured populations. Methods: A narrative review of peer-reviewed literature identified through targeted PubMed/MEDLINE and Crossref searches, with each candidate source individually verified against its publisher or bibliographic record before inclusion. Findings were organized thematically around cost-effectiveness threshold methodology, managed-entry and risk-sharing agreements, cross-country and cross-income disparities in access, and patient-level financial toxicity within nominally covered populations. Findings: Cost-effectiveness thresholds lack a rigorous empirical basis and are applied largely unmodified to orphan and cell-based oncology therapies for which the evidence base is systematically thinner, producing inconsistent reimbursement outcomes across similar submissions. Managed-entry agreements, the principal policy response to resulting uncertainty, are unevenly available across systems as a function of institutional and analytical capacity rather than clinical need. Time to patient-level reimbursement after regulatory approval varies from months to several years even within the European Union, while access disparities between high-income and low- and middle-income countries are considerably larger and are compounded by diagnostic-funding gaps and treatment-center infrastructure shortfalls. Financial toxicity persists within nominally covered populations, including under Medicare in the United States, indicating that formal reimbursement status alone is an insufficient equity metric. Conclusions: Equitable access to novel cancer therapies depends jointly on value-assessment methodology, managed-entry agreement capacity, and patient cost-sharing design; national health insurance schemes and policymakers should address these as jointly determined equity levers rather than as separate technical problems.

Keywords: *health technology assessment; managed-entry agreements; cancer drug access; cost-effectiveness threshold; health equity*

Citation: Goossens T, Potocnik J and Papadopoulos I (2025) Equity in Access to Novel Cancer Therapies Under National Health Insurance Schemes. Int J Health Policy Econ Manag, 3(1): 01-07.
DOI: 10.5281/zenodo.22656397

Corresponding Author: *Thomas Goossens*

E-mail Address: *thomas.goossens@ghentuniversity.edu*

Article History: *Received 3 January 2025 | Accepted 9 April 2025 | Published 24 June 2025*

Copyright: *© 2025 Thomas Goossens, et al. This is an open access article distributed under the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited (**https://creativecommons.org/licenses/by/4.0/**).*

Introduction

Over the past decade, oncology has produced a wave of therapies whose clinical promise is matched by unprecedented acquisition cost: immune checkpoint inhibitors, chimeric antigen receptor T-cell (CAR-T) therapies, and molecularly targeted agents now routinely enter national formularies at list prices ranging from tens of thousands to several hundred thousand US dollars per course of treatment. Health technology assessment (HTA) bodies and national health insurance schemes were built to evaluate incremental therapeutic gains against comparatively modest cost increments; they are increasingly required instead to adjudicate transformative but uncertain survival benefits against list prices that, in absolute terms, can exceed a country's per-capita health expenditure many times over [1,2]. This mismatch between the pace of oncology drug development and the capacity of reimbursement systems to absorb it without threatening the sustainability of universal coverage is not a peripheral financing question; it is now a central determinant of whether patients with the same diagnosis and the same treatable disease receive materially different care depending on where, and under which national insurance architecture, they happen to be treated.

The equity stakes of this mismatch are high because the diffusion

of novel cancer therapies is not incidental to overall survival gains in oncology; several of the drug classes at issue — checkpoint inhibitors in melanoma and non-small-cell lung cancer, CAR-T therapy in relapsed or refractory lymphoma, and molecularly targeted agents in oncogene-addicted tumors — have produced some of the largest survival improvements recorded in modern oncology. When national reimbursement systems delay, restrict, or altogether decline coverage of these therapies, the resulting access gap does not distribute randomly across the population; it concentrates among patients in lower-income countries, patients covered by less generous public insurance tiers, and patients treated in health systems with weaker health technology assessment capacity or narrower fiscal space for high-cost innovation [3,4,5]. Understanding how national health insurance schemes structure this access gap — through cost-effectiveness thresholds, managed-entry agreements, formulary restrictions, and out-of-pocket cost-sharing — is therefore a question of health equity as much as health economics.

