

# Finding Equity in Value

Racial and Health Equity Implications  
of U.S. HTA Processes



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## **ABOUT IVI**

The Innovation and Value Initiative (IVI) is a 501(c)3 nonprofit organization whose mission is advancing the science of value assessment in healthcare. IVI is a membership organization with both organizational and individual members. We partner with leading organizations and researchers to put patients first, ensure transparent research, and widen the stakeholder tent in order to drive scientific advancement for the benefit of all people and communities.

## **ABOUT SICK CELLS**

Sick Cells is a national advocacy nonprofit for sickle cell disease founded on February 28, 2017, by siblings Ashley and Marqus Valentine. Sick Cells' mission is to elevate the voices of the SCD community and their stories of resilience. In highlighting the grave disparities this community faces, they hope to influence decision makers and propel change at all levels.

# Racial Equity and Value Assessment

## FINDING EQUITY IN VALUE

This paper is co-created by [IVI](#) and [Sick Cells](#) in pursuit of a shared goal to advance racial and health equity in and through the practice of HTA in the U.S.

Part of IVI's multi-year [Health Equity Initiative](#), this goal reflects one of the core [Principles for Value Assessment](#) that guide IVI's work—the fundamental need for HTA to advance health equity.

This work reinforces Sick Cells' commitment to promote health equity and elevate community voices in research, policy, and value assessment.

### **Racism, both interpersonal and structural, is the primary cause of health inequities,**

with profound impacts on the health and wellbeing of communities of color.<sup>1</sup> While the effects of racism are clearly visible in the disproportionate impact of the SARS-CoV-19 pandemic on Black, Indigenous, and People of Color (BIPOC) individuals and communities, these racial disparities are not new. For example, the average life expectancy for Black Americans was more than four years lower than white Americans even before the pandemic.<sup>1,2</sup> Black and Native Americans have the highest asthma rates compared to other ethnicities.<sup>3</sup> Racial biases impact pain assessments and treatment recommendations in hospital settings.<sup>4</sup> Conversations about health inequities<sup>†</sup> have been ongoing for years, but disparities persist.<sup>5</sup>

In the United States, the healthcare system is vast and involves many actors. This paper focuses on how racism can influence health technology assessments (HTAs) and determination of “value” when assessing new treatments.

High launch prices for new therapies with uncertain, but potentially significant, clinical benefits have prompted both public and private payers to increasingly request better insights into “value”—benefits relative to cost—as a driver for benefit design, care delivery, and payment. This has prompted growing interest in and use of systematic health technology assessment (HTA) approaches—including economic analyses and use of simulation models—to inform decisions about coverage, access, and out-of-pocket expenses. These decisions directly affect the health and financial outcomes of patients, making the methods, evidence basis, and uses for HTA a major focus of debate.

When decisions affecting coverage and access to potentially beneficial therapies are based on their estimated value, several vital questions arise, including, “Value for whom?” and whether clinical and other data inputs represent real-world patient communities and lived experience. These decisions bear significant consequences for equity and disparities in outcomes.<sup>6</sup> As the use of HTA gains increasing traction in the U.S., it is especially important to

<sup>†</sup> See Appendix Table 1 for a Glossary of Key Terms.



HTA generates insights and recommendations to **shape the prioritization, coverage, and reimbursement of therapies** for a given diagnosis.

understand and explore how racism is built into the current structures of the HTA process, and how that widens or contributes to existing health and racial inequalities. This paper discusses the potential implications of flawed or incomplete analyses for health and racial equity in future decision-making and identifies recommendations for improvements in key focus areas to advance racial equity in HTA.

## HTA AS A PROCESS THAT IMPACTS EQUITY

Based on estimates of therapies' relative value (value assessments), HTA generates insights and recommendations to shape the prioritization, coverage, and reimbursement of therapies for a given diagnosis.<sup>†</sup> These findings and recommendations are the results of complex processes made up of a series of choices—who is included in the process and how; what treatments are compared; the evidence used for comparison; which stakeholders' perspectives will be reflected; the methods used in economic analyses; how these analyses are used in generating recommendations; and many more (see **Figure 1**).

Ultimately, the results of HTA depend on the composition and outcomes of the choices arising in the HTA process. Each of these choices is shaped by multiple factors, with potential implications for racial equity and health equity in general. Identifying racial equity concerns in HTA and potential levers for change requires that we first understand how the environment in which HTA is conducted influences these choices.

In this paper, we adapt the [Racial Equity and Policy \(REAP\) Framework](#) to assess the potential equity implications of the HTA process. Recently introduced as a framework for understanding racial equity implications in the policy-making process, it identifies three key considerations affecting racial equity: decentralization, disproportionality, and voice.<sup>7</sup> With minor adaptations, this framework provides similarly valuable insights that can point the way for necessary improvement in the practice and use of HTA in the U.S.

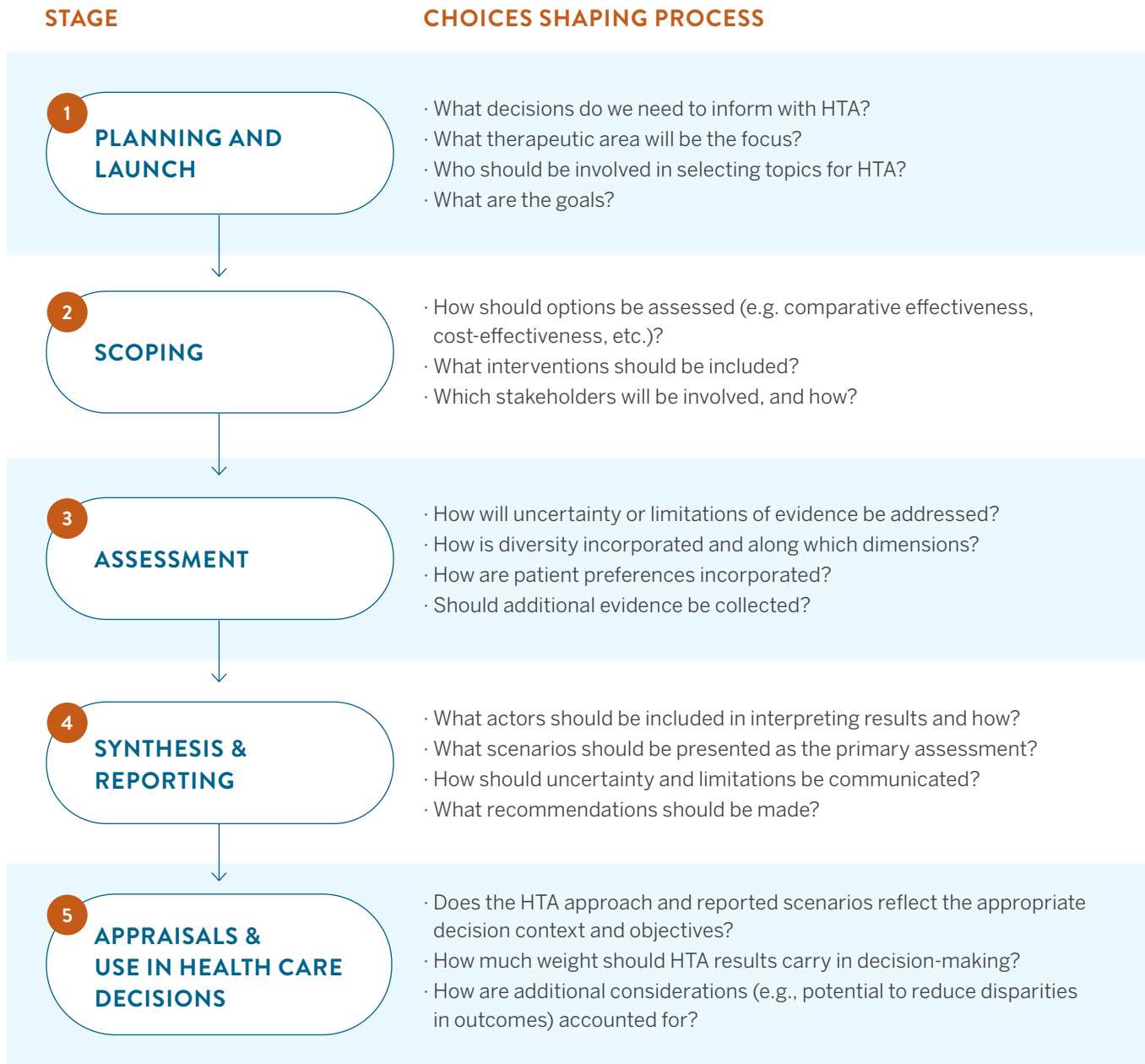
### In the following sections, we:

