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Toward Equitable Cellular Therapy: Addressing Disparities and Expanding Access to HSCT and CAR T-Cell Therapy

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Abstract

Cellular therapies, such as autologous hematopoietic stem cell transplantation (auto-HSCT), allogeneic HSCT (allo-HSCT), and chimeric antigen receptor (CAR) T-cell therapy, have transformed the field of malignant hematology, offering curative and life-extending potential that was never previously available. Yet despite these therapeutic advances, persistent disparities in access by race, ethnicity, socioeconomic status, geography, and practice setting block the equitable delivery of these therapies. Black and Hispanic patients remain significantly less likely to receive auto-HSCT for multiple myeloma, even after referral to transplant centers. Under-representation of racial and ethnic minorities in donor registries has historically limited access to allo-HSCT, though the advent of post-transplant cyclophosphamide (PTCy)-based platforms and haploidentical donors is reshaping this landscape. CAR T-cell therapy, which primarily occurs at large academic medical centers, imposes geographic, logistical, and financial burdens that disproportionately affect underserved populations. This review evaluates the multilevel barriers to HSCT and cellular therapy access, highlights recent advances in the field, and proposes actionable strategies at the patient, provider, system, and policy levels to advance equity in cellular therapy delivery.

Take Home Messages

1. Major disparities in access to HSCT and CAR T-cell therapy persist across race/ethnicity, socioeconomic status, geography, and practice setting, despite the transformative potential of these therapies.
2. PTCy-based haploidentical and mismatched unrelated donor transplantation has substantially reduced the historical donor-access barrier, making allo-HSCT feasible for nearly all patients regardless of ancestry, with survival comparable to matched unrelated donor transplants.
3. CAR T-cell access remains constrained by geography, cost, caregiver requirements, and manufacturing delays, disproportionately affecting underserved patients.
4. Expanding equity will require both therapeutic innovation and system-level change, including outpatient/decentralized CAR T-cell delivery, bispecific antibodies, early referral, patient and financial navigation, and policy reform.

Introduction

Over the past three decades, the field of malignant hematology has been revolutionized by the development and refinement of cellular therapies. Autologous hematopoietic stem cell transplantation (auto-HSCT) remains the standard of care for eligible patients with multiple myeloma (MM) and relapsed lymphomas, serving as a key consolidative approach to enhance progression-free survival. In contrast, allogeneic HSCT (allo-HSCT) offers curative potential for acute leukemias, myelodysplastic syndromes, and other high-risk hematologic disorders. Chimeric antigen receptor (CAR) T-cell therapy has recently emerged as a transformative treatment modality for relapsed or refractory B-cell malignancies and multiple myeloma, with six U.S. food and drug administration (FDA)-approved products and rapidly expanding indications. Despite these advances, a paradox persists: as cellular therapies become increasingly effective, they remain inequitably distributed. Racial and ethnic minorities, patients of lower socioeconomic status, those residing in rural or geographically remote areas, and individuals treated in community practice settings face systematic barriers to accessing these potentially life-saving treatments. The consequences of this access gap are unfortunately not just theoretical; they translate directly into preventable, inequitable morbidity and mortality.

This review examines barriers to cellular therapy access organized across a multilevel framework encompassing patient-level factors (financial toxicity, caregiver burden, health literacy), provider-level factors (referral patterns, implicit bias, knowledge gaps), system-level factors (geographic concentration of centers, insurance and payer barriers, workforce limitations), and structural factors (racism, poverty, policy failures). For each therapy modality, auto-HSCT, allo-HSCT, and CAR T-cell therapy, the evidence for disparities is reviewed, followed by a unified discussion of emerging solutions and actionable strategies.

