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October 6, 2025

Sarah K. Emond, MPP
President and Chief Executive Officer
Institute for Clinical and Economic Review
Two Liberty Square, Ninth Floor
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Dear Ms. Emond:

Global Liver Institute (GLI) appreciates the opportunity to provide comments on the draft evidence report for treatments for obesity from the Institute for Clinical and Economic Review (ICER).

GLI is a nonprofit organization founded in the belief that liver health must take its place on the global public health agenda commensurate with the prevalence and impact of liver illness. GLI promotes innovation, encourages collaboration, and supports the scaling of optimal approaches to help eradicate liver diseases. Operating globally, GLI is committed to solving the problems that matter to liver patients and equipping advocates to improve the lives of individuals and families impacted by liver disease and co-existing conditions such as obesity.

Obesity and Liver Disease

The prevalence of obesity in the United States has risen in recent years, paralleling rising rates in liver diseases such as metabolic dysfunction-associated steatotic liver disease (MASLD), also known as nonalcoholic fatty liver disease (NAFLD), and its advanced form, metabolic dysfunction-associated steatohepatitis (MASH), also known as nonalcoholic steatohepatitis (NASH). These diseases

negatively impact our nation's health and economy. The financial burden of obesity is exacerbated by the costs associated with MASH/NASH, including inpatient and outpatient care, professional services, emergency department visits, and drug costs.[1] These diseases also drive indirect costs, such as lost work productivity and expenses due to caregiving.[2] By 2039, it is predicted that healthcare cost per patient due to MASH/NASH will almost double, most likely driven by the growing number of patients with MASH and advanced fibrosis. Costs are higher for patients with obesity and MASH/NASH.[3]

ICER's model must look at liver impacts beyond just cirrhosis

GLI appreciates that ICER included liver-related outcomes in its model but believes these outcomes were too narrowly defined. ICER's assessment incorporates cirrhosis as a patient-important outcome but only includes MASH/NASH as a surrogate endpoint. It is well known in the literature that MASH/NASH impacts clinical outcomes of patients with obesity. Addressing MASH/NASH by promoting steatohepatitis resolution and reducing fibrosis progression in patients before it advances to cirrhosis will both lead to better outcomes for patients and less cost to the system. FDA has approved semaglutide for MASH, and the American Association for the Study of Liver Disease (AASLD) guidelines recommend semaglutide for treatment of MASH, also recognizing its cardiovascular benefits for patients with obesity/overweight.[4] Patients with non-cirrhotic NASH with subsequent progression to a more severe disease state are estimated to have 1.6 times higher follow-up spending than non-progressors, indicating that treatment preventing progression has a significant impact on financial burden for patients.[5] In order to better capture the benefits of treatments for obesity, GLI would encourage ICER to account for the benefits of treating MASH in its model.

ICER Fails to Differentiate Treatments

Patients will respond differently to the same treatments. They have different characteristics, biology, and treatment goals that will mean a treatment that is optimal for one patient will not be optimal for a different patient. In reviewing the ICER draft report, we are very concerned that it does not clarify how the two treatments assessed may differ in providing value to patients. Too often, health economics models assume that each patient is the average and that treatments are one-size-fits-all. In our experience with patients using medications indicated for obesity and

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[1] Zobair M. Younossi et al., "Burden of Illness and Economic Model for Patients with Nonalcoholic Steatohepatitis in the United States," *Hepatology* 69, no. 2 (January 8, 2019): 564–72, https://doi.org/10.1002/hep.30254.

[2] Michal Witkowski et al., "The Economic Burden of Non-Alcoholic Steatohepatitis: A Systematic Review," *PharmacoEconomics* 40, no. 8 (July 5, 2022): 751–76, https://doi.org/10.1007/s40273-022-01140-y.

[3] Alina M. Allen, et al, Healthcare and socioeconomic costs of NAFLD: A global framework to navigate the uncertainties, Journal of Hepatology, Volume 79, Issue 1,
2023, Pages 209-217, ISSN 0168-8278, https://doi.org/10.1016/j.jhep.2023.01.026.

[4] Mary E. Rinella et al., "Aasld Practice Guidance on the Clinical Assessment and Management of Nonalcoholic Fatty Liver Disease," *Hepatology* 77, no. 5 (March 17, 2023): 1797–1835, https://doi.org/10.1097/hep.0000000000000323.