- **Describe the environmental features** that shape choices in HTA
- **Apply the REAP Framework** to assess environmental features influencing HTA
- **Describe implications for racial equity** that arise from these various influences
- **Explore these influences** using as a specific case the Institute for Clinical and Economic Review (ICER) 2019 review of sickle cell disease (SCD) therapies<sup>8</sup>
- **Identify high-priority issues** in HTA processes and opportunities to advance equity in and through U.S. HTA

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<sup>†</sup> The terms "value assessment" and "HTA" are often used interchangeably. For simplicity and clarity, we refer to the two jointly as HTA.

Figure 1: Examples of choices that shape the multi-stage HTA Process



Note: HTA: health technology assessment.

# Environmental Features Shaping HTA

Modern HTA is the result of many decades of effort in economics and related fields,<sup>9,9</sup> and these technical underpinnings are a central influence on HTA processes—but far from the only one.

Many features of the environment shape HTA processes, “producing and structuring” the choices in the process and shaping the meaning and consequences of those choices (**Figure 2**). These include the entities and individuals involved in HTA processes (actors), the relationships between them (networks), and the various facets of the social, cultural, and economic landscape in which they operate (institutions, ideas, context, and events) (see **Table 1**).<sup>7</sup>

**Table 1: Six major features of HTA environment**

1	<b>INSTITUTIONS</b>	Create the rules and constraints that structure the behavior of [HTA] actors
2	<b>ACTORS</b>	Organizations and individuals exerting an influence on the process
3	<b>NETWORKS</b>	Patterns of relationships between various actors
4	<b>IDEAS</b>	Framing the discourse, logic, and justification for [HTA], ideas are an ever-present part of the [HTA] environment that can sometimes channel racism” or enable perpetuation of biases and inequities
5	<b>CONTEXT</b>	Policy actors and institutions are embedded within specific economic, social, and political contexts that fundamentally shape efforts to enact, implement, and advance equitable [HTA]
6	<b>EVENTS</b>	Critical events that bring policy issues into sharp relief also often accentuate existing racial inequities

Note: Adapted from Michener 2022<sup>7</sup>

Figure 2: Features of the HTA environment



Note: The lists of examples for each environmental factor are intended as illustration and are not comprehensive. Adapted from Michener 2022<sup>7</sup>

## 1 INSTITUTIONS

In many countries abroad, HTA conducted and regulated by governmental bodies is an established part of the healthcare system. For example, HTAs in Europe are regulated by the European Commission,<sup>10</sup> and in the United Kingdom, the HTA process is regulated by the National Health Service.<sup>11</sup> In contrast, HTA in the U.S. is not conducted by any central body or within public programs. HTAs do not interact with or fall under the influence of any public institutions, nor is it formally regulated.<sup>12</sup>

Instead, U.S. HTA is conducted by teams of individuals within insurers, pharmaceutical manufacturers, nonprofits, professional organizations, and others, as well as by researchers working within academia or as consultants. Throughout this paper, we refer to all institutions within which HTA is conducted as “HTA organizations.”

## 2 ACTORS

HTA is conducted as an initiative of a given HTA organization, and those organizations—and the teams of individual staff members and consulting experts—are the principal actors in HTA processes, managing the process and possessing ultimate authority over decision making. Decisions about the pricing, coverage, utilization, and reimbursement of therapies have consequences for a wide range of stakeholders such as public and private payers, health plans, manufacturers and technology developers, and patients, who are directly or indirectly affected by coverage and access policies. All of these stakeholders play a potential role in HTA processes that inform these decisions.

## 3 NETWORKS

The various actors outlined above interact with each other in myriad ways within and outside of HTA processes. For the most part, networks’ influence on the HTA process depends on the strength and structure of connections with HTA organizations and their teams managing the process.

## 4 IDEAS

Ideas frame the discourse, logic, and justification underlying the execution, interpretation, and outcomes of HTAs.<sup>7</sup> HTA processes are rooted in scientific evidence and analysis but intended to inform real-world decisions, and broader social and cultural ideas and biases play an important role in HTA choices. Even “objective” scientific concepts and practices are influenced by ideas, past and present, that frequently inform actors’ perceptions and judgments in fundamental and sometimes unconscious ways.

## 5 CONTEXT

Numerous contextual factors shape HTA processes. For example, the structure, content, and results of HTA are dependent upon the availability, quality, and relevance of scientific evidence and outcomes data.

## 6 EVENTS

Periodically, specific events change the context and perception of HTA. For example, high-profile drug introductions have elevated debates about value and drug pricing to front-page stories (e.g., Sovaldi for treatment of hepatitis C), while the SARS-CoV-19 epidemic and the racial reckoning sparked by the murders of George Floyd, Breanna Taylor, Ahmaud Arbury, and many others have brought the importance of racial and health equity—and its role in HTA—to the forefront of discussions in health care.



# Examination of Racial Equity in U.S. Health Technology Assessment

## KEY CONSIDERATIONS FOR RACIAL EQUITY

The REAP Framework<sup>7</sup> points to three key considerations for assessing racial equity in processes like creation of public policy<sup>8</sup> and, with our minor adaptations<sup>‡</sup>, practice of HTA:

- **Disproportionality:** “refers to the way [HTAs] differentially allocate benefits and burdens to racial groups.”
- **Decentralization:** “the level of [organization and geography at and] through which a given policy benefit or burden is designed or implemented.”
- **Voice:** “the ability of communities of color to shape the [HTA] environment.”