Disparities in Access to Autologous HSCT – The Case of Multiple Myeloma

Multiple myeloma is the most common indication for auto-HSCT, with over 10,000 auto-HSCT performed annually, and serves as a critical lens through which to examine access disparities.[1] The disease disproportionately affects Black populations, who have approximately twice the incidence of myeloma compared with White populations and present at a younger age.[2] The National Comprehensive Cancer Network (NCCN) Guidelines for MM explicitly acknowledge that Black/African American individuals have the highest rate of myeloma of any racial/ethnic group and more severe symptoms at presentation, including increased anemia, higher calcium levels, worse renal dysfunction, and more extramedullary disease.[3] Despite this higher disease burden, significant barriers still exist that prevent Black patients from undergoing HSCT, with some studies reporting that African Americans are 37% less likely to undergo auto-HSCT for myeloma when compared to White patients.[4] Similarly, a large National Cancer Database analysis of 171,261 patients diagnosed between 2004 and 2017 confirmed that Black patients had significantly reduced access to HSCT compared with White patients (OR 0.69, $p < 0.0001$).[5] In a Center for International Blood and Marrow Transplant Research (CIBMTR) analysis that evaluated

the stem cell transplant utilization rate (STUR) for multiple myeloma, the authors noted that while utilization increased across all groups from 2008 to 2014, it remained substantially lower among non-Hispanic Blacks (12.2% to 20.5%) compared with non-Hispanic Whites (22.6% to 7.8%).[6] Critically, these disparities persist even after referral to a transplant center. Wu et al. analyzed 1,266 patients seen at an academic transplant center for myeloma consultation between 2012 and 2022 and found that non-Hispanic White race was associated with more than three-fold higher odds of receiving auto-HSCT compared with non-Hispanic Black race (OR 3.32; 95% CI, 2.17–5.08; $p < 0.0001$), even after controlling for age, cytogenetics, stage, comorbidities, and time from diagnosis to consultation.[7] Figure 1 showcases the relative utilization ratio for auto-HSCT across different races and ethnicities, emphasizing that the highest utilization of auto-HSCT is in non-Hispanic White patients and that auto-HSCT utilization declines with age.[8] Ultimately, these disparities in access translate to inferior outcomes for minority patients.

The question of whether race affects outcomes in MM is still undefined. Several studies suggest that when Black patients receive equivalent treatment, outcomes are comparable or even superior to those of White patients. In the Connect MM Registry, African American patients who received auto-HSCT had significantly longer overall survival (OS) compared with White patients who underwent auto-HSCT (hazard ratio (HR) 0.56; 95% CI, 0.35–0.89; $p = 0.014$).[9] Similarly, a single-center analysis demonstrated that Black patients who underwent frontline auto-HSCT had superior progression-free survival (PFS) compared with White patients (5.9 vs. 3.6 years, $p = 0.039$), despite disparities in optimal induction therapy.[10] These findings underscore that the biology of myeloma in Black patients may be inherently favorable, and that observed outcome disparities may be driven by differential access to and utilization of effective therapies.

Beyond race and ethnicity alone, broader measures of social determinants of health further illuminate the structural barriers affecting auto-HSCT outcomes. A retrospective analysis of 225 MM patients undergoing auto-HSCT evaluated the impact of the U.S. Centers for Disease Control and Prevention (CDC) Social Vulnerability Index (SVI)—a composite measure encompassing socioeconomic status, household characteristics, racial and ethnic minority status, and housing type and transportation.[11] Higher composite SVI values were significantly associated with lower odds of both PFS (OR 0.52; 95% CI, 0.41–0.66; $p < 0.01$) and OS (OR 0.59; 95% CI, 0.46–0.76; $p < 0.01$) at five years post-transplant. Notably, the composite SVI exerted a stronger effect than any individual subtheme, suggesting a synergistic impact of overlapping vulnerabilities.