[5] Kim Y, Medicis J, et al. Costs associated with nonalcoholic steatohepatitis disease progression in Medicare patients: a retrospective cohort study. J Comp Eff Res. 2024 Dec;13(12):e240096. doi: 10.57264/cer-2024-0096. Epub 2024 Nov 22. PMID: 39576038; PMCID: PMC11610050.

related conditions, they will report that one treatment provides them with a desired outcome with fewer side effects compared to others. We are very concerned that ICER's final report may be used by payers to force patients into a treatment protocol that does not optimize their outcomes.

ICER's artificial budget cap threatens to limit needed access for patients

ICER correctly finds treatments for obesity to be beneficial to patients and cost-effective. That being said, ICER uses its artificial budget threshold to assume that only 1% of eligible patients could be treated. ICER's use of a budget threshold that inherently devalues treatments for large populations is problematic. The United States is not like foreign countries operating in a single payer market that embraces health care rationing. It is inappropriate for ICER to artificially impose a budget threshold that supports an unnecessary — and un-American — health care rationing scheme that payers may use to limit patient access to needed treatments.

ICER's use of finite fiscal thresholds in assessing budget impact biases its assessments against any intervention for a common condition, regardless of the severity of the condition or the cost-effectiveness of the intervention. It also ignores the compelling studies and real-world experiences indicating that access to obesity medications reduce other health system costs.[6] It would be more efficient to tackle population health problems by empowering solutions that work for large populations — not to penalize health care with expansive potential patient populations that would benefit. The precedent for this direction would be contrary to American efforts to prevent and reduce chronic disease. Therefore, we have significant concerns that ICER's final report will be used by payers to justify reduced access to care through restrictive coverage decisions.

QALYs are discriminatory and should not be used in value assessment

Multiple studies have shown that cost-effectiveness models relying on the quality-adjusted life year (QALY) discriminate against patients with chronic conditions[7] and people with disabilities.[8] There is widespread recognition that the use of the QALY is discriminatory. The QALY has historically been opposed by the American public and policy makers. The National Council on Disability (NCD), an independent federal agency, concluded in a 2019 report that QALYs discriminate by placing a lower value on treatments which extend the lives of people with chronic illnesses and disabilities. NCD recommended that policymakers and insurers reject QALYs as a method of measuring value for medical treatments.[9]

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[6] Rika Kanaoka, "Lifetime Social Returns from Expanding Access to Anti-Obesity Medications," USC Schaeffer, March 2025, https://schaeffer.usc.edu/research/lifetime-social-returns-from-expanding-access-to-anti-obesity-medications/.

[7] Mike Paulden, "Recent Amendments to Nice's Value-Based Assessment of Health Technologies: Implicitly Inequitable?," *Expert Review of Pharmacoeconomics & Outcomes Research* 17, no. 3 (May 4, 2017): 239–42, https://doi.org/10.1080/14737167.2017.1330152.

[8] Erik Nord et al., "Incorporating Societal Concerns for Fairness in Numerical Valuations of Health Programmes," *Health Economics* 8, no. 1 (February 1999): 25–39, https://doi.org/10.1002/(sici)1099-1050(199902)8:1<25::aid-hec398>3.0.co;2-h.

[9] "National Council on Disability: Quality-Adjusted Life Years and the Devaluation of Life with a Disability," National Council on Disability | Quality-Adjusted Life Years and the Devaluation of Life with a Disability, November 6, 2019, https://www.ncd.gov/report/quality-adjusted-life-years-and-the-devaluation-of-life-with-a-disability/.

Conclusion

GLI urges ICER to review some of its modeling decisions and to ensure it is capturing the full impact of these treatments by considering the impact on MASH/NASH.

Sincerely,

Larry R. Holden
President & Chief Executive Officer
Global Liver Institute

About Global Liver Institute

Global Liver Institute (GLI) is a 501(c)3 nonprofit organization founded in the belief that liver health must take its place on the global public health agenda commensurate with the prevalence and impact of liver illness. GLI promotes innovation, encourages collaboration, and supports the scaling of optimal approaches to help eradicate liver diseases. Operating globally, GLI is committed to solving the problems that matter to liver patients and equipping advocates to improve the lives of individuals and families impacted by liver disease. GLI holds Platinum Transparency with Candid/GuideStar, is a member of the National Health Council and NORD, and serves as a Healthy People 2030 Champion. Follow GLI on Facebook, Instagram, LinkedIn, and YouTube or visit www.globalliver.org.