



What Else Should I Know About ICER and Its Sickle Cell Disease Value Assessment?

Why does ICER's assessment of sickle cell treatments matter?

ICER's assessments are used by private payers, including private Medicare Advantage plans, some Medicaid programs, and the Veterans Administration (VA) to inform formulary development and utilization management, such as step therapy. ICER's assessments are precluded by law from being used directly by Medicare. An assessment of low to intermediate value by ICER could lead Medicaid programs, the VA, private insurers, and pharmacy benefit managers to restrict access to the new treatment.

ICER's website says it "conducts rigorous analyses of all clinical data and publicly convenes key stakeholders." What is their method for determining if a treatment is or is not valuable?

ICER's reports are explicitly not intended to be used for shared decision-making and are instead tailored for use by insurers, payers, and policymakers. While ICER takes public feedback, their methodology has strict limitations on incorporating patient-centered outcomes. ICER's drug assessment reports use "quality-adjusted life years" or QALYs to establish a "cost-per-QALY" for treatments. ICER independently determined that a \$100,000-\$150,000 "cost-per-QALY" should be the threshold for a treatment to be "cost-effective." The QALY methodology is well established to discriminate due to its reliance on averages and population-based surveys that do not necessarily reflect the impact of treatment on individuals living with the disease. The method is unable to capture the value of health improvements for people living with a disease or condition, as well as the attribution of a lower value for a year of life lived with a disability or serious chronic condition.

If ICER's methods are flawed, why should we engage and provide feedback?

Though ICER's methods are flawed, payers and policymakers pay attention to ICER, so it is important to make sure the patient voice and perspective are heard. Some patient groups feel that by engaging and providing ICER with the patient perspective, they have been able to improve ICER's conclusions to be more favorable toward treatment value. Others are glad they engaged even if the review is unfavorable because they are able to demonstrate how ICER omitted information provided to them about patient-centered outcomes, caregiver burden, and other factors. These groups then have the ability to show the flaws in ICER's methods and communicate to payers why a treatment has value to patients in the real world.

How is ICER funded?

ICER began in 2006 as a small research entity primarily funded by private insurers seeking information on the cost-effectiveness of treatments to inform their coverage determinations. Since 2017, ICER reports are produced with funding primarily from the Laura and John Arnold Foundation which has infused around \$20 million into ICER, although insurers and some life sciences companies, including pharmaceutical manufacturers, also provide funding and serve on ICER's governance and advisory board.