Delayed referral or under-referral also remains a critical contributor to disparities. Bhatnagar et al. found that referral for transplant was significantly delayed in Black patients (median 1.3 years vs. 0.9 years for White patients, $p = 0.003$).[12] Saunders et al. confirmed that the median time from diagnosis to SCT was longer for African American than White patients (255 vs. 225 days), and African American patients were less likely to receive auto-HSCT (OR 0.66; 95% CI, 0.58–0.76).[13] Consequently, longer time from diagnosis to consultation has been independently associated with lower auto-HSCT utilization (OR 0.97; 95% CI, 0.95–0.98; $p < 0.0001$).[7] Whether these delays stem from implicit bias, outdated perceptions about transplant eligibility, or knowledge gaps regarding the safety of auto-HSCT in diverse populations remains unclear.

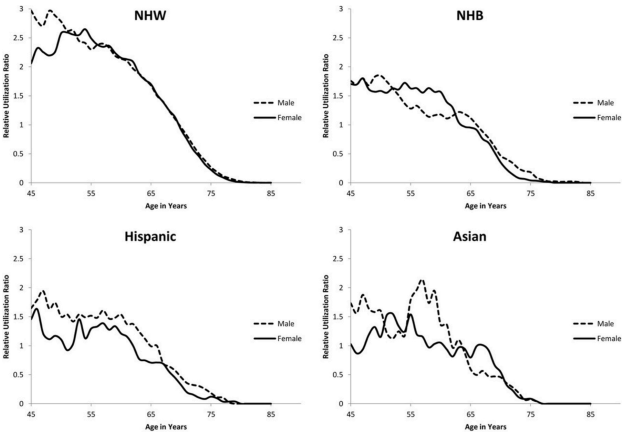

Figure 1. Relative utilization ratio for Auto-HSCT in MM according to sex and age in the different race and ethnicity categories. Figure reproduced with permission from Costa LJ, Huang JX, Hari PN. Disparities in utilization of autologous hematopoietic cell transplantation for treatment of multiple myeloma. Biol Blood Marrow Transplant. 2015;21(4):701-706. doi:10.1016/j.bbmt.2014.12.024

Disparities in Access to Allogeneic HSCT

For decades, the primary barrier to allo-HSCT for racial and ethnic minorities was the inability to identify a fully Human Leukocyte Antigen (HLA)-matched donor. Patients of African descent harbor substantially greater HLA diversity than patients of European descent, a consequence of longer evolutionary history and greater genetic mix, which means that even with large donor registries, the probability that two unrelated individuals from these populations share identical HLA genotypes is markedly lower.[14] Traditional reliance on 8/8 HLA-matched unrelated donors (MUDs) created a profound inequity: while White patients of European descent have a 75% probability of finding a MUD through registries, this probability drops to 16-19% for Black patients and is similarly reduced for other minority groups.[15] This disparity reflects both the underrepresentation of racial and ethnic minorities in volunteer donor registries and the greater HLA diversity within these populations.

However, the development and widespread adoption of post-transplant cyclophosphamide (PTCy)-based graft-versus-host disease (GVHD) prophylaxis represents a significant advancement with profound implications for health equity. PTCy has enabled the safe use of HLA-haploidentical related donors, available to virtually every patient regardless of race or ethnicity, and HLA-mismatched unrelated donors (MMUDs), dramatically expanding the donor pool.[16] In a CIBMTR analysis of 10,025 HSCT recipients from 2017–2021, the authors demonstrated that MMUD HSCT with PTCy achieved similar OS (HR 0.96; 95% CI, 0.82–1.11; p = 0.60) and GVHD-free, relapse-free survival (HR 0.90; 95% CI, 0.79–1.02; p = 0.10) compared with MUD HSCT with PTCy.[17] Notably, the benefit from PTCy was independent of patient ancestry, and global registry-level analysis reported that MMUD inclusion increased donor availability regardless of ancestry.[17] In a National Marrow Donor Program (NMDP)-sponsored phase II trial of MMUD bone marrow transplantation with PTCy, 80 patients were enrolled over 11 US transplant centers, with 48% of patients being ethnic minorities.[18] Notably, 39% of donor-recipient pairs were only matched at 4–6 of 8 HLA alleles, yet survival outcomes were comparable to controls.[18] Haploidentical transplantation with PTCy has yielded similarly encouraging results. Bashey et al. reported that survival and disease-free survival were not significantly different between haploidentical recipients and HLA allele-matched unrelated donor recipients, and that haploidentical recipients had lower rates of chronic GVHD.[19,20]

