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Policy and System-Level Constraints to Timely Access of FDA-Approved Oncology Therapies in the United States: A Qualitative Systematic Review

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Abstract: Despite the growing number of therapies receiving regulatory approval from the U.S. Food and Drug Administration, ensuring timely patient access to innovative oncology treatments remains a significant challenge. This qualitative systematic review synthesizes evidence from 20 studies to examine policy and system-level constraints that delay patient access to FDA-approved oncology therapies in the United States. The review identifies five interconnected categories of barriers: regulatory governance and approval processes, health system infrastructure and institutional capacity, pharmaceutical supply chain vulnerabilities, socioeconomic and geographic disparities, and clinical implementation challenges. Findings indicate that these barriers rarely operate in isolation. Regulatory and reimbursement delays cascade into clinical implementation bottlenecks, infrastructure gaps compound supply chain vulnerabilities, and socioeconomic disparities amplify constraints at every stage of the access pathway. The review concludes that fragmented policy interventions targeting individual barriers are insufficient. Improving timely and equitable access to oncology therapies requires coordinated reforms that align regulatory efficiency with reimbursement processes, strengthen infrastructure alongside supply chain resilience, and embed equity monitoring across all stages of the access pathway.

Keywords: Oncology access, FDA approval, health policy, pharmaceutical supply chain, cancer treatment disparities, health equity.

INTRODUCTION

Advances in oncology research have expanded therapeutic options for cancer treatment in the United States, particularly through developments in precision medicine, targeted therapies, and genomics. These innovations have improved survival outcomes and enabled more personalized treatment strategies for patients (Elmore *et al*., 2021). Increased investment in translational research has further supported the integration of novel therapies into clinical practice, while the growth of precision oncology and genomics-based treatments has introduced new possibilities for patients with previously limited options (Farhangfar *et al*., 2022).

However, translating oncology innovations from regulatory approval to routine clinical access remains complex. Multiple systemic factors influence whether patients can receive these therapies promptly, including clinical adoption processes, provider familiarity with emerging treatments, and the integration of new therapies into community oncology practice (Ellis *et al*., 2023; Dombeck *et al*., 2024). Persistent barriers such as limited clinical trial access and disparities affecting underserved populations continue to affect the implementation of targeted therapies (Farhangfar *et al*., 2022).

Timely access to oncology therapies plays a critical role in improving patient outcomes and reducing mortality. Delays in treatment initiation can significantly affect survival rates, particularly in aggressive or advanced-stage cancers. Despite ongoing progress in therapeutic innovation, timely access remains uneven across patient populations and healthcare delivery systems. Comparative analyses have demonstrated that access to newly developed therapies may vary due to regulatory pathways, reimbursement structures, and health system organization (Akodad *et al*., 2025). Qualitative research examining oncology healthcare professionals has further identified operational and organizational barriers that affect the timely delivery of oral anticancer medications, particularly for vulnerable populations such as older adults (Chavez *et al*., 2025).

Policy and regulatory frameworks play a fundamental role in shaping how quickly approved oncology therapies become accessible to patients. The U.S. regulatory environment is designed to ensure the safety and effectiveness of new treatments; however, the processes governing approval, post-market evaluation, and clinical implementation can introduce additional layers of complexity. Regulatory policies surrounding evidence standards, post-approval monitoring, and risk evaluation strategies influence the conditions under which therapies enter clinical practice. Analyses of regulatory evaluation frameworks have highlighted the importance of clearly defined effectiveness endpoints and data governance structures to support regulatory decision-making and post-market surveillance (FDA, 2023;

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Toyserkani *et al*., 2020). Furthermore, regulatory compliance requirements related to clinical trials, data integrity, and quality assurance shape the broader pharmaceutical innovation ecosystem, affecting not only the approval process but also the subsequent adoption and distribution of therapies within healthcare systems (Alhammad *et al*., 2024).