<sup>‡</sup> See Appendix Table 2 for additional information.

### Understanding the environmental features that shape the HTA process is the first step,

but assessing the implications of the HTA enterprise as a whole for racial and health equity requires a closer look. Examining U.S. HTA in terms of the considerations outlined in the REAP Framework reveals ways in which the HTA environment may directly or indirectly impact racial equity in coverage and access decisions, helping to identify key areas of concern and potential steps to improve HTA processes.

### BIASES IN EVIDENCE AND METHODS

Economic value assessment, especially when based on cost-effectiveness analysis (CEA), depends on mathematical models intended to predict outcomes in a simplified version of the real world. As a result, any biases or gaps in these methods or inputs will naturally carry forward into the estimates of cost-effectiveness (and therefore, value) produced by these assessments.<sup>13,14</sup> Given the widespread and growing use of HTA to support coverage and reimbursement, this aspect alone has the potential to produce policy and delivery decisions that reinforce or worsen existing racial biases in health care.

HTA depends upon scientific evidence and data to simulate real-world processes, but the accuracy of such analyses depends upon how well the evidence used reflects the lived experience of all patients with a given health condition. This requires a representative sample population, but BIPOC communities—along with women, children, low-income communities, LGBTQIA+ communities, and certain geographical groups—are regularly and systemically underrepresented.<sup>15</sup> Such underrepresentation is particularly well-documented in the context of randomized clinical trials,<sup>16</sup> but this pattern is also often true of observational studies, survey data, and

other evidence-generating research.<sup>17-20</sup> As a result, clinical evidence tends to be biased toward more educated and higher-income populations.<sup>15,21</sup> That evidence drives results in HTA, and therefore, coverage and access decisions may be biased toward maximizing value to those same populations.

## DISPROPORTIONATE POWER IN HTA DECISIONS


The centralization of decision authority, and the resulting power dynamics in HTA decision making, have far-reaching implications for racial equity.

HTA efforts in the U.S. are generally “owned”—directed, managed, executed, and communicated—by dedicated teams within independent organizations and academic or technical experts. These organizations and individuals have ultimate decision authority in HTA processes, bound to varying degrees by institutional constraints and other factors. The influence afforded to other actors, and often the role other actors can play, is decided by these same teams.

A rigorous scientific approach to HTA is essential for ensuring estimates of comparative effectiveness and value are as accurate, relevant, and credible as possible. Consequently, these HTA teams are predominantly composed of scientific experts with specialized training in economics, modeling, and other related disciplines, resulting in the concentration of decision authority within a small professional community. Due to persistent structural racism, members of this community are disproportionately white and relatively affluent compared to the diverse populations potentially impacted by their decisions. While the technical complexity of HTA makes such expertise a necessity, making it a prerequisite for decision authority can exclude BIPOC voices and other communities and perpetuate existing inequities.

The gap between HTA teams and affected communities is widened by a significant knowledge gap—the expert community shares specialized knowledge about HTA and related sciences but often lacks knowledge of the lived experiences and priorities of other affected communities, and vice versa. The resulting difference in perspective and decision approach has consequences for equity, particularly when HTA focuses on therapies for medical conditions affecting BIPOC communities and other underrepresented populations.

As part of a larger scientific community, HTA teams’ perspectives and decision making are most heavily influenced by relationships with “peers” with similar specialized knowledge. Strong networks in the scientific community connect clinical, academic, and technical experts and the individuals conducting HTA; these networks of relationships are made stronger by a sense of group identity characterized by similar experiences, training, working in academia, and in some instances, similar cultural and ethnic backgrounds. Being “insiders” places these individuals in a privileged position that gives their voices more weight.



**BIPOC**—along with **women, children, low-income communities,** certain **geographical groups** and others—are regularly and systematically excluded from research

Subsequently, there is a form of gatekeeping based on specialized knowledge and position within the scientific community that determines influence in HTA processes. BIPOC voices are persistently underrepresented in the sciences and therefore in expert networks engaged with HTA. The resulting inequality in access to decision-making and influence in the process raises concerns about racial equity in the outcomes and recommendations of HTA.

### LACK OF BIPOC VOICE IN PATIENT ADVOCACY

The lack of BIPOC voices is not exclusive to networks of HTA experts. This issue extends to many patient groups, disease-focused organizations, and patient advocates.<sup>22</sup> These groups exist to represent, support, and advocate for patient communities, but historically, they have infrequently elevated the voice of BIPOC communities explicitly or through representation.

Representation of BIPOC individuals tends to be particularly limited in nationally recognized organizations and the rare disease space. At the same time, these large organizations are also most likely to have the resources, networks, financial support, and experience needed to effectively engage in HTA processes, further limiting the voice of BIPOC individuals overall.

Rectifying this lack of representation is made more challenging by resource and capacity deficits. Many small, community-level patient groups are less likely to have the resources needed to engage with HTA. When these groups serve or represent communities more likely to face racism or other biases, the likelihood of financial hardship increases.



**BIPOC voices are persistently underrepresented** in the sciences and therefore in expert networks engaged with HTA.

# Case Study:

## 2019 ICER Sickle Cell Disease Review

### SICKLE CELL DISEASE (SCD) AND THE 2019 ICER REVIEW

#### Key aspects:

- **SCD is an inherited blood disorder** that disproportionately affects Black/African American and Latinx people in the United States.
- **Racism has heavily affected the health care and outcomes** of the SCD patient population since the clinical discovery of the disorder.<sup>23</sup>
- **Following decades with no advances in SCD therapy**, three new SCD-related treatments were approved in 2017 (L-glutamine) and 2019 (crizanlizumab and voxelotor).
- **ICER undertook an assessment** of crizanlizumab, voxelotor, and L-glutamine in 2019/2020.<sup>8</sup>

**The Institute for Clinical and Economic Review (ICER) assessment of therapies for sickle cell disease (SCD)<sup>8</sup> provides an instructive example of complex equity issues arising in and from the HTA process.** This review stands out because of the clear importance of racial equity for the topic, given the disproportionate impact of SCD on BIPOC communities and the crippling influence of racism<sup>23</sup> and stigma on patients with SCD in the U.S. In addition, Sick Cells engaged closely with ICER throughout the 2019 SCD review, and the first-hand knowledge and insights resulting from this experience provide a unique opportunity for detailed examination of racial equity in an HTA process.

Below we analyze the 2019 ICER SCD review utilizing elements from the REAP Framework to examine how the entire HTA process may impact racial inequities and perpetuate racism. This exercise underscores the importance of understanding and addressing the multiple factors shaping HTA processes identified in the analysis above—an essential first step toward implementing changes in HTA processes to reduce racial bias and advance health equity.