Umbilical cord blood transplantation (UCBT) has further contributed to broadening donor access, particularly for patients without a matched unrelated or haploidentical donor. Historically, standard UCBT has been limited by small unit cell doses and prolonged time to engraftment, disadvantages that disproportionately affect minority patients, for whom available cord blood units are often smaller and less well-matched.[21,22] However, the approval of omidubicel, an ex vivo expanded UCB product, addresses these limitations directly. In a phase 3 randomized trial, Horwitz et al. demonstrated that omidubicel significantly accelerated hematopoietic recovery compared with standard UCBT, with a median time to neutrophil engraftment of 12 days versus 22 days ($p < .001$) and reduced incidence of bacterial and fungal infections.[23] By overcoming the cell-dose barrier through ex vivo expansion, omidubicel has the potential to make UCBT a more viable option for diverse patient populations who previously faced inferior outcomes with this modality. Ultimately, real-world data from the CIBMTR confirm that ethnically diverse patients are undergoing allo-HSCT at higher rates, largely using haploidentical donors, UCB expansion technologies, and incorporation of PTCy.[24]

Despite these advances, significant barriers remain. A critical gap exists in community physician awareness of the changed donor landscape. The American Society for Transplantation and Cellular Therapy (ASTCT)-NMDP ACCESS Initiative reported that transplant guidelines are not distributed to community hematologists/oncologists, and thus these clinicians may operate under outdated assumptions that minority patients are unlikely to find suitable donors, leading to premature exclusion from transplant consideration.[25] Transplant centers also remain geographically concentrated at large academic medical centers, creating access barriers for patients in rural and underserved areas.[26] Workforce limitations, including shortages of transplant physicians, advanced practice providers, and specialized nursing staff, further limit capacity and availability.[27] Figure 2 summarizes the complexities and barriers patients face in obtaining cellular therapies.

Figure 2. Summary of pathways and barriers to cell therapies. This figure illustrates the complex crosstalk necessary for a successful journey towards equitable access to cellular therapies. Figure reproduced with permission from Munshi PN et al. Breaking Access Barriers to Autologous Stem Cell Transplantation and Chimeric Antigen Receptor T Cell Therapy in Hematologic Malignancies-an ASTCT-NMDP ACCESS Initiative. Transplant Cell Ther. doi:10.1016/j.jtct.2026.02.001

Disparities in Access to CAR T-Cell Therapy

CAR T-cell therapy has been approved for multiple indications across B-cell acute lymphoblastic leukemia (ALL), diffuse large B-cell lymphoma (DLBCL), mantle cell lymphoma, follicular lymphoma, and MM, with rapid expansion of both approved products and indications. Despite its potentially lifesaving role, access remains inequitable.[28] Ahmed et al. reported that both Black patients with relapsed/refractory large B-cell lymphoma and those in the lowest income group were less than half as likely to be CAR T-cell recipients compared to White patients (OR 0.44, p = 0.01) and those in the highest income group (OR 0.44, p = 0.002).[29] Driving time of 120 to 240 minutes to the nearest treatment center was also associated with reduced likelihood of receiving CAR T-cell therapy (OR 0.64, p = 0.04).[29] An analysis of Medicare data from 2007-2020 showed that only 5% of patients on Medicare received CAR T-cell therapy and were more likely to live in high-income regions (OR, 1.176; P = .004).[30] Other studies confirmed that patients residing in areas of lower socioeconomic status had decreased odds of completing CAR T-cell therapy.[31]