Beyond regulatory factors, structural characteristics of healthcare systems significantly influence access to oncology therapies. Health system infrastructure, provider capacity, and organizational practices determine how efficient treatments reach patients after approval. Research has identified systemic barriers such as limitations in care coordination, resource availability, and integration of precision medicine into routine practice (Cooper *et al*., 2022). These challenges are particularly evident in community oncology settings, where differences in institutional resources and expertise affect the adoption of advanced therapies (Ellis *et al*., 2023). Drug availability and supply stability are also critical for consistent treatment access. Studies highlight the need for resilient pharmaceutical distribution systems to prevent shortages and ensure equitable availability of essential medicines (NASEM, 2022; HHS, 2024). Supply chain disruptions can directly affect oncology treatment availability, compounding the structural barriers that already limit access in underserved settings (Ghazal *et al*., 2025).

Socioeconomic and demographic factors further contribute to disparities in oncological treatment access. Variations in income, geographic location, and healthcare infrastructure can create unequal opportunities for patients to receive advanced cancer therapies. Research examining socioeconomic determinants of health outcomes has demonstrated that disparities in economic resources and healthcare access can significantly influence treatment utilization and health outcomes (Braveman *et al*., 2010; Kim *et al*., 2023). Geographic analyses of cancer treatment patterns reveal regional variations in surgical care and treatment availability, particularly among historically underserved populations (Roberson, 2021). Health equity considerations have therefore become central to contemporary discussions on oncology care delivery, with policy frameworks that address structural determinants of health and legal mechanisms for promoting equitable access increasingly recognized as critical components of health system reform (Yang, 2024; Manzano *et al*., 2025).

Although previous research has examined individual aspects of oncology treatment access, including regulatory processes, clinical implementation barriers, and health disparities, the literature remains fragmented across multiple domains. Existing studies often focus on specific components of the oncology care continuum without providing an integrated understanding of how policy and system-level factors interact to influence timely access to FDA-approved therapies. Given the complexity of the U.S. healthcare system and the increasing reliance on advanced oncology treatments, there is a need for a comprehensive synthesis of evidence examining systemic barriers to treatment access.

Therefore, this study addresses the following research question: *What policy and system-level factors constrain timely patient access to FDA-approved oncology therapies in the United States, and how do these factors interact across the access pathway?*

The objective is to synthesize existing literature on policy and system-level constraints affecting timely access to FDA-approved oncology therapies through a qualitative systematic review. By identifying recurring structural, regulatory, and implementation barriers and examining their interactions, this review aims to provide a comprehensive understanding of the factors shaping access to cancer treatments within the U.S. healthcare system and to inform integrated policy reform.

METHODOLOGY

Study Design and Review Approach

This study adopted a qualitative systematic review to synthesize evidence on policy and system-level constraints affecting timely access to FDA-approved oncology therapies in the United States. The approach was appropriate because research on oncology treatment access spans multiple domains, including health policy, regulatory systems, healthcare delivery, and socioeconomic determinants. Prior studies highlight the complex interaction between regulatory processes, healthcare infrastructure, and socioeconomic conditions in shaping treatment availability and utilization (Cooper *et al*., 2022; Ellis *et al*., 2023). Research on pharmaceutical supply chains and healthcare delivery systems further emphasizes the role of institutional structures and distribution

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networks in translating medical innovations into clinical practice (NASEM, 2022; HHS, 2024). Given this multidisciplinary evidence base, qualitative synthesis enables the identification of recurring themes across policy analyses, implementation studies, and health systems research. This integrative approach supports a comprehensive understanding of regulatory frameworks, drug distribution challenges, and disparities in healthcare access affecting oncology therapy availability.

Search Strategy

A structured literature search was conducted across multiple electronic databases, including PubMed, Scopus, Web of Science, CINAHL, and Google Scholar, covering publications from January 2020 through March 2026. The search was supplemented by targeted review of gray literature from policy-oriented sources, including reports from the U.S. Food and Drug Administration (FDA), the Centers for Medicare and Medicaid Services (CMS), and relevant health policy journals such as Health Affairs and Frontiers in Medicine.