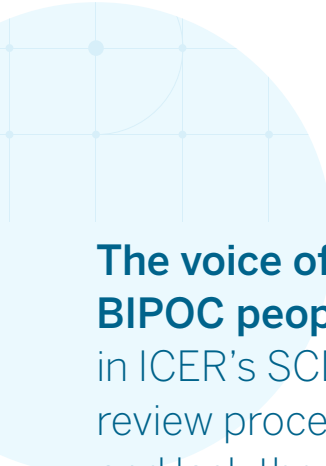
### DISPROPORTIONATE POWER IN ICER REVIEW PROCESS

The voice of BIPOC people in ICER's SCD review process, and lack thereof—in terms of both representation and power in decision making—is a central influence on implications for racial equity.

ICER's process for the SCD review followed the approach used in previous reviews. Following selection of topics for reviews through internal ICER

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In this section, we discuss the sickle cell disease (SCD) community, which is majority comprised of Black and Latinx people. This is a community within the BIPOC community. We use both terms when discussing the 2019 ICER review.



**The voice of BIPOC people in ICER's SCD review process, and lack thereof—in terms of both representation and power in decision making—is a central influence on implications for racial equity.**

processes, early outreach and engagement with stakeholders, including members of the SCD patient community, was conducted during the scoping phase. Sick Cells and other SCD community groups were engaged as key stakeholders, to provide input and guidance through the review. In addition, BIPOC and SCD patient groups were provided the opportunity to submit formal comments on scoping documents and reports at specified points in the ICER review process.

Despite these multiple opportunities for engagement, including outreach efforts by ICER motivated by the SCD community's push for awareness of the equity relevance of SCD, the voice of the SCD community was consistently external to the HTA process. The HTA team within ICER retained exclusive control over decision making at all points in the process, creating disproportionate power dynamics. The team responsible for making decisions had limited BIPOC representation that could understand the nuances of how racial equity and historical racism play a fundamental role in measuring value for the disease state.

Recognizing this issue, Sick Cells initiated new strategies for engaging with ICER, including hiring health economists as consultants to support Sick Cells' engagement and advocating to be included in ICER's Model Transparency Program. These strategies allowed Sick Cells to provide more specific and concrete feedback in both formal public comments and ongoing discussions. In practice, however, taking these steps without also addressing disproportionality in decision authority ultimately led to little measurable impact on the HTA process.

### **EXCLUSION OF BIPOC VOICE IN SCIENTIFIC DECISION-MAKING**

Like any HTA process, the foundations of ICER's 2019 SCD review were scientific. No choice in HTA is purely scientific, however, and the many environmental factors described above are inseparable from scientific considerations. **Table 2** includes examples of the many choices that arose while conducting the 2019 SCD review. These choices vary in scope, from decisions about selection of specific parameters in the cost-effectiveness modeling to overarching decisions about whether and how to conduct the review.

A close examination of these choices reveals patterns that raise concerns for health equity, driven by several key factors discussed above: bias and underrepresentation in existing evidence; centralized decision making by a closed network of experts; and general bias toward the voice of HTA experts over BIPOC and other stakeholders. In addition, the tension between pressures to advance the process and limitations or uncertainty in methods or evidence quickly emerges as a central theme in equity-impacting decisions.

**Table 2: Examples of Potential Equity Implications in Scientific Decisions**

DECISION POINT	ISSUE	OUTCOME	VOICE	DISPROPORTIONALITY	DECENTRALIZATION
<p><b>Should the review proceed despite stakeholders' concerns about limited clinical evidence?</b></p>	<p>In early input provided in ICER stakeholder outreach and public comment, ICER was encouraged to postpone the SCD review until more robust clinical evidence is available</p>	<p>ICER decided to proceed with the review</p>	<p>Selection of topics for review was made internally by ICER, with no known effort to include BIPOC or other marginalized communities</p> <p>Concerns about limited available data were voiced by multiple stakeholders, including physicians, patients, academics, and others</p> <p>SCD community recommended that ICER postpone the review until more clinical evidence was available</p>	<p>Disproportionate lack of representation of BIPOC and SCD patients in identification of topics</p>	<p>Sole decision authority was ICER and their voting committee</p> <p>Review focused on incomplete evidence that did not reflect diversity in outcomes based on geography or demographics</p>
<p><b>Should estimates based on research in UK population be used for health utility scores?</b></p>	<p>Health state utility estimate as a key parameter in disease models and cost-effectiveness analyses</p> <p>It is important that health state utility estimates reflect health preferences of the modeled population</p> <p>The ICER SCD review used estimates available in the literature for SCD patients in the United Kingdom.</p> <p>Sick Cells and others expressed concerns in public comments and recommended that ICER seek another source</p>	<p>ICER proceeded with use of UK population health utility estimates for model of US patient population</p>	<p>Sick Cells voiced specific concerns with this parameter in public comments developed with consulting health economists, supported by scientific literature</p> <p>SCD community voice was limited to these formal comments, with no involvement in internal discussions by HTA organization's team</p>	<p>High level of disproportionate representation in evidence base, with US SCD community and specific segments excluded from research</p> <p>Use of health utility estimates from UK population introduces uncertainty over relevance to US, with potential for disproportionate impacts on patients' coverage and access to treatments</p>	<p>Centralized decision making minimized BIPOC and other stakeholders' influence</p>

Table 2, continued

DECISION POINT	ISSUE	OUTCOME	VOICE	DISPROPORTIONALITY	DECENTRALIZATION
<b>Should modeling framework or methodological approach be adapted based on qualitative input from SCD community?</b>	<p>Early engagement by ICER with the SCD community provided broad evidence of the social and health concerns of SCD patients, especially in terms of racism and health equity</p> <p>ICER acknowledged the importance of understanding value of SCD therapies in this context, as well as the limitations of existing VAF approach to account for these issues</p>	<p>ICER chose to proceed using standard VAF approach, excluding some additional patient-important outcomes, societal outcomes, and methodological changes based on concerns that evidence is lacking and methods are unproven</p>	<p>The voice of BIPOC members of the SCD community was explicitly sought out and documented by ICER as part of early engagement</p> <p>Concerns around equity, racism, and additional outcomes of importance were clearly articulated</p> <p>These voices were not involved in final decision processes</p>	<p>Disproportionate emphasis on scientific justifications over real-world evidence and patient needs</p> <p>Using traditional VAF that excludes equity and patient-important outcomes presents risk of value estimates that undervalue therapies for BIPOC patients and disproportionately affect access to helpful therapies</p>	<p>Decision making centralized in one HTA organization limits utilization of alternative data, methods or processes</p>
<b>Should resources be invested to ensure patient-important outcomes are included?</b>	<p>Published evidence or real-world data on patient-important outcomes was not available</p> <p>Inclusion of these important outcomes depended on having supporting evidence</p>	<p>ICER agreed to include one outcome (missed work and school due to SCD) with evidence generated through research carried out by Sick Cells</p>	<p>Intensive advocacy by Sick Cells required to influence ICER to consider using additional data</p>	<p>Disproportionate burden on SCD patient community to advocate for outcomes' inclusion, fund evidence generation, and carry out research</p>	

Note: These examples represent interpretation from Sick Cells and IVI perspective. See main text for supporting references. BIPOC: black, indigenous, and people of color; HTA: health technology assessment; ICER: Institutes for Clinical and Economic Review; SCD: sickle cell disease.