This review synthesizes peer-reviewed evidence on how national health insurance and reimbursement systems shape equitable access to novel cancer therapies. Rather than treating "access" as a binary reimbursed/non-reimbursed status, the review distinguishes four interlocking dimensions along which inequity manifests: the cost-effectiveness and value-assessment frameworks that determine whether a therapy is judged worth funding at all; the managed-entry and risk-sharing arrangements that increasingly substitute for straightforward listing decisions; the cross-country and cross-income disparities in the speed and breadth of access that result; and the patient-level financial burden that persists even where formal reimbursement exists. The aim is to characterize not only where access gaps are largest, but which specific features of national reimbursement architecture drive them, since these are the features most amenable to policy intervention.

Methods

This is a narrative review, appropriate to a topic that spans health economics, comparative health policy, and clinical oncology and for which no single registered systematic review protocol could adequately span the disciplinary breadth required. Literature was identified through targeted searches of PubMed/MEDLINE and Crossref-indexed journals using combinations of terms including "cost-effectiveness threshold," "managed entry agreement," "risk-sharing agreement," "health technology assessment," "reimbursement," "immune checkpoint inhibitor," "CAR-T," "targeted therapy," "orphan drug," "financial toxicity," "out-of-pocket," and "low- and middle-income countries," combined with "cancer" or "oncology." Candidate sources were restricted to peer-reviewed journal articles, and each candidate reference was individually verified against its publisher record or PubMed/Crossref bibliographic entry (author list, journal, volume, issue, pagination, and DOI) before inclusion; sources whose bibliographic details could not be independently confirmed were excluded rather than retained on the strength of a plausible title alone.

Included sources were organized thematically into four domains that structure the Findings section: (1) the cost-effectiveness and value-assessment architecture that national HTA bodies apply to novel cancer therapies, including the specific difficulties posed by high list prices, immature survival data, and orphan or ultra-orphan indications; (2) managed-entry agreements and other risk-sharing arrangements that reimbursement systems have adopted to reconcile uncertain value with high acquisition cost; (3) empirical evidence of cross-country and cross-income disparities in the timeliness and breadth of access to novel cancer therapies once they are approved; and (4) patient-level financial burden and financial toxicity that can persist even within nominally universal national health insurance schemes. As a narrative synthesis rather than a systematic review or meta-analysis, no formal risk-of-bias appraisal or pooled effect estimation was undertaken; quantitative findings from individual studies are reported as illustrative of documented patterns rather than as directly comparable point estimates, since underlying methods, country settings, and outcome definitions differ substantially across the included literature.

Cost-Effectiveness Thresholds and the Value-Assessment Architecture for Novel Cancer Therapies

National health insurance schemes generally reimburse new therapies conditional on a favorable determination by a health technology assessment body that the therapy's incremental cost per quality-adjusted life-year (QALY) — or, in some jurisdictions, per life-year or disability-adjusted life-year — falls within an accepted cost-effectiveness threshold. Systematic reviews of how these thresholds are actually set find, however, that there is no consensus empirical basis for any specific threshold value in any jurisdiction; thresholds in current use are more often the product of historical precedent, political negotiation, or crude multiples of per-capita gross domestic product than of a formal empirical estimation of the health forgone elsewhere in the system when a costly new therapy displaces other spending [6]. This absence of a rigorously derived threshold matters disproportionately for oncology because novel cancer therapies are systematically more likely than other drug classes to be evaluated on the basis of immature survival data — often a single-arm trial or an interim overall-survival analysis — which widens the uncertainty around the incremental cost-effectiveness ratio precisely where the price tag is highest.

Orphan and ultra-orphan oncology indications sharpen this tension further. Case studies evaluating the United Kingdom's National Institute for Health and Care Excellence (NICE) methods find that successive revisions to end-of-life and severity-of-disease modifiers have produced inconsistent outcomes across near-identical orphan oncology submissions, such that whether a therapy for a rare cancer subtype is judged cost-effective can depend as much on which modifier a submission happens to qualify for as on the underlying clinical evidence [1]. A broader review of European value-assessment frameworks similarly finds that most national HTA systems apply the same core cost-utility methodology to orphan oncology drugs as to common-disease therapies, despite small trial populations, single-arm designs, and correspondingly wide confidence intervals around effectiveness estimates that make conventional cost-per-QALY thresholds a poor discriminating instrument for this drug class; only a minority of national systems have adopted formally distinct decision criteria — such as an explicitly higher threshold or additional weighting for disease rarity and severity — for orphan oncology products [2]. The consequence is that value-assessment architecture built for typical pharmaceutical submissions is applied, largely unmodified, to the drug class for which it is least well suited methodologically, and the resulting reimbursement decisions vary correspondingly across otherwise similar national systems.