Search terms were organized into four conceptual clusters combined using Boolean operators:

- **Disease and treatment context:** "oncology," "cancer therapy," "cancer treatment," "targeted therapy," "precision oncology," "gene therapy," "oral anticancer," "immunotherapy"
- **Access and implementation:** "patient access," "treatment access," "timely access," "treatment delay," "clinical implementation," "therapy adoption," "therapy uptake"
- **Policy and system factors:** "health policy," "regulatory approval," "FDA approval," "reimbursement," "prior authorization," "insurance coverage," "Medicaid," "formulary," "drug pricing"
- **Structural and equity dimensions:** "healthcare infrastructure," "supply chain," "drug shortage," "health disparities," "health equity," "socioeconomic," "geographic disparities," "underserved populations"

Clusters were combined with at least one term from the disease/treatment cluster appeared alongside at least one term from any of the other three clusters (e.g., "oncology" AND "patient access" AND "health policy"; "cancer therapy" AND "drug shortage" AND "health disparities"). Reference lists of included studies were also hand-searched to identify additional relevant sources not captured in the initial database search.

Eligibility Criteria

Eligibility criteria were developed to ensure that the included literature addressed themes relevant to policy and system-level factors influencing access to oncology therapies. Studies were included if they met the following criteria:

1. Topical relevance: The study examined issues related to oncology care delivery, access to innovative cancer therapies, healthcare policy, regulatory frameworks, pharmaceutical supply chains, or healthcare system infrastructure affecting treatment availability.
2. Contextual relevance: Studies addressing the United States healthcare system or comparative analyses including the United States were included.
3. Publication type: Peer-reviewed journal articles, policy reports, and academic analyses addressing healthcare policy, oncology care delivery, and health system governance were eligible.
4. Analytical focus: Studies that explored structural barriers, implementation challenges, regulatory processes, or socioeconomic disparities affecting healthcare access were included.

Studies examining unrelated domains such as non-healthcare industrial systems or financial markets were excluded. However, research addressing broader health system governance, pharmaceutical regulation, or healthcare supply chains was retained where findings contributed to understanding systemic factors influencing treatment availability (NASEM, 2022; HHS, 2024).

Literature Identification, Screening and Study Selection

The initial database search yielded approximately 210 records. After removing duplicates across databases, approximately 155 unique records remained for screening. Titles and abstracts were screened for relevance to the study's focus on policy and system-level constraints affecting access to FDA-approved oncology therapies in the United States. Studies that addressed oncology treatment access, healthcare policy frameworks, regulatory governance, pharmaceutical supply chains, or socioeconomic determinants of healthcare availability were retained for full-text review.

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Full-text assessment was conducted on approximately 58 articles against the eligibility criteria defined in Section 2.3. Studies were excluded at this stage if they focused exclusively on clinical efficacy without addressing access or system-level barriers, addressed healthcare systems outside the United States without comparative relevance, or lacked substantive engagement with policy, structural, or implementation dimensions of therapy access.

A final set of 20 studies was retained for inclusion in the qualitative synthesis. While a formal PRISMA flow diagram was not employed, the screening process followed a structured and iterative approach consistent with established qualitative systematic review methodology (Thomas & Harden, 2008).

Emphasis was placed on research exploring barriers to precision oncology adoption, healthcare infrastructure limitations, and disparities in cancer care delivery (Cooper *et al*., 2022; Ellis *et al*., 2023; Farhangfar *et al*., 2022). Studies investigating pharmaceutical supply chain resilience, drug availability, and coordination within healthcare systems were included because of their relevance to treatment accessibility (NASEM, 2022; HHS, 2024). Policy-focused research examining regulatory evaluation frameworks, risk management mechanisms, and governance structures influencing healthcare access was also incorporated to provide insight into institutional factors shaping oncology treatment availability (Toyserkani *et al*., 2020; Yang, 2024).