**The mismatch between conventional HTA methods and the requirements of an equity-centered assessment of SCD therapies was clear from the outset**

In some instances, the ICER review process proceeded despite important limitations identified by SCD patients and other stakeholders. For example, a key concern raised by SCD patients and many in the research and clinical communities was the lack of sufficient clinical evidence to support an analysis intended to inform coverage and access decisions. In particular, the lack of clinical evidence for meaningful comparator therapies and potential exclusion of segments of the SCD community in trials were cited as potential sources of bias and uncertainty in HTA results. These stakeholders called on ICER to postpone the review until additional evidence became available. In this case, ICER chose to proceed with the assessment despite these limitations.<sup>24</sup>


On a more granular level, Sick Cells raised concerns about ICER's decision to use health state utility estimates—a key parameter in the model that captures patients' relative preferences for different states of health—drawn from a study conducted in the United Kingdom. Given the distinct social, racial, and economic differences between the U.S. and U.K., patients were concerned that these estimates would inadequately measure value for SCD patients in the U.S. ICER acknowledged this limitation but proceeded to use the U.K. data to parameterize the model, stating it was “the best available data we could find for this input.”<sup>24</sup>

Both of the above examples illustrate decision points at which ICER, as the ultimate decision authority, chose to proceed with modeling and valuation despite known limitations in evidence and clear input from BIPOC stakeholders concerned about the equity implications of the decisions. Notably, both decisions are examples in which BIPOC members and members of the SCD community voiced concerns about scientific decisions already made by ICER.

Perhaps more important in the context of health equity are the changes and additions to ICER's approach that SCD community members and others called for to account for the importance of equity, racism, and the true value of therapy to SCD patients. In these cases, the lack of reliable evidence or uncertainty related to methods were more often cited as reasons for inaction.

The mismatch between conventional HTA methods and the requirements of an equity-centered assessment of SCD therapies was clear from the outset and was voiced by the SCD community as a major concern for ICER's review.<sup>25</sup> With this assessment, ICER was explicitly confronted with the need to account for racism and racial equity as a critical element of understanding value. Extensive qualitative evidence from early outreach with SCD patients and their caregivers made clear to ICER the importance of racism and racial equity in understanding SCD.<sup>26,27</sup>





Many patient-important outcomes—**transportation costs and annual pain events treated outside the hospital system, for example**—were omitted from ICER’s analysis entirely

Patient groups, members of the SCD community, and other stakeholders advised ICER to develop an equity-sensitive value assessment framework that could more accurately measure value for the SCD community. The HTA team within ICER was prompted to make a choice: continue with the review using its conventional Value Assessment Framework or explore adaptations to the framework to address the issues identified by SCD patients. ICER ultimately decided to utilize their conventional Value Assessment Framework without adaptation, arguing that: 1) the methods needed to ensure equity considerations were addressed in the value assessment were not sufficiently established in the field; and 2) there was not sufficient evidence available to account for BIPOC patient-identified outcomes of importance.<sup>24</sup>

In developing the model, many patient-important outcomes—transportation costs and annual pain events treated outside the hospital system, for example—were omitted from ICER’s analysis entirely despite strong and repeated emphasis on their importance in qualitative input from the SCD community because the evidence was deemed inadequate. The exclusion of these outcomes from the model effectively assumed that the impact of these outcomes on value is equal to zero, meaning that any value estimate lacking these outcomes may systematically bias results and, in the case of an illness like SCD, perpetuate issues like stigma and patients’ experiences of racism during pain events.

From a practical standpoint, of course, ICER was unable to include outcomes in the model without relevant evidence. This nonetheless represents a choice in the HTA process: given the lack of evidence, should the review proceed—and if the need to proceed is urgent, should additional steps be taken to ensure high-importance outcomes are included?

ICER elected not to delay the review due to lack of evidence, nor to collect evidence through research of its own. In the case of one patient-important outcome, missed work and school due to the disease, Sick Cells successfully advocated for inclusion of the outcome in ICER’s CEA modeling. Realizing this change in ICER’s process required an intensive effort and investment of resources by Sick Cells to collect primary data by developing and fielding a survey of the SCD community. ICER provided Sick Cells \$5000 in funding support to conduct the work needed to generate this important evidence. Sick Cells estimates its outlay for health economics expertise, community engagement, and analysis of the survey at \$50,000.

In light of the relatively limited resources available to patient and community groups, particularly those representing BIPOC communities, this points to disproportionate burden on patient communities to identify and fund the evidence generation needed to correct equity-blind value assessment processes and analyses.

## DECENTRALIZATION AND IMPACTS ON SCD COMMUNITY

Centralization of decision making, as discussed, is a primary determinant of the voice (or lack thereof) of the SCD community in the 2019 SCD review, but centralization of the HTA process arises in other important dimensions. In particular, the centralized focus on a generalized national U.S. SCD population in both the evidence base and in ICER's review has implications for the representativeness of results. The ICER review, limited by the available evidence, was not able to provide results reflecting differences in geography, income, or insurance coverage, for example. This leads to potential misrepresentation of costs and benefits to specific populations and disproportionate impacts and risks to these populations flowing from decisions informed by the results.

For example, Medicaid is the nation's largest insurance program for people with SCD and a major source of coverage for BIPOC beneficiaries, but ICER's SCD analysis did not include data from Medicaid databases. Instead, their primary sources were data from commercial or Medicare populations.<sup>24</sup> Individuals with commercial insurance have been shown to experience fewer acute complications than those insured through public insurance programs,<sup>23</sup> which suggests this assessment may be fundamentally flawed in measuring value within the largest SCD population, specifically those covered by Medicaid. Through attendance at various Medicaid Drug Utilization Review Board and Pharmacy and Therapeutics (P&T) committee meetings, Sick Cells has observed how public officials have utilized ICER's report to inform coverage policies and decision-making, raising concerns for the potential widening of health inequities across the SCD population without proper analysis of the costs and benefits to this population.<sup>28</sup>

# From Implications to Recommendations: Advancing Racial Equity in HTA

## KEY ISSUES HTA MUST ADDRESS

- BIPOC communities and patients must have **meaningful voice**—and power—in the HTA process
- The **evidence base and HTA methods** must be improved to remove implicit biases
- HTA must be understood as a product of and contributor to **systems of inequity and bias**

### Understanding the racial equity implications of HTA processes is

**critical**—the coverage, access, and pricing decisions it shapes have direct consequences for the health and wellbeing of all patients but may be especially consequential for BIPOC communities.


To ensure that HTA and value assessment support greater racial equity, the Innovation and Value Initiative, together with Sick Cells and an advisory group of experts in health equity, are engaged in a multi-year effort to identify and prioritize changes needed in both process and methods. As a first step in developing a framework for advancing health equity in HTA, the REAP Framework is a helpful approach to mapping and examining the complex factors influencing equity in both the process and outcomes of HTA.