Precision oncology adds a further layer of assessment difficulty

specific to targeted therapies. Because many targeted agents are approved for genomically defined subpopulations identified through companion diagnostic testing, health economic evaluation must jointly assess the cost-effectiveness of the therapy and the diagnostic test that selects its recipients, and national reimbursement systems vary substantially in whether — and how completely — they fund the diagnostic infrastructure required to identify eligible patients in the first place. Analyses of global implementation challenges in precision oncology find that health systems with less developed molecular diagnostic infrastructure or reimbursement pathways that treat companion diagnostics as a separate, unfunded cost frequently see formally reimbursed targeted therapies go substantially underused in practice, because patients who could benefit are never identified as eligible [7]. This diagnostic-access bottleneck is a distinct and under-recognized equity mechanism: a therapy can appear equitably available on paper, as a listed reimbursed medicine, while remaining functionally inaccessible to the sub-population it targets because the health system has not funded the test required to prescribe it.

Managed-Entry Agreements and Risk-Sharing Arrangements

Faced with the combination of high list prices and immature clinical evidence characteristic of novel cancer therapies, an increasing number of national health insurance systems have moved away from binary listing decisions toward managed-entry agreements (MEAs) that condition reimbursement on confidential discounts, outcomes-based payment, or coverage-with-evidence-development arrangements. Systematic review of European experience with oncology-specific MEAs finds that financial-based agreements — simple confidential rebates or price-volume agreements — are considerably more common in practice than outcomes-based or performance-linked agreements, largely because the latter require data infrastructure, agreed clinical endpoints, and monitoring capacity that many national systems, even within the European Union, do not consistently possess [8]. Where genuinely outcomes-based agreements are implemented, evidence from health technology assessment case studies of cancer medicines across multiple countries indicates that HTA appraisal criteria themselves — specifically, how a jurisdiction weighs uncertainty in the clinical evidence base — are a primary driver of whether a coverage decision is accompanied by a managed-entry agreement at all, meaning the propensity to use risk-sharing tools is itself unevenly distributed across systems with different assessment cultures rather than uniformly applied wherever clinical uncertainty is high.

Country-level cost analyses illustrate both the promise and the operational complexity of these arrangements. A comparative evaluation of managed-entry agreement techniques applied to high-cost anticancer drugs in Thailand's national health security scheme, using real-world claims data, found that different MEA structures — simple price discounts, price-volume caps, and free-goods arrangements — produced materially different net costs to the payer for chemically similar drug classes, and that the technique yielding the lowest effective cost was not consistent across drugs, implying that a single default MEA template applied uniformly across an oncology formulary can leave substantial achievable savings unrealized [9]. This finding is significant for equity because the administrative and analytical capacity required to negotiate, monitor, and renegotiate drug-specific MEA structures is itself unevenly distributed: national systems with dedicated pharmacoeconomic units and established data-linkage infrastructure can extract more favorable terms per drug than systems attempting to apply MEAs with more limited institutional capacity, even when both formally list the same medicine as reimbursed.

Managed-entry agreement types used to reconcile cost-effectiveness thresholds with access to novel cancer therapies under national health insurance schemes.