Data Extraction Procedures

Data extraction was conducted through a structured review of each included study. Key information extracted from the literature included:

- Study objectives and thematic focus
- Healthcare policy or system-level factors examined
- Identified barriers to oncology therapy access
- Healthcare delivery or implementation challenges
- Evidence related to disparities in treatment access
- Policy implications for healthcare systems

Studies exploring oncology care delivery and clinical implementation were examined for insights into operational barriers affecting treatment access, including provider-level challenges, institutional capacity, and clinical trial participation (Chavez *et al*., 2025; Dombeck *et al*., 2024). Similarly, research examining drug supply chains and pharmaceutical distribution systems was analyzed to identify structural issues affecting medication availability and treatment continuity (NASEM, 2022; Ghazal *et al*., 2025). Policy analyses were reviewed to extract findings related to regulatory governance, data integrity requirements, and legal frameworks shaping healthcare access and treatment adoption (Alhammad *et al*., 2024; FDA, 2023).

Qualitative Data Synthesis

A thematic synthesis approach was applied to analyze and integrate findings across the included studies, enabling qualitative evidence from diverse research designs to be organized into conceptual categories reflecting recurring patterns in the literature. Iterative analysis identified key themes, including regulatory and policy constraints affecting therapy approval and adoption, healthcare system infrastructure and implementation challenges, pharmaceutical supply chain disruptions and drug availability issues, socioeconomic and geographic disparities in oncology treatment access, and clinical practice and provider-level barriers to therapy utilization. Existing research indicates that barriers to oncology care often emerge from the interaction of policy frameworks, institutional practices, and socioeconomic conditions shaping healthcare delivery (Cooper *et al*., 2022; Ellis *et al*., 2023). Consequently, the synthesis examined how these interconnected structural factors collectively influence timely access to FDA-approved oncology therapies in the United States.

Quality and Contextual Assessment of Included Studies

Although the included literature spans multiple study designs, contextual evaluation of each source was conducted to assess the relevance and contribution of the evidence to the research question. Studies providing empirical data on oncology care delivery, treatment access disparities, or health system implementation were considered particularly valuable for identifying practical barriers within clinical settings (Chavez *et al*., 2025; Farhangfar *et al*., 2022).

Policy analyses and regulatory evaluations were also assessed for their relevance in explaining institutional frameworks governing pharmaceutical innovation and healthcare system governance (Toyserkani *et al*., 2020; Yang, 2024). This contextual assessment ensured that the final

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synthesis reflected a balanced representation of policy, healthcare system, and clinical practice perspectives relevant to oncology therapy access.

RESULTS

Characteristics of Included Studies

A total of 20 studies were included in the qualitative synthesis, representing diverse research designs such as qualitative studies, policy analyses, systematic reviews, clinical implementation research, and healthcare systems studies. These studies examined oncology treatment access, healthcare policy frameworks, regulatory governance, pharmaceutical supply chains, and socioeconomic determinants of healthcare availability. Several studies focused on oncology care delivery and the implementation of targeted therapies, precision medicine, and oral anticancer treatments in clinical settings (Chavez *et al*., 2025; Ellis *et al*., 2023; Farhangfar *et al*., 2022). Other research explored broader structural influences, including health policy frameworks, governance structures, and regulatory processes shaping treatment accessibility (Toyserkani *et al*., 2020; Yang, 2024). Additionally, some studies addressed healthcare supply chain resilience and drug availability, emphasizing the role of distribution systems and pharmaceutical logistics in maintaining consistent access to essential medicines (NASEM, 2022; HHS, 2024).

Table 1 Characteristics of Included Studies

Category	Description
Oncology care delivery	Studies examining clinical implementation of cancer therapies
Precision oncology and genomics	Research exploring adoption of targeted therapies
Health policy and regulatory governance	Analyses of regulatory frameworks and policy structures
Pharmaceutical supply chains	Studies on medicine distribution and supply resilience
Socioeconomic disparities	Research examining inequities in healthcare access

Sources: *NASEM, 2022; HHS, 2024; Ellis et al., 2023; Farhangfar et al., 2022*

Policy and Regulatory Constraints Affecting Oncology Therapy Access

Policy and regulatory frameworks emerged as a critical determinant of treatment access across the reviewed literature. Studies examining pharmaceutical regulation emphasize that regulatory approval processes, post-market monitoring, and evidence requirements influence how quickly new therapies transition from approval to clinical adoption.