This initial analysis and case example point to several key issues that the entire field of HTA must address.

### **BIPOC COMMUNITIES AND PATIENTS MUST HAVE MEANINGFUL VOICE—AND POWER—IN THE HTA PROCESS**

Members of affected BIPOC and patient communities bring vital insights through their lived experience—understanding of racial equity, disease features, outcomes of importance to patients, and factors that influence decision-making and adherence, for example. HTA practitioners must prioritize and support mechanisms and processes that ensure such inputs are heard and accounted for.

To achieve this, the basic mechanisms for HTA decision making must be reconsidered and revised. HTA organizations should recognize the need to include members of affected populations as equals in planning and



**Ensuring inclusivity** is the responsibility of those actors with greater influence and resources

executing HTA projects from the beginning, at a minimum.<sup>§</sup> Clinical and academic researchers should similarly prioritize community-based and partnered research to ensure the ongoing generation of evidence and methods reflects the perspectives of historically underrepresented communities. In both cases, patient and community collaborators should be recognized and compensated for their time and contributions.

Ensuring inclusivity is the responsibility of those actors with greater influence and resources—namely, the HTA organizations, health technology manufacturers, insurers, and purchasers. These actors have an obligation to conduct HTA (or to demand that it be conducted) through processes that include BIPOC communities—including outreach, engagement, inclusion in co-creation and co-authorship, and financial support. There are few existing mechanisms to ensure accountability for inclusive practices, but as the first step, all organizations engaging with HTA processes must take explicit steps to hire leadership and staff from BIPOC communities and other underrepresented groups. This is a priority not only for HTA organizations but also for actors such as pharmaceutical firms, insurers, and patient groups.

### **THE EVIDENCE BASE AND HTA METHODS MUST BE IMPROVED TO REMOVE IMPLICIT BIASES**

If the U.S. is to conduct HTA that promotes racial equity, significant effort is required to advance the scientific methods available and refocus the research enterprise to produce the evidence needed to discern the value of health care for BIPOC patients, other patients, and society.

Steps are already being taken in this direction. New methods are gaining traction—distributional comparative effectiveness analysis (DCEA),<sup>29</sup> used to examine how the value of therapies may vary across a population, is one example. Such methods require vigorous evaluation and testing in analyses to ensure fit-for-purpose. In addition to methodological innovation in modeling and analysis, improvements in direct engagement and evidence generation regarding the lived experience of diverse patients, families and caregivers are equally important. Though progress has been slow, FDA continues efforts to increase representativeness of BIPOC communities in clinical trials.<sup>30,31</sup> Recent revisions to strategic plans for the Patient-Centered Outcomes Research Institute (PCORI)<sup>32</sup> and Centers for Medicare & Medicaid Services (CMS) include explicit prioritization of equity as a focus of their work,<sup>33</sup> and the Centers for Medicare & Medicaid Innovation (CMMI) recently took the admirable step of publishing an analysis of implicit bias in its model portfolio.<sup>34</sup>

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<sup>§</sup>IVI is modeling such an approach in the development of its current model in major depressive disorder (MDD), with a multi-stakeholder Advisory Group both guiding HTA processes and supporting research efforts. These projects are ongoing but already benefiting from this approach.<sup>36</sup> Such approaches may also serve as intentional first steps and guideposts for more racially representative HTA processes.



**Progress  
in equity-  
centered HTA**  
is possible.

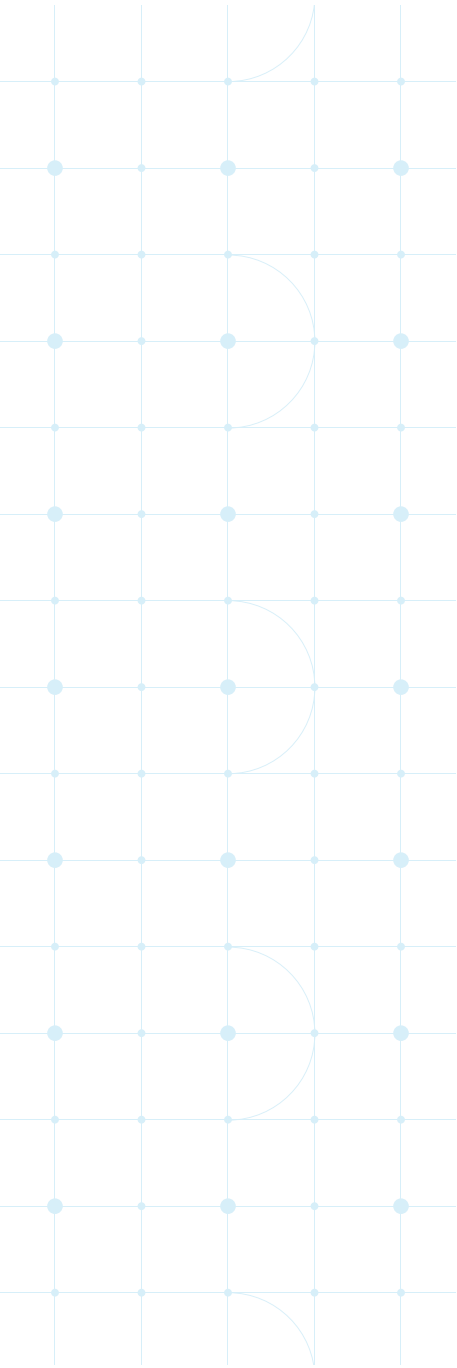
Academic researchers, manufacturers, and clinicians designing studies must follow suit and increase representation by hiring researchers from BIPOC communities, engaging BIPOC individuals as partners and even co-creators in research, investing in ensuring studies recruit a truly representative sample population, and pursuing research to advance theory and methods to quantitatively (and qualitatively) incorporate relevant issues in HTA modeling and analysis.

Moreover, HTA practitioners, the scientific community, and the decision makers using HTA findings must rapidly embrace changes in process and advances in methods to ensure a learning HTA system that tests and improves methods in practice.<sup>35</sup> Delaying use of methods until thoroughly tested and established in academic canon simply serves to delay consideration of racial and health equity in HTA.

### **HTA MUST BE UNDERSTOOD AS A PRODUCT OF AND CONTRIBUTOR TO SYSTEMS OF INEQUITY AND BIAS**

We must recognize that HTA is not an objective scientific process standing apart from social concerns like inequity in our policy, payment, and delivery systems. Longstanding systemic and structural racism defines the contexts that underlie health care, clinical research and HTA.

Progress in equity-centered HTA is possible. To achieve racial equity and begin to dismantle structures that reinforce racism, all actors involved will need clear understandings of the interplay between HTA and systemic racism, and how the broader community engages in meaningful discussion and action around the issue.



# Conclusion

## **Understanding the environmental dynamics and process mechanisms**

that shape the creation and use of HTA in the U.S. is a critical first step toward addressing its potential impacts on racial and health equity.