MEA type	Mechanism	Access objective	Documented limitation	Key reference
Confidential financial discount / rebate	Undisclosed price reduction from list price negotiated between payer and manufacturer	Bring effective cost within cost-effectiveness threshold without lowering public list price	Most common MEA type in practice, but leaves list-price-anchored external reference pricing distorted	Pauwels et al. 2017
Price-volume agreement / cap	Price or total expenditure adjusted once a predefined utilization volume is reached	Limit budget impact as patient population or usage expands	Requires reliable utilization monitoring; net cost varies substantially by drug	Owat et al. 2026
Outcomes-based / coverage-with-evidence-development agreement	Reimbursement or payment level conditioned on real-world clinical outcomes data	Fund therapies with immature survival evidence while limiting payer risk	Requires data infrastructure and agreed endpoints many systems lack; comparatively rare in practice	Pauwels et al. 2017
HTA-linked risk-sharing trigger	Use of MEA determined by how a jurisdiction's HTA process weighs clinical uncertainty	Match risk-sharing tool to the specific evidentiary gap identified in appraisal	Propensity to deploy MEAs varies by national assessment culture, not only by clinical uncertainty	Nieto-Gómez & Castaño-Amores 2024

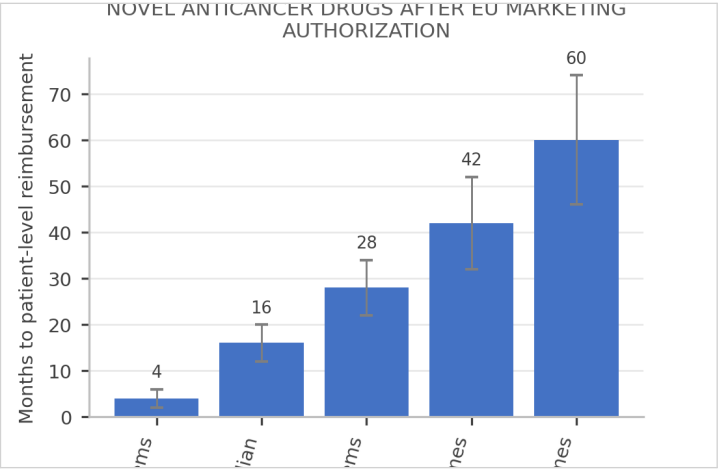
A separate scoping review of factors influencing cancer drug reimbursement decisions across Europe found that budget-impact considerations, alongside clinical effectiveness and cost-effectiveness evidence, were consistently among the most influential determinants of a positive reimbursement outcome — more so than for non-oncology drug classes — indicating that national fiscal capacity, and not clinical evidence alone, systematically shapes which cancer therapies clear the reimbursement bar in a given country [10]. Table 1 summarizes the principal managed-entry agreement types identified in this literature, the access objective each is intended to serve, and the documented limitation that constrains its equity-promoting potential in practice.

Cross-Country and Cross-Income Disparities in Access to Novel Cancer Therapies

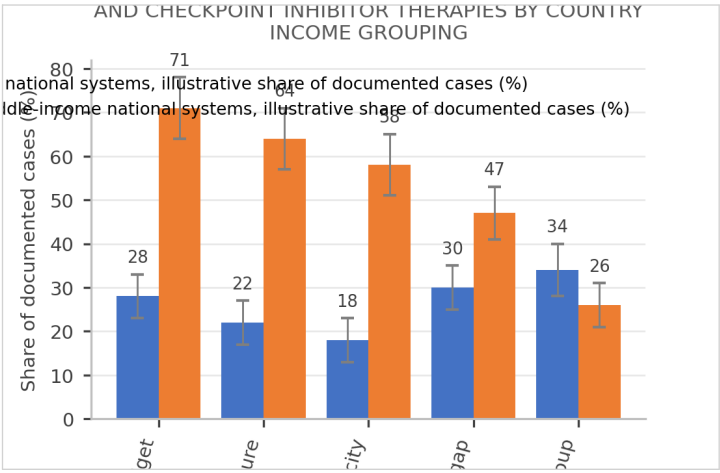
The combined effect of divergent value-assessment methodology and unevenly applied managed-entry agreements is measurable, and increasingly well documented, disparity in the timeliness and completeness of access to novel cancer therapies across countries

