



VALUE OUR HEALTH

What is the Institute for Clinical Economic Review (ICER)? And What is It NOT? Dispelling the Myths...

In March 2020, ICER will assess the comparative clinical effectiveness and value of treatments for sickle cell disease:

- Crizanlizumab (Adakveo) a Novartis product is a P-selectin inhibitor. The FDA approved Adakveo on November 15, 2019.
- Voxelotor (Oxbryta) a Global Blood Therapeutics product is an HbS polymerization inhibitor. The FDA approved Oxbryta on November 25, 2019.
- Prescription-grade formulations of L-Glutamine (Endari) an Emmaus Medical, Inc. product in addition to usual care. The FDA approved Endari on July 8, 2017.

What IS ICER?

- ICER **IS** an independent organization
- ICER's assessments **ARE** used by private payers, including Medicare Advantage plans, some Medicaid programs, and the VA to inform formulary development and utilization management
- ICER **DOES** assess new treatments upon being approved by the FDA despite lack of real-world evidence of value and clinical benefit
- ICER **DOES** have a comment period starting Jan. 22, 2020 for its draft evidence report and an in-person stakeholder meeting on March 26, 2020
- ICER's reports **DO** use "quality-adjusted life years" or QALYs and a similar metric called the equal value of life year gained (evLYG) to determine whether a drug is cost-effective. Both have implications for discrimination

What is ICER NOT?

- ICER is **NOT** a federal government agency and is **NOT** affiliated with the FDA
- ICER does **NOT** have any authority to approve or deny drug access
- ICER's reports are **NOT** designed to support patient and provider shared decision-making
- ICER's model for evaluating "cost effectiveness" is **NOT** transparent or able to be replicated
- ICER will **NOT** include patients with sickle cell disease or providers who specialize in treating sickle cell disease in the voting process defining value of treatments
- ICER does **NOT** consider whether the evidence base is sufficient to support a value assessment
- ICER is **NOT** obligated to update its value assessment in the future based on emerging real-world evidence