## **The analysis and discussion above highlights three key areas for improvement:**

1. **Engagement, inclusion, and voice** of BIPOC communities in HTA
2. **Exploration of** evidence generation and methods to support equity-centered HTA
3. **Recognition of** HTA's position within wider systems of racism

Further work is encouraged to identify the mechanisms that undermine equity in these three areas, better understand racial equity concerns in HTA, and identify and implement actionable steps to prevent the perpetuation of racism in healthcare decision making.

# References

1. Centers for Disease Control & Prevention (CDC). Impact of racism on our nation's health. Published 2022. Accessed July 17, 2022. <https://www.cdc.gov/healthequity/racism-disparities/impact-of-racism.html>
2. Kaiser Family Foundation. Key facts on health and health care by race and ethnicity. Published 2022. Accessed July 17, 2022. <https://www.kff.org/racial-equity-and-health-policy/report/key-facts-on-health-and-health-care-by-race-and-ethnicity/>
3. U.S. Department of Health and Human Services Office of Minority Health. Asthma and African Americans. Published February 21, 2021. Accessed August 22, 2022. <https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=15>
4. Hoffman KM, Trawalter S, Axt JR, Oliver MN. Racial bias in pain assessment and treatment recommendations, and false beliefs about biological differences between blacks and whites. *Proceedings of the National Academy of Sciences of the United States of America*. 2016;113(16):4296-4301. doi:10.1073/PNAS.1516047113/SUPPL\_FILE/PNAS.201516047SI.PDF
5. Centers for Disease Control & Prevention (CDC). What Is health equity? Published 2022. Accessed July 17, 2022. <https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/racial-ethnic-disparities/index.html>
6. Field RJ. How to motivate equity in health decision modeling. *AMA Journal of Ethics*. 2021;23(8):E648-652. doi:10.1001/amajethics.2021.648
7. Michener J. A racial equity framework for assessing health policy. Commonwealth Fund. doi:<https://doi.org/10.26099/ej0b-6g71>
8. Institutes for Clinical and Economic Review (ICER). Sickle Cell Disease. Published 2022. Accessed July 17, 2022. <https://icer.org/assessment/sickle-cell-disease-2020/>
9. National Library of Medicine. HTA 101: Introduction to health technology assessment. Published 2019. Accessed August 22, 2022. <https://www.nlm.nih.gov/nichsr/hta101/ta10103.html>
10. Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on Health Technology Assessment and Amending Directive 2011/24/EU. *Official Journal of the European Union*; 2021. Accessed September 7, 2022. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2021:458:TOC>
11. Woolf SH, Henshall C. Health technology assessment in the United Kingdom. *International Journal of Technology Assessment in Health Care*. 2000;16(2):591-625. doi:10.1017/S0266462300101175
12. Neumann PJ, Willke RJ, Garrison LP. A Health Economics Approach to US Value Assessment Frameworks—Introduction: An ISPOR Special Task Force Report [1]. *Value in Health*. 2018;21(2):119-123. doi:10.1016/j.jval.2017.12.012
13. Husereau D, Drummond M, Augustovski F, et al. Consolidated Health Economic Evaluation Reporting Standards 2022 (CHEERS 2022) statement: Updated reporting guidance for health economic evaluations. *Value in Health*. 2022;25(1):3-9. doi:10.1016/J.JVAL.2021.11.1351/ATTACHMENT/7116762F-A07D-4E40-8C59-3D8E43DDE53F/MMC2.DOCX

14. Sanders GD, Neumann PJ, Basu A, et al. Recommendations for conduct, methodological practices, and reporting of cost-effectiveness analyses: Second Panel on Cost-Effectiveness in Health and Medicine. *JAMA*. 2016;316(10):1093-1103. doi:10.1001/JAMA.2016.12195
15. National Academies of Sciences Engineering and Medicine. *Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups*. The National Academies Press; 2022. doi:10.17226/26479
16. Murthy VH, Krumholz HM, Gross CP. Participation in cancer clinical trials: Race-, sex-, and age-based disparities. *JAMA*. 2004;291(22):2720-2726. doi:10.1001/JAMA.291.22.2720
17. Clark LT, Watkins L, Piña IL, et al. Increasing diversity in clinical trials: Overcoming critical barriers. *Current Problems in Cardiology*. 2019;44(5):148-172. doi:10.1016/J.CPCARDIOL.2018.11.002
18. Patient-Centered Outcomes Research Institute (PCORI). Proposed principles for the consideration of the full range of outcomes data in PCORI-funded research (2020). Published 2021. Accessed August 22, 2022. <https://www.pcori.org/about/provide-input/past-opportunities-provide-input/proposed-principles-consideration-full-range-outcomes-data-pcori-funded-research-2020>
19. Gilmore-Bykovskiy AL, Jin Y, Gleason C, et al. Recruitment and retention of underrepresented populations in Alzheimer's disease research: A systematic review. *Alzheimer's & Dementia: Translational Research & Clinical Interventions*. 2019;5:751-770. doi:10.1016/J.TRCL.2019.09.018
20. Concannon TW, Grant S, Welch V, et al. Practical guidance for involving stakeholders in health research. *Journal of General Internal Medicine*. 2019;34(3):458-463. doi:10.1007/S11606-018-4738-6/TABLES/2
21. Turner BE, Steinberg JR, Weeks BT, Rodriguez F, Cullen MR. Race/ethnicity reporting and representation in US clinical trials: A cohort study. *The Lancet Regional Health - Americas*. 2022;11:100252. doi:10.1016/J.LANA.2022.100252/ATTACHMENT/C11CA5F8-6DA2-4E92-B9B6-B767E366B9E3/MMC1.DOCX
22. Mitchell F. Nonprofit leadership is out of step with America's changing demographics. *Urban Wire*. Published December 9, 2021. Accessed September 7, 2022. <https://www.urban.org/urban-wire/nonprofit-leadership-out-step-americas-changing-demographics>
23. Power-Hays A, McGann PT. When actions speak louder than words — Racism and sickle cell disease. *New England Journal of Medicine*. 2020;383(20):1902-1903. doi:10.1056/NEJMp2022125
24. Institute for Clinical and Economic Review. Crizanlizumab, Voxelotor, and L-Glutamine for Sickle Cell Disease: Response to Public Comments on Draft Evidence Report. Published online March 12, 2020. Accessed September 7, 2022. [https://icer.org/wp-content/uploads/2020/10/ICER\\_SCD\\_Response-to-Comments\\_031220.pdf](https://icer.org/wp-content/uploads/2020/10/ICER_SCD_Response-to-Comments_031220.pdf)
25. Sick Cells. Early recommendations to ICER: Importance of racial equity topic. Published online August 20, 2019. Accessed September 7, 2022. [https://sickcells.org/wp-content/uploads/2022/07/Recommendations-for-ICER\\_8.20.2019-3.pdf](https://sickcells.org/wp-content/uploads/2022/07/Recommendations-for-ICER_8.20.2019-3.pdf)
26. Sick Cells. Public Comment on Draft Evidence Report. Published online February 2, 2020. Accessed September 7, 2022. [https://sickcells.org/wp-content/uploads/2021/06/Sickle-Cells-Public-Comments-to-ICER\\_final.pdf](https://sickcells.org/wp-content/uploads/2021/06/Sickle-Cells-Public-Comments-to-ICER_final.pdf)