at every income level. Within the European Union — a setting with a harmonized centralized marketing authorization process through the European Medicines Agency, and therefore a natural experiment in how national-level reimbursement decisions alone can generate disparity after approval — a case study of seven European countries found median times from EU marketing authorization to patient-level reimbursement of novel anticancer drugs ranging from several months in the fastest-acting national systems to well over two years in the slowest, with delay driven predominantly by national HTA and price-negotiation timelines rather than by any residual regulatory step [11]. A related analysis across six European countries similarly found that time to patient access to innovative cancer medicines diverged substantially by country and was systematically associated with national health expenditure per capita and the structure of the national HTA process rather than with any clinical characteristic of the drugs themselves [12]. A more recent update synthesizing access to novel cancer medicines across the wider set of European countries confirms that these inequities have persisted rather than converged over time, and identifies national HTA capacity, price-negotiation practice, and overall health-budget constraints as the principal drivers of the continuing gap between the fastest- and slowest-access countries [13].

Illustrative median time from EU marketing authorization to patient-level reimbursement of novel anticancer drugs across selected European health systems, synthesized from cross-country reimbursement-timeline studies (Post et al., 2023; Vancoppenolle et al., 2024; Hofmarcher et al., 2025).



Reported barriers to equitable access to immune checkpoint inhibitor and CAR-T cell therapies by country income grouping, synthesized from the comparative access literature reviewed (Cai et al., 2025; Jenei, 2026; Chung et al., 2025; Tfayli et al., 2025).



These within-Europe disparities are, however, modest in scale compared with the disparities documented between high-income and low- or middle-income countries. Reviews of cancer therapeutic access in low- and middle-income countries describe a structural treatment gap in which a substantial share of the global cancer burden occurs in settings where essential and even off-patent cytotoxic agents are inconsistently available, let alone novel targeted or immune-based therapies whose acquisition cost can exceed a country's entire per-capita annual health expenditure many times over [3,4,14]. Comparative analyses of cancer care outcomes across income strata attribute a meaningful share of the survival gap between high-income and low-income countries specifically to differential access to effective systemic therapy rather than to differences in stage at diagnosis alone, indicating that unequal drug access is itself a driver — not merely a symptom — of global cancer mortality disparities [15]. A more recent synthesis of affordability and access barriers reaches a similar conclusion, finding that even where a novel cancer therapy is formally registered in a low- or middle-income country, list prices calibrated to high-income-country willingness to pay routinely place the therapy beyond the reach of national insurance schemes with far smaller total health budgets, producing a pattern in which formal drug registration substantially overstates real population access [5].

The two most cost-intensive contemporary oncology drug classes — immune checkpoint inhibitors and CAR-T cell therapies — illustrate this disparity acutely because their cost structure differs qualitatively from conventional chemotherapy. A serial cross-sectional study comparing immune checkpoint inhibitor approvals and access across the United States, the European Union, and mainland China found substantial and persistent gaps in both the number of approved indications reimbursed and the time to reimbursement, with China's National Reimbursement Drug List achieving broader nominal coverage over time but through aggressive price negotiation that produced list prices markedly below those in the United States and the European Union, underscoring that national price-negotiation leverage — not clinical judgment alone — is a primary determinant of population-level access [16]. CAR-T therapy access is even more constrained by manufacturing, infrastructure, and reimbursement complexity: a commentary on global CAR-T markets notes that despite regulatory approval in dozens of countries, functional patient access remains concentrated in a small number of health systems with both the specialized treatment-center infrastructure and the reimbursement mechanisms needed to fund a single-administration therapy priced in the hundreds of thousands of dollars [17]. Even within the United States, a SEER-Medicare data analysis of patients with relapsed or refractory diffuse large B-cell lymphoma found that receipt of commercial CAR-T therapy was significantly less likely among Medicare beneficiaries who were Black, who lived in areas of higher social deprivation, or who were treated outside a small number of high-volume specialized centers, demonstrating that formal Medicare coverage of CAR-T therapy did not translate into equitable utilization even within a single national insurance program [18]. A systematic review of economic evaluations of CAR-T therapies across hematologic and solid malignancies further finds that cost-effectiveness estimates for CAR-T are highly sensitive to modeling assumptions about long-term durability of response, meaning that the same product can appear cost-effective or not depending on modeling choices that vary across national HTA bodies, compounding the access disparity documented empirically [19]. Figure 1 summarizes illustrative comparative timelines to patient access across health system

types drawn from this literature, and Figure 2 summarizes documented barriers to equitable CAR-T and checkpoint inhibitor access by country income grouping.