Financial toxicity is another underrecognized barrier to cellular therapy access and outcomes. CAR T-cell therapy alone costs roughly $400,000, and most therapies are administered inpatient, requiring prolonged hospitalizations that accrue further costs.[32] Beyond direct treatment costs, indirect expenses such as lost wages, caregiver burden, travel, lodging, and prolonged post-discharge monitoring requirements disproportionately affect low-income and minority patients, who are more likely to be uninsured or underinsured and less likely to have the financial reserves to afford these expenses.[33] Among indirect costs, the caregiver requirement stands out as one of the most significant non-medical barriers to cellular therapy access. A national survey of 31 NCCN member institutions found that over 80% of centers required a dedicated caregiver, along with local housing and transportation, for patients to proceed with HSCT or CAR T-cell therapy.[34] The ASTCT expert panel opinion on outpatient CAR T-cell administration further recommends that patients "have an acceptable caregiver with one backup", requirements that disproportionately affect patients who are socially isolated, of lower socioeconomic status, or from communities with limited family support.[35] Compounding these financial and logistical barriers is the phenomenon of "waitlist mortality", in which patients die from disease progression before receiving CAR T-cell therapy due to long manufacturing times.[36] Figure 3 showcases the survival function of patients in the JULIET trial who remained eligible for CAR T-cell infusions over time.

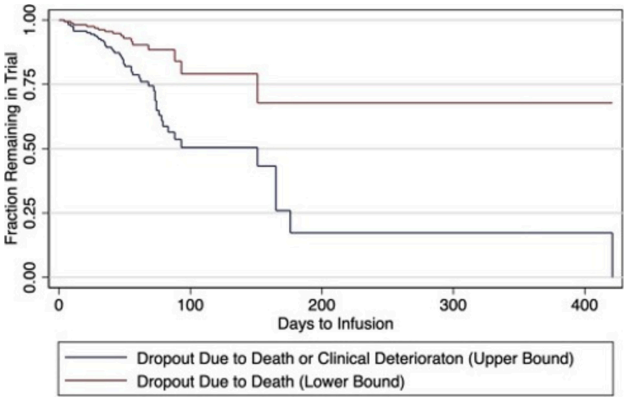

Figure 3. Proportion of patients remaining eligible for CAR T-cell infusion over time (JULIET trial). Kaplan-Meier estimates show eligibility for infusion; the lower bound accounts for ineligibility due to death, and the upper bound includes death or non-mortality dropout. Reproduced with permission from Chen et al., Value in Health. 2022. doi:10.1016/j.jval.2022.02.007.

Emerging Solutions and Strategies for Broadening Access

Addressing the disparities outlined above requires coordinated action across multiple stakeholders. The following sections describe emerging therapeutic, technological, and systemic strategies organized by domain.

Bispecific Antibodies as a Bridge to Equity

The emergence of BsAbs as an alternative or complement to CAR T-cell therapy has significant implications for access and equity. BsAbs are off-the-shelf agents that avoid many of the logistical challenges associated with CAR T-cell products, including the need for leukapheresis, lymphodepleting chemotherapy, centralized manufacturing, and prolonged lead times.[37] Their lower toxicity profiles and outpatient dosing capabilities, make them particularly attractive for patients who cannot access or tolerate CAR T-cell therapy.[38] A meta-analysis by Kim et al. reported lower rates of grade ≥3 cytokine release syndrome (CRS) in patients treated with BsAbs compared to CAR T-cell therapy (2% vs. 8%) in DLBCL.[39]