Analyses of regulatory frameworks highlight the importance of clearly defined evidence standards and effectiveness endpoints in guiding regulatory decision-making. Ambiguities in regulatory evaluation processes may create uncertainty regarding therapy implementation and reimbursement, potentially contributing to delays in patient access to innovative treatments (FDA, 2023).

Similarly, studies examining risk evaluation and mitigation strategies indicate that regulatory oversight mechanisms are designed to ensure patient safety but may introduce additional administrative requirements affecting therapy implementation (Toyserkani *et al*., 2020). These regulatory structures influence both pharmaceutical development pathways and post-approval distribution systems within healthcare institutions.

Quality assurance and compliance frameworks within the pharmaceutical industry also shape treatment availability by determining how clinical trial data are evaluated and validated for regulatory approval (Alhammad *et al*., 2024). Collectively, these regulatory factors illustrate the complex institutional environment governing oncology therapy access.

Table 2: Policy and Regulatory Constraints Identified in the Literature

Policy Factor	Description
Regulatory approval processes	Evaluation of evidence and safety data
Risk evaluation and mitigation programs	Safety monitoring mechanisms affecting therapy adoption
Data integrity and regulatory compliance	Clinical trial data requirements influencing approval
Health policy governance	Legal frameworks influencing healthcare access

Sources: *Alhammad et al., 2024; Toyserkani et al., 2020*

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Health System and Infrastructure Barriers

Health system infrastructure emerged as another major determinant of oncology therapy access. Several studies highlighted how institutional capacity, provider expertise, and organizational practices influence the implementation of innovative cancer treatments. Research examining oncology practice settings demonstrates that the adoption of targeted cancer therapies often depends on institutional resources, provider training, and access to specialized diagnostic technologies (Ellis *et al*., 2023). Variations in healthcare infrastructure between large academic centers and community oncology practices may therefore contribute to differences in treatment availability. Qualitative investigations involving oncology healthcare professionals also identified operational challenges affecting the delivery of oral anticancer medications. These challenges include coordination of multidisciplinary care, patient monitoring requirements, and logistical constraints associated with medication management (Chavez *et al*., 2025). In addition, research on clinical trial integration into routine care indicates that structural barriers such as limited institutional resources and complex trial protocols may restrict patient access to innovative therapies (Dombeck *et al*., 2024).

Figure 1. Health system factors influencing oncology therapy access.

Pharmaceutical Supply Chain and Drug Availability Challenges

Drug availability and pharmaceutical distribution systems were identified as important structural factors influencing oncology therapy access. Studies examining healthcare supply chains highlight the need for resilient distribution networks capable of ensuring continuous availability of essential medicines.

Research on pharmaceutical supply chain resilience indicates that disruptions in procurement, manufacturing, or distribution systems can significantly affect treatment availability across healthcare institutions (NASEM, 2022). These challenges are particularly relevant for specialized oncology drugs that require complex storage, distribution, and monitoring processes.

Furthermore, investigations of cancer care delivery within national oncology research networks have documented the impact of drug shortages on treatment continuity and patient care (Ghazal *et*

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al., 2025). Drug shortages can lead to treatment delays, substitution of therapies, or disruptions in clinical trial protocols.

Additional studies emphasize the importance of data-driven supply chain management and coordinated healthcare logistics in improving the reliability of pharmaceutical distribution systems (HHS, 2024).