Financial Toxicity and Patient-Level Equity Within National Health Insurance Schemes

Even where a novel cancer therapy is nominally covered by national health insurance, patient-level cost-sharing, indirect costs, and coverage gaps can reproduce inequity within a single insured population. In the United States, an analysis of Medicare beneficiaries with cancer found that out-of-pocket spending in the final year of life, and in the two years surrounding a cancer diagnosis, was substantially higher for beneficiaries with cancer than for demographically matched beneficiaries without cancer, and that a meaningful share of this burden was attributable specifically to prescription drug cost-sharing rather than to hospital or physician services, despite near-universal formal insurance coverage in this population [20]. A comparative analysis of financial toxicity across three distinct health care systems — including both insurance-based and safety-net settings — found that patient-reported financial burden varied significantly by insurance type and system, with patients in less generous coverage tiers reporting substantially higher rates of treatment nonadherence, delayed care, and material hardship attributable to cancer treatment costs, even though all patients in the study were nominally covered by some form of health insurance [21]. These findings indicate that financial toxicity functions as a distinct, patient-level equity mechanism operating beneath the level of the formal reimbursement decision: a therapy can be listed, reimbursed, and clinically accessed, while the associated co-payment, deductible, or indirect cost burden still falls disproportionately on lower-income patients within the same insurance scheme.

This within-scheme inequity interacts with the cross-country disparities described above in a way that compounds rather than offsets them. National health insurance schemes that achieve nominally broad reimbursement of novel cancer therapies by relying on high patient cost-sharing to manage budget impact — a strategy documented particularly where budget-impact concerns are reported as a primary driver of reimbursement decisions [10] — may show favorable headline access statistics while still producing substantial financial-toxicity-driven inequity in practice. Conversely, systems that limit patient cost-sharing but respond to budget pressure through slower or more restrictive formulary listing, of the kind documented in the cross-country reimbursement-timeline literature [11,12], shift the equity burden from the individual patient to the population of patients who do not yet have formulary access at all. Neither strategy resolves the underlying tension between novel-therapy cost and insurance-scheme sustainability; each merely relocates where in the system the resulting inequity is absorbed.

Discussion

Three broad conclusions emerge from this synthesis. First, the value-assessment methodology that national health insurance systems apply to novel cancer therapies is not neutral with respect to equity: cost-effectiveness thresholds lack a rigorous empirical basis in any jurisdiction [6], are applied largely unmodified to orphan oncology indications for which the underlying evidence base is systematically thinner [1,2], and interact with diagnostic-funding gaps to leave some formally reimbursed targeted therapies substantially underused in practice [7]. Second, managed-entry agreements — the dominant policy response to the resulting reimbursement uncertainty — are unevenly available across national systems as a function of institutional and analytical capacity rather than of clinical need, meaning that the tool most directly capable of reconciling cost-effectiveness thresholds with equitable access is itself distributed inequitably [8,9]. Third, the resulting access gaps are large and multidimensional, spanning modest but persistent within-Europe disparities in time to reimbursement [11,12,13], much larger disparities between high-income and low- or middle-income countries in whether novel therapies are accessible at all [3,4,5,15], and a further layer of within-country, within-scheme inequity driven by patient cost-sharing and financial toxicity that persists even where formal insurance coverage exists [20,21].

These findings carry direct policy implications. National HTA bodies evaluating novel cancer therapies, and particularly orphan oncology and cell-based therapies, would benefit from methodologically explicit, pre-specified adaptations to standard cost-utility assessment — rather than ad hoc application of general severity or end-of-life modifiers — given the demonstrated inconsistency this produces across near-identical submissions [1]. Where managed-entry agreements are used, international technical cooperation to share negotiation expertise, model MEA structures, and monitoring infrastructure could narrow the capacity gap that currently allows better-resourced systems to extract more favorable terms for the same drug [9,8]. Cross-country reimbursement-timeline disparities within regions with harmonized regulatory approval, such as the European Union, point to a specific and tractable policy target: national reimbursement and price-negotiation processes, not regulatory approval, are the rate-limiting step, and mechanisms for joint HTA assessment or coordinated pricing negotiation — building on existing EU joint clinical assessment initiatives — could plausibly narrow this gap without requiring harmonization of underlying willingness-to-pay thresholds [11,13]. Finally, patient-level financial toxicity data suggest that formal reimbursement status is an insufficient equity metric on its own; national health insurance schemes should track and report patient cost-sharing burden for novel cancer therapies specifically, since headline reimbursement rates can mask substantial residual inequity in who can actually afford to use a covered therapy [20,21].

