

## Traditional Value Assessment Methods Fail Communities of Color and Exacerbate Health Inequities

Policymakers in the United States have historically rejected methods to determine the value of treatments that discriminate against people with disabilities and seniors, and that exacerbate disparities in care, such as those relying on the Quality-Adjusted Life Year (QALY). In fact, there is an explicit prohibition against use of QALYs in the Affordable Care Act. As far back as 1992, the U.S. Department of Health and Human Services established that the reference to QALYs in state Medicaid programs would violate the Americans with Disabilities Act.

Despite this precedent, entities such as the Institute for Clinical and Economic Review (ICER), which has significant funding from Arnold Ventures, embrace the QALY methodology, conducting studies based on data sets that do not fully represent communities of color. We now see those studies used to inform coverage decisions by private payers and state Medicaid programs, thereby influencing patients' access to treatment, with implications for communities of color that already experience inequities in health care. We are concerned about the recent increase in reference to traditional value assessments by private payers and policymakers, as well as Congressional consideration of policies, particularly related to prescription drugs, that would authorize reference to QALY-based studies conducted by ICER or more explicitly reference international pricing and reimbursement decisions based on QALYs.

Patient and disability advocates have a long history of opposing the use of traditional methods of cost-effectiveness analysis because they value a life year lived with disability as less than a non-disabled life and exclude consideration of outcomes that matter to patients. These assessments become even more concerning related to treatments for conditions that disproportionately impact communities of color. Their use could exacerbate health inequities when referenced to make coverage and reimbursement decisions.

### Limitations in applying traditional value assessments to communities of color:

- QALY-based value assessments tend to rely on inputs from highly homogeneous populations. These values come from two sources, randomized clinical trials (RCTs) and health utility preference weighting surveys, which are primarily white and male.
- The failure to achieve meaningful diversity in clinical trials limits information about drug response and measures of safety and efficacy, which can exacerbate health inequities. For example, if a value assessment is conducted on a drug that is highly efficacious in African-American populations but less efficacious for Caucasian populations, based solely on homogeneous RCT data-sets, it may be deemed not clinically effective and not be widely covered by payers. Multiply this effect by the hundreds and thousands of trials that have evaluated the thousands of therapies that have been approved – or not – over the decades and you have a systemic bias of available therapies favoring Caucasians.
- Value assessments are largely based on population level averages, and rarely are results specific to minorities identified in final results. This is concerning, because generating and reporting differential value assessment across subgroups leads to substantial health gains, both through treatment selection and coverage, which is why we have seen such a push toward personalized medicine.
- QALY's place less weight on the life of those with disabilities and chronic conditions. African Americans, and often other minorities such as Hispanic populations, have higher rates as well as earlier onset of both chronic conditions and disabilities.
- Traditional value assessments do not attempt to factor in social determinants of health. Instead, they base their assessments on largely Caucasian population averages, which assume levels of healthcare access and utilization, treatment delivery patterns, disease burden and severity, presence of co-morbidities, and adherence to therapies that will almost always lead to an underestimate of the value of such therapies to communities of color.

## **Implications of ICER's Assessment of Treatments for Sickle Cell Disease**

The concerning pattern detailed above was clearly depicted in ICER's recent assessment of treatments for sickle cell disease, which puts these patients at risk by providing payers with justification for non-coverage and stringent use of pre-authorization and other utilization management strategies, despite its flaws. The report relies on the QALY, a metric highly inappropriate for the assessment of sickle cell disease treatments, and fails to incorporate community concerns about factors such as standard of care and outcomes that matter to patients. Sickle cell disease patient groups have been vocal that they feel this study put an undue burden on their community and employed methods that move us away from the goal of health equity.

## **Real-World Impacts of Relying on Traditional Value Assessments to Determine "Value" and Coverage of Treatments**

We already know that when payers rely on QALY-based studies to determine coverage and utilization management strategies, patients suffer the consequences. Many countries already rely on QALY-based cost-effectiveness analyses to determine what drugs may be covered by their national health systems. The result is restricted and delayed access to new treatments. For example: In the U.K., between 2002 and 2014, 40% of medicine to treat orphan conditions were rejected. U.K. Patients are also 2/3 less likely to receive PD-1 inhibitors, an innovative new cancer treatment, as compared to U.S. patients. Methodologies for determining clinical and cost effectiveness based on averages are particularly detrimental for minority populations, as it ignores critical social determinants of health and further bakes inequities into our healthcare system by relying on homogeneous population-level data. It is critical that policymakers do not base health care policy on these flawed value assessments.

**Traditional value assessments are inappropriate references for coverage decisions. The use of and reference to QALYs and similar average metrics should be banned across federal programs as recommended by [the National Council on Disability's recent bioethics report](#).**