Table 3: Supply Chain Factors Affecting Oncology Therapy Availability

Supply Chain Issue	Impact on Oncology Care
Drug shortages	Treatment delays and therapy substitutions
Distribution inefficiencies	Reduced availability of essential medicines
Supply chain coordination challenges	Delays in medicine delivery

Sources: *Ghazal et al., 2025; NASEM, 2022; HHS, 2024*

Socioeconomic and Geographic Disparities in Access

Socioeconomic and demographic disparities were consistently identified as significant determinants of oncological treatment access. Research examining health outcomes demonstrates that economic resources, insurance coverage, and geographic location influence patient access to advanced medical treatments (Braveman *et al*., 2010; Kim *et al*., 2023). Geographic analyses of cancer treatment patterns reveal notable regional variations in treatment utilization, particularly among historically underserved populations. Studies focusing on breast cancer treatment patterns in the United States highlight disparities in surgical care access among Black women in certain regions (Roberson, 2021).

Policy-oriented research further emphasizes the role of structural determinants of health in shaping healthcare access. Legal and policy frameworks aimed at promoting health equity have been identified as critical mechanisms for addressing systemic disparities within healthcare systems (Yang, 2024; Manzano *et al*., 2025).

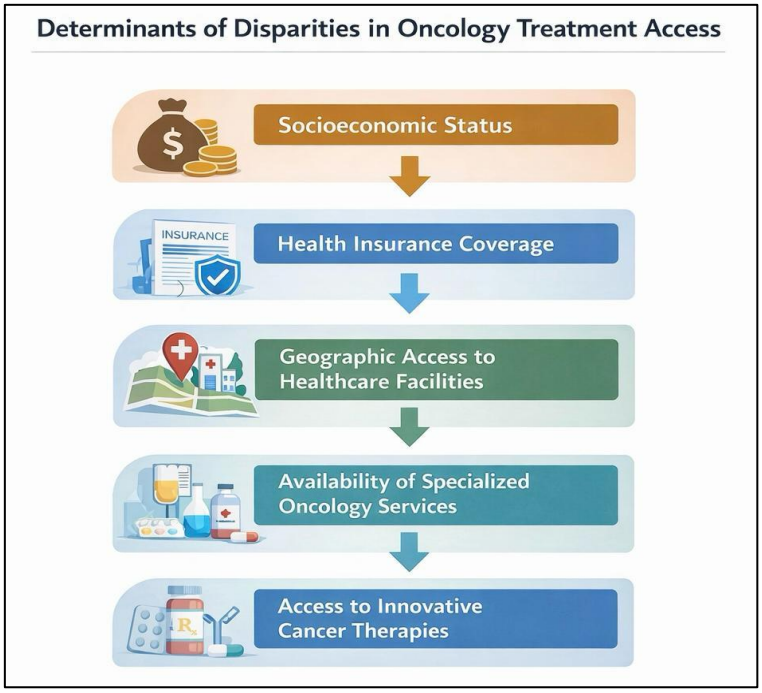

Figure 2. Determinants of disparities in oncology treatment access.

Clinical Implementation Barriers

Clinical implementation barriers represent the final stage in the pathway from regulatory approval to patient access. Even after therapies receive regulatory authorization, several operational challenges may affect their adoption within clinical practice.

Studies examining oncology practice environments highlight the importance of provider knowledge, institutional resources, and patient support systems in facilitating treatment adoption (Ellis *et al*., 2023). Similarly, clinical genomics programs have identified challenges related to patient recruitment, trial participation, and integration of precision

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medicine into routine oncology care (Farhangfar *et al*., 2022).

These findings illustrate how systemic factors including regulatory structures, healthcare infrastructure, supply chain dynamics, and socioeconomic conditions interact to shape the accessibility of oncology therapies in the United States.

DISCUSSION

Overview of Key Findings

This qualitative systematic review synthesized evidence from 20 studies examining policy and system-level constraints affecting timely access to FDA-approved oncology therapies in the United States. The findings reveal that access barriers do not operate in isolation. Regulatory governance, health system infrastructure, pharmaceutical supply chains, socioeconomic disparities, and clinical implementation challenges interact in ways that compound delays and deepen inequities. The discussion that follows departs from a theme-by-theme restatement of results and instead examines how these structural factors intersect, where they create feedback loops that amplify access delays, and what these interactions imply for policy reform.