This review has limitations inherent to its narrative design. The literature search, while targeted and individually verified for each included source, was not exhaustive and may underrepresent national-level policy analyses published outside major English-language journals, particularly for reimbursement systems in Latin America, the Middle East, and much of sub-Saharan Africa, where the treatment gap is likely to be at least as large as the literature captured here suggests. The quantitative findings drawn from individual studies — reimbursement timelines, cost-effectiveness estimates, and financial-burden measures — are heterogeneous in method, population, and outcome definition, and are presented here as illustrative of documented directional patterns rather than as a pooled or directly comparable estimate. Finally, because novel cancer therapy pricing, national HTA methodology, and managed-entry agreement practice are evolving rapidly — particularly as CAR-T and other cell and gene therapies mature and additional real-world evidence accumulates — some conclusions drawn from sources published earlier in this decade

may understate reimbursement arrangements that have since been renegotiated or reformed.

Conclusion

Equitable access to novel cancer therapies under national health insurance schemes is shaped jointly by how a system assesses the value of a therapy, what risk-sharing tools it has the capacity to deploy when that value is uncertain, and how much of the resulting cost it transfers to patients rather than absorbing collectively. None of the major reimbursement architectures reviewed here — conventional cost-utility thresholds, orphan-drug modifiers, or managed-entry agreements — currently resolves this tension without producing some form of documented inequity, whether across countries, across income strata, or within a single insured population. The most consequential access gaps identified in this review are not primarily about whether a novel cancer therapy is eventually approved and listed somewhere in a health system, but about how long that process takes, how much institutional capacity it requires, and how much of the resulting cost still falls on the individual patient once a formal reimbursement decision has been made. Closing these gaps will require national health insurance schemes to treat value-assessment methodology, managed-entry agreement capacity, and patient cost-sharing design as jointly determined equity levers, rather than addressing reimbursement timeliness, price negotiation, and financial protection as separate policy problems.