However, BsAbs are not a direct substitute for CAR T-cell therapy in every setting.[40] In relapsed/refractory DLBCL, a meta-analysis of 16 studies comprising 1,347 patients found that CAR T-cell therapy achieved higher complete response rates than BsAbs (51% vs. 36%, $p = 0.01$) and superior 1-year progression-free survival (44% vs. 32%, $p = 0.01$).[39] In heavily pretreated patients with relapsed/refractory follicular lymphoma, certain trials report complete response rates of 79% and 94% for axicabtagene ciloleucel and lisocabtagene maraleucel, respectively, compared to a 62% overall response rate for mosunetuzumab, a CD20xCD3 BsAb.[41] However, it is imperative to note that these agents have not been compared in a prospective, randomized fashion, and thus, this data must be considered in the context of cross-trial comparisons. Ultimately, CAR T-cell therapy offers higher complete response rates and potentially more durable remissions, particularly in aggressive disease, but BsAbs may serve as an important bridge or alternative for patients facing access barriers.

Decentralizing CAR T-Cell Delivery

CAR T-cell delivery remains concentrated at large academic medical centers, creating significant geographic and logistical barriers. However, real-world data support the feasibility of outpatient CAR T-cell administration. Multiple single-center studies have demonstrated that patients can receive CAR T-cell infusions in the outpatient setting, with some patients never requiring hospitalization.[42,43] A community oncology practice reported treating 41 patients with outpatient CAR T-cell therapy between 2022 and 2024, with 49% of patients requiring hospital admission throughout treatment, and remission rates at day 100 and one year consistent with published data.[44]

Several complementary models for expanding CAR T-cell delivery beyond large academic centers are emerging. Remote patient monitoring (RPM) technologies involve wearable devices that collect vital signs and patient-reported symptoms, allowing for early detection of toxicity and reducing the need for treatment center proximity.[45,46] Patient symptom questionnaires, post-visit phone calls, and telehealth visits can further ensure safe monitoring for adverse events.[47] Local manufacturing models are also being advocated to reduce manufacturing times and logistical complexity, bringing production closer to the patient rather than relying on centralized facilities. This decentralized approach has already been implemented internationally, where investigators in low- and middle-income countries have demonstrated the potential for dramatic cost reductions. In both Mexico and India, investigators have estimated the cost of manufacturing CAR T-cell products to be approximately $32,000-35,000 per product, representing roughly a 90% reduction compared to commercial U.S. pricing.[48,49] These international experiences offer a proof of concept that could inform efforts to expand access within the United States, particularly for patients in rural and underserved communities who face the greatest logistical barriers to reaching centralized academic manufacturing facilities. However, while expert panel opinions support outpatient CAR T-cell administration and decentralized delivery, they emphasize that safe delivery requires 24/7 access to specialized cancer care, proximity to hospital services, established workflows for rapid triage and management of toxicities, and evolution of regulatory and accreditation frameworks to ensure uniform product quality across geographically dispersed sites.[47,50]

Additionally, allogeneic "off-the-shelf" CAR T-cell products, derived from healthy donors and manufactured in advance as cryopreserved batches,

represent a promising strategy to further reduce barriers to timely treatment.[51] Unlike autologous CAR T-cell therapy, allogeneic products eliminate the need for patient-specific leukapheresis and individualized manufacturing, thereby avoiding the prolonged lead times.[52] Phase I data from the ALPHA/ALPHA2 studies of an allogeneic CD19 CAR T-cell product demonstrated a median time from enrollment to lymphodepletion of just two days.[53] Ultimately, batch manufacturing from healthy donor T-cells can allow for scalable production with standardized quality and decreased costs.[54] However, allogeneic CAR T-cell therapy remains investigational and faces unique challenges, including the risk of graft-versus-host disease and host-mediated immune rejection.[55]