The Regulatory-Reimbursement-Implementation Pathway: Cascading Delays

A central finding across the reviewed literature is that delays in oncology therapy rarely stem from a single bottleneck. Instead, they cascade through a sequential pathway from regulatory approval to reimbursement authorization to clinical implementation. Regulatory processes designed to ensure safety and efficacy, including evidence requirements, post-approval monitoring, and risk evaluation and mitigation strategies, establish necessary safeguards but also set the pace for downstream adoption (FDA, 2023; Toyserkani *et al*., 2020). Once a therapy clears regulatory approval, reimbursement decisions introduce a second layer of delay. Insurance coverage limitations, formulary restrictions, and prior authorization requirements determine whether approved therapies are financially accessible to patients, particularly within public insurance programs such as Medicaid where coverage practices vary by state.

Even when both regulatory and reimbursement conditions are met, clinical implementation introduces a third stage of potential delay. Provider familiarity with new treatment protocols, institutional capacity to deliver advanced therapies, and the availability of specialized diagnostic technologies all influence how quickly approved and covered therapies reach patients in practice (Ellis *et al*., 2023; Dombeck *et al*., 2024). This cascading structure means that a delay at any single stage propagates forward. A therapy that receives rapid FDA approval but encounters prolonged prior authorization timelines or limited provider readiness will still reach patients late. The reviewed evidence suggests that policy interventions targeting only one stage of this pathway, without addressing constraints at adjacent stages, are unlikely to produce meaningful improvements in overall access timelines.

Infrastructure Gaps and Supply Chain Vulnerability: Compounding Structural Barriers

The interaction between health system infrastructure limitations and pharmaceutical supply chain vulnerabilities creates a second axis of compounding barriers. Studies examining oncology practice settings demonstrate that treatment adoption depends heavily on institutional resources, including diagnostic technologies, multidisciplinary care teams, and specialized storage and handling capabilities for complex oncology drugs (Ellis *et al*., 2023; Chavez *et al*., 2025). When these institutional capacities are limited, as is frequently the case in community oncology practices and rural healthcare settings, the system becomes more vulnerable to supply chain disruptions.

Pharmaceutical supply chain research included in this review documents how manufacturing challenges, procurement inefficiencies, and distribution bottlenecks can interrupt treatment availability (NASEM, 2022; Ghazal *et al*., 2025; Patel *et al*., 2025). These disruptions are particularly consequential for specialized oncology drugs that require cold chain storage, complex handling protocols, or time-sensitive administration. When supply chain disruptions coincide with infrastructure limitations, the effects compound: institutions with fewer resources have less capacity to manage shortages through therapy substitution, alternative sourcing, or clinical protocol adjustment (HHS, 2024; Patel *et al*., 2025).

This interaction has direct implications for treatment continuity. Drug shortages may force treatment delays or therapeutic substitutions that

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compromise clinical outcomes, and these effects fall disproportionately on institutions and regions with the least structural resilience. Strengthening supply chain management without simultaneously investing in institutional infrastructure addresses only one dimension of a two-sided problem.

Socioeconomic Disparities as a Cross-Cutting Amplifier

Perhaps the most consistent finding across the reviewed studies is that socioeconomic and geographic disparities do not operate as a separate category of barriers but rather amplify every other constraint identified in this review. Patients with fewer economic resources, limited insurance coverage, or residence in underserved geographic areas experience each stage of the access pathway more acutely.

At the regulatory-reimbursement stage, patients in states with more restrictive Medicaid coverage practices face greater barriers to accessing newly approved therapies, even when those therapies have cleared FDA review. At the infrastructure stage, geographic analyses reveal that specialized oncology services are concentrated in urban academic medical centers, leaving patients in rural areas with fewer options for receiving advanced treatments (Roberson, 2021). At the supply chain stage, institutions serving lower-income populations may have less purchasing power and fewer supplier relationships to buffer against drug shortages. At the clinical implementation stage, complex treatment regimens and monitoring requirements create adherence challenges that are intensified by economic constraints and limited access to supportive care services.