References

1. Lee D, McCarthy G, Saeed O, Allen R, Malottki K, Chandler F (2023) The challenge for orphan drugs remains: three case studies demonstrating the impact of changes to NICE methods and processes and alternative mechanisms to value orphan products. PharmacoEconomics Open, 7(2):175-187, DOI:10.1007/s41669-022-00378-8.
2. Blonda A, Denier Y, Huys I, Simoens S (2021) How to value orphan drugs? A review of European value assessment frameworks. Frontiers in Pharmacology, 12:631527, DOI:10.3389/fphar.2021.631527.
3. Ruff P, Al-Sukhun S, Blanchard C, Shulman LN (2016) Access to cancer therapeutics in low- and middle-income countries. American Society of Clinical Oncology Educational Book, 35:58-65, DOI:10.1200/EDBK_155975.
4. Lopes G Jr, de Souza JA, Barrios C (2013) Access to cancer medications in low- and middle-income countries. Nature Reviews Clinical Oncology, 10(6):314-322, DOI:10.1038/nrclinonc.2013.55.
5. Tfayli AH, El-Halabi LN, Khuri FR (2025) Global disparities in cancer care: bridging the gap in affordability and access to medications between high and low-income countries. Cancer, 131(1):e35590, DOI:10.1002/cncr.35590.
6. Cameron D, Ubels J, Norström F (2018) On what basis are medical cost-effectiveness thresholds set? Clashing opinions and an absence of data: a systematic review. Global Health Action, 11(1):1447828, DOI:10.1080/16549716.2018.1447828.
7. Shih YT, Pan IW, Teich N (2022) Global challenges in access to and implementation of precision oncology: the health care manager and health economist perspective. American Society of Clinical Oncology Educational Book, 42:429-437, DOI:10.1200/EDBK_359650.
8. Pauwels K, Huys I, Vogler S, Casteels M, Simoens S (2017) Managed entry agreements for oncology drugs: lessons from the European experience to inform the future. Frontiers in Pharmacology, 8:171, DOI:10.3389/fphar.2017.00171.
9. Owat P, Sooksriwong C, Ratanabunjerdkul H, Phodha T (2026) Comparative cost evaluation of managed entry agreement techniques using real-world data from high-cost anticancer drugs in Thailand. Journal of Market Access & Health Policy, 14(1):17, DOI:10.3390/jmahp14010017.
10. Nieto-Gómez P, Castaño-Amores C (2024) Factors influencing the reimbursement of cancer drugs in Europe: a scoping review. Journal of Evaluation in Clinical Practice, 30(8):1546-1555, DOI:10.1111/jep.14080.
11. Post HC, Schutte T, van Oijen MGH, van Laarhoven HWM, Hollak CEM (2023) Time to reimbursement of novel anticancer drugs in Europe: a case study of seven European countries. ESMO Open, 8(2):101208, DOI:10.1016/j.esmoop.2023.101208.
12. Vancoppenolle JM, Franzen N, Koole SN, Retèl VP, van Harten WH (2024) Differences in time to patient access to innovative cancer medicines in six European countries. International Journal of Cancer, 154(5):886-894, DOI:10.1002/ijc.34753.
13. Hofmarcher T, Charalambous A, Normanno N, Szmytke E, Wilking N (2025) Access to novel cancer medicines in Europe: inequities across countries and their drivers. ESMO Open, 10(10):105810, DOI:10.1016/j.esmoop.2025.105810.
14. Cardone C, Arnold D (2023) The cancer treatment gap in lower- to middle-income countries. Oncology, 101(Suppl 1):2-4, DOI:10.1159/000530416.
15. de Souza JA, Hunt B, Asirwa FC, Adebamowo C, Lopes G (2016) Global health equity: cancer care outcome disparities in high-, middle-, and low-income countries. Journal of Clinical Oncology, 34(1):6-13, DOI:10.1200/JCO.2015.62.2860.
16. Cai JX, Wang SY, Hu H, Ung COL, Li FX, Lin TF, Luo SF, Song HB, Yang ZR, Tang JL, Meng WH (2025) Disparities in the access to immune checkpoint inhibitors approved in the United States, the European Union and mainland China: a serial cross-sectional study. BMJ Public Health, 3(1):e001995, DOI:10.1136/bmjph-2024-001995.
17. Jenei K (2026) Access to CAR T-cell therapy across diverse global markets. Blood, 147(14):1509-1510, DOI:10.1182/blood.2025032585.
18. Chung AP, Shafrin J, Vadgama S, Hurley K, Perales MA, Alsfeld LC, Muthukrishnan S, Patel AR, Shah GL, Maziarz RT (2025) Inequalities in CAR T-cell therapy access for US patients with relapsed/refractory DLBCL: a SEER-Medicare data analysis. Blood Advances, 9(18):4727-4735, DOI:10.1182/bloodadvances.2024015634.
19. Tran TH, Kim HSJ (2026) Comparative economic evaluations of CAR-T therapies for relapsed or refractory diffuse large B-cell lymphoma: a systematic review. PharmacoEconomics, 44(3):287-298, DOI:10.1007/s40273-025-01566-0.
20. Narang AK, Nicholas LH (2017) Out-of-pocket spending and financial burden among Medicare beneficiaries with cancer. JAMA Oncology, 3(6):757-765, DOI:10.1001/jamaoncol.2016.4865.

21. Parikh DA, Ragavan M, Dutta R, Garnet Edwards J, Dickerson J, Maitra D, Aggarwal S, Lee FC, Patel MI (2021) Financial toxicity of cancer care: an analysis of financial burden in three distinct health care systems. JCO Oncology Practice, 17(10):e1450-e1459, DOI:10.1200/OP.20.00890.