27. Crizanlizumab, Voxelotor, and L-Glutamine for Sickle Cell Disease: Public Comments on Draft Scoping Document. Published online September 20, 2019:169-172. Accessed September 7, 2022. [https://icer.org/wp-content/uploads/2020/10/ICER\\_SCD\\_Draft-Scope\\_Public-Comments\\_093019.pdf](https://icer.org/wp-content/uploads/2020/10/ICER_SCD_Draft-Scope_Public-Comments_093019.pdf)
28. Sick Cells and Avalere Health. *Medicaid Access & Landscape Review for Prescription Drugs Treating Sickle Cell Disease.*; 2022. Accessed September 11, 2022. [https://sickcells.org/wp-content/uploads/2022/08/Sick-Cells\\_Medicaid-Access-and-Landscape-Review\\_Final-Report.pdf](https://sickcells.org/wp-content/uploads/2022/08/Sick-Cells_Medicaid-Access-and-Landscape-Review_Final-Report.pdf)
29. Cookson R, Mirelman AJ, Griffin S, et al. Using cost-effectiveness analysis to address health equity concerns. *Value in Health*. 2017;20(2):206-212. doi:10.1016/J.JVAL.2016.11.027
30. U.S. Food and Drug Administration (FDA). *Collection of Race and Ethnicity Data in Clinical Trials: Guidance for Industry and Food and Drug Administration Staff*; 2016. Accessed August 22, 2022. <https://www.fda.gov/media/75453/download>
31. Lolic M, Okeke M, Menschik D, Fleischer J. *2015-2019 Drug Trials Snapshots Summary Report: Five-Year Summary and Analysis of Clinical Trial Participation and Demographics*. Center for Drug Evaluation and Research, U.S. Food and Drug Administration; 2020. Accessed September 11, 2022. <https://www.fda.gov/media/143592/download>
32. Patient-Centered Outcomes Research Institute (PCORI). Strengthening diversity in research partnerships: Knowledge to action. Published 2017. Accessed August 23, 2022. <https://www.pcori.org/research-results/2017/strengthening-diversity-research-partnerships-knowledge-action>
33. Mclver L. Establishing the framework for health equity at CMS. Centers for Medicare & Medicaid Services Blog. Published July 8, 2022. Accessed August 23, 2022. <https://www.cms.gov/blog/establishing-framework-health-equity-cms>
34. Majerol M, Hughes DL. CMS Innovation Center tackles implicit bias. *Health Affairs Forefront*. Published online July 5, 2022. Accessed August 23, 2022. <https://www.healthaffairs.org/doi/10.1377/forefront.20220630.238592>
35. Bright J. Patient value is the root of a learning health system. *The American Journal of Accountable Care*. 2021;9(4):34-36. doi:10.37765/AJAC.2021.88805
36. Xie RZ, Malik E de F, Linthicum MT, Bright JL. Putting stakeholder engagement at the center of health economic modeling for health technology assessment in the United States. *Pharmacoeconomics*. 2021;39(6):631-638. doi:10.1007/S40273-021-01036-3/TABLES/3

# Appendices

Appendix Table 1: Defining Key Terms

<p><b>HEALTH TECHNOLOGY ASSESSMENT (HTA)</b></p>	<p>A multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its life cycle. A health technology is the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures, and systems developed to solve a health problem and improve quality of life for individuals affected.</p>
<p><b>HTA ORGANIZATION</b></p>	<p>In this paper, refers to any institution within which U.S. HTA is conducted by teams of individuals including both internal staff and external consultants. May include payers, pharmaceutical manufacturers, nonprofits, professional organizations, and others.</p>
<p><b>VALUE ASSESSMENT (VA)</b></p>	<p>A key component of HTA that entails the comparison of the relative benefits to the costs of a given technology or service for a specific person or population. Though distinct from the definition of HTA, this paper includes VA under the general term HTA.</p>
<p><b>COST-EFFECTIVENESS ANALYSIS</b></p>	<p>A method to examine both the costs and health outcomes (i.e., effectiveness) of one or more interventions. An intervention is compared to another intervention (or the status quo) by estimating the cost of gaining an additional unit of a health outcome such as a life year gained or a case prevented.</p>
<p><b>HEALTH ECONOMIC MODELING</b></p>	<p>A set of analytic approaches in health economic analysis that synthesize clinical, epidemiological, and economic evidence from different data sources into an evaluation framework that enables researchers or decision-makers to generate estimates for specific outcomes of interest. Models are simplified representations of the real world to inform decision-making.</p>
<p><b>RACIAL EQUITY</b></p>	<p>A system that aims to give all people, regardless of race, what they need to enjoy full, healthy lives.</p>
<p><b>HEALTH EQUITY</b></p>	<p>“The state in which everyone has a fair and just opportunity to attain their highest level of health. Achieving this requires focused and ongoing societal efforts to address historical and contemporary injustices; overcome economic, social, and other obstacles to health and healthcare; and eliminate preventable health disparities.”**</p>

\*\* Centers for Disease Control & Prevention. “Health Equity.” Accessed September 12, 2022. <https://www.cdc.gov/healthequity/index.html>

### Appendix Table 2: Adaptation of REAP Framework

The REAP Framework<sup>††</sup> identifies the following key considerations for assessing racial equity in public policy, but these can also be adapted to the HTA context:

RACIAL EQUITY CONSIDERATION	REAP DEFINITION FOR POLICY	HTA CONTEXT
<b>Disproportionality</b>	“... refers to the way policies differentially allocate benefits and burdens to racial groups. Disproportionality can involve disparities in the distribution of beneficiaries of a given policy, such as the proportion of Medicaid beneficiaries who are Black; incongruity in the proportion of a racial group affected by a policy, such as the proportion of Black people who are Medicaid beneficiaries; disparities in benefit size and take-up; and differences in the share of benefits that some racial groups receive relative to others”	Includes unequal inclusion of BIPOC communities and relevant data in research, as well as allocation of authority and power in decision making
<b>Decentralization</b>	“... the level of government through which a given policy benefit or burden is designed or implemented. In the U.S. system of federalism, national, state, and local governments have the power to affect a wide variety of policy outcomes — often with striking consequences for racial equity.”	Practice of HTA in US is highly decentralized, conducted by non-governmental organizations with varying levels of transparency and no formal accountability; decentralization in HTA pertains to this consideration, as well as the degree of centralization in HTA decision making and authority
<b>Voice</b>	“... the ability of communities of color to shape the policy environment. Equity and voice are intertwined, because policy processes that incorporate the voices of people of color are better positioned to facilitate racially equitable outcomes.”	Translates directly to HTA context, but with additional consideration of inclusion and power of BIPOC communities in decision making

<sup>††</sup> Michener J. A Racial Equity Framework for Assessing Health Policy. Commonwealth Fund. doi:<https://doi.org/10.26099/ej0b-6g71>