Addressing Financial Toxicity

Poverty has been identified as a fundamental barrier to access across all cellular therapies, with variations in Medicaid coverage, the complexity of insurance navigation, and the financial toxicity extending to caregivers all contributing to inequitable access.[25] Several evidence-based strategies for mitigating financial toxicity have been described. Oncology financial navigation (OFN) programs, in which trained financial navigators provide counseling, resource identification, and insurance assistance, have demonstrated significant decreases in financial toxicity scores for both patients and caregivers.[56] Other approaches emphasize culturally appropriate, universal financial hardship screening tools, specialized training for financial navigators, and integration of screening into daily workflows.[57] The University of Kansas Cancer Center developed an artificial intelligence (AI)-based platform that integrates demographic information, social determinants of health, and financial toxicity screening tools to ultimately improve scalability and reduce disparities.[58]

Provider Education and Referral Optimization

Continuing medical education (CME) programs should address evolving indications and eligibility criteria for cellular therapies, with particular emphasis on dispelling outdated myths. Key messages include: (1) there is no absolute age cutoff for HSCT and eligibility should be based on functional status and comorbidity assessment rather than chronological age; (2) in the PTCy era, nearly every patient has access to a potential allogeneic donor regardless of race or ethnicity; (3) CAR T-cell therapy is increasingly deliverable in outpatient and community settings; and (4) racial and ethnic minority patients who receive standard-of-care cellular therapies achieve outcomes comparable to or better than those of White patients.[59] Community colleagues should be encouraged to reach out to cellular therapy specialists early on in a patient's treatment course to ensure that eligible patients are identified early and facilitate real-time consultation.

Patient Navigation and System-Level Interventions

Patient navigation programs and support programs should be scaled and adapted to the cellular therapy setting. Culturally and linguistically appropriate resources are essential for engaging diverse patient populations, and in-person or video translation should be available when possible. Caregiver support services, including respite care, financial assistance, and psychosocial support, should also be offered to families early, with regular check-ins to ensure needs are being met. Standardized referral algorithms embedded in electronic health record systems can ensure that all eligible patients are systematically identified for cellular therapy evaluation, reducing reliance on individual provider judgment and mitigating the impact of implicit bias. These algorithms should incorporate validated frailty assessments and comorbidity indices rather than arbitrary age cutoffs.

Policy-Level Interventions

At the policy level, interventions should include insurance reform to ensure consistent coverage of cellular therapies across state Medicaid programs, elimination of prior authorization delays for time-sensitive treatments, and employer and disability protections during treatment.[60] The ASTCT-NMDP ACCESS Initiative has called for the development of physician-led advocacy teams to promote targeted campaigns for policy change at the state and federal levels.[25]

Conclusion

Substantial disparities in access to cellular therapies exist across various races, ethnicities, socioeconomic statuses, geographies, and practice settings. These inequities are not inevitable consequences of biology or patient preference; they are the products of modifiable barriers at the patient, provider, system, and structural levels. Over the past decade, multiple advancements in the field of malignant hematology have revolutionized how we treat various diseases. PTCy-based transplant platforms have effectively eliminated the donor barrier that historically excluded minority patients from allo-HSCT. Bispecific antibodies and allogeneic CAR T-cell products offer an off-the-shelf alternative, potentially bypassing many of the logistical barriers to CAR T-cell therapy. Outpatient and decentralized CAR T-cell delivery models, supported by remote patient monitoring technologies, are demonstrating feasibility and safety. Yet, translating these advances into equitable access requires coordinated action across multiple stakeholders. Clinicians must ensure timely referral of all eligible patients for cellular therapy evaluation, health systems must invest in patient navigation, financial counseling, and social support infrastructure, and policymakers must address insurance coverage gaps and eliminate prior authorization delays for time-sensitive therapies. Ultimately, achieving these goals will require sustained commitment, accountability, and collaboration across the entire cellular therapy ecosystem.

Conflict(s) of Interest

The authors declare no conflicts of interest.

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Informed Consent

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Author Contributions

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Drafting of the manuscript: LE, IV
Critical revision of the manuscript: LE, IV
All authors (LE, IV) approved the final version of the manuscript and agree to be accountable for all aspects of the work, in accordance with the International Committee of Medical Journal Editors criteria.

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