Research examining socioeconomic determinants of health outcomes confirms that these disparities translate into measurable differences in treatment utilization and survival (Braveman *et al*., 2010; Kim *et al*., 2023). Policy and legal frameworks aimed at promoting health equity have been identified as critical mechanisms for addressing these systemic inequities (Yang, 2024; Manzano *et al*., 2025). However, the cross-cutting nature of socioeconomic disparities means that equity-focused interventions must be embedded within regulatory, infrastructure, and supply chain reforms rather than treated as a standalone policy domain. Addressing disparities only through coverage expansion, for example, will have limited impact if infrastructure gaps and supply chain vulnerabilities continue to restrict access in the communities where those newly covered patients live.

Implications for Integrated Policy Reform

The interconnected nature of these barriers carries a clear implication: fragmented policy interventions that target individual constraints in isolation are insufficient. The reviewed evidence supports a systems-level approach to improving oncology therapy access, one that recognizes the cascading and compounding dynamics identified above.

Several integrated policy directions emerge from the synthesis. First, regulatory coordination and reimbursement alignment should be pursued concurrently. Streamlining the transition from FDA approval to payer coverage, including standardizing prior authorization timelines and reducing state-level variability in Medicaid formulary decisions, would compress the regulatory-reimbursement segment of the access pathway (FDA, 2023; Yang, 2024). Second, infrastructure investment and supply chain resilience should be addressed as complementary priorities. Expanding oncology service capacity in underserved areas has limited value if pharmaceutical distribution systems cannot reliably deliver therapies to those settings. Conversely, strengthening supply chains without building institutional capacity to administer complex treatments does not translate into patient access (NASEM, 2022; HHS, 2024). Third, equity monitoring must be integrated into every stage of the access pathway rather than treated as a downstream evaluation. Tracking demographic patterns in therapy utilization, referral rates, and treatment completion across regulatory, reimbursement, infrastructure, and implementation stages would enable early detection of emerging disparities before they become entrenched (Braveman *et al*., 2010; Kim *et al*., 2023; Manzano *et al*., 2025).

These directions do not represent novel policy categories. Rather, they represent a reorientation from siloed interventions toward coordinated reforms that account for how barriers interact across the access pathway.

Strengths and Limitations of the Review

This review provides a comprehensive qualitative synthesis of policy and system-level factors affecting oncology therapy access, drawing upon evidence from multiple disciplines including health policy research, healthcare systems analysis,

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and oncology care delivery studies. A key strength lies in its cross-thematic analytical approach, which captures interactions between regulatory governance, healthcare infrastructure, supply chain management, and socioeconomic determinants of health that are often examined in isolation.

Several limitations should be acknowledged. First, the review relies on 20 selected studies, which may not capture all relevant evidence on this topic. Second, the studies included vary in research design and methodological approach, which may influence the comparability of findings. Third, the screening and selection process, while structured and iterative, did not employ a formal PRISMA flow diagram or standardized quality appraisal tool, which limits methodological transparency. Fourth, the synthesis reflects the policy landscape as of early 2026 and may require periodic reassessment as regulatory and reimbursement structures evolve. Despite these limitations, the review provides valuable insights into the systemic factors shaping access to oncology therapies in the United States and offers a foundation for integrated policy analysis.

CONCLUSION

Timely access to FDA-approved oncology therapies in the United States is influenced by a complex interaction of policy and system-level factors. Regulatory frameworks, healthcare infrastructure, pharmaceutical supply chains, and clinical implementation processes collectively shape how quickly new cancer therapies become available to patients. While regulatory approval represents a critical milestone, effective integration into clinical practice depends on healthcare system capacity, provider readiness, and institutional coordination. In addition, socioeconomic and geographic disparities continue to influence equitable access to innovative cancer treatments across different patient populations. Addressing these challenges requires coordinated policy interventions that strengthen regulatory efficiency, expand healthcare infrastructure, improve supply chain resilience, and enhance the integration of novel therapies into clinical practice. Such efforts are essential to ensure that advancements in oncology research translate into timely, equitable, and sustainable access to life-saving treatments.

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