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January 8, 2024

Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS–9895–P, Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: CMS-9895-P

Dear Administrator Brooks-LaSure:

I am writing on behalf of Global Liver Institute (GLI) on the HHS Notice of Benefit and Payment Parameters for 2025. As members of the Obesity Care Action Network (OCAN), we share their views about the proposed reforms as discussed in the letter sent by the OCAN co-chairs.

As discussed in the OCAN comment letter, obesity is a chronic disease and it is a disease that co-exists with and exacerbates other chronic diseases. The recently published SELECT study finding obesity treatment reduces cardiovascular events is not surprising. Research has long recognized the relationship obesity has with other burdensome and costly conditions such as nonalcoholic fatty liver disease (NAFLD) or metabolic dysfunction-associated steatotic liver disease (MASLD), and its advanced form, nonalcoholic steatohepatitis (NASH) or metabolic dysfunction-associated steatohepatitis (MASH). Worldwide, NASH/MASH affects more than 148 million people and continues to become more prevalent each year. Research has closely linked the presence of NASH/MASH to metabolic comorbidities such as obesity and diabetes. Diabetes contributes to a faster fibrosis progression of NASH/MASH and can accelerate the progression to cirrhosis and liver cancer. With the expectation that 1 in 4 individuals will be obese by 2035, it is crucial that we utilize unbiased and science-based approaches to both NASH/MASH and obesity care.

Additionally, without addressing obesity, experts predict NASH/MASH could increase by over 50 percent by 2030.[6] 12 percent of people with NASH/MASH will go on to have liver cancer. Chronic liver failure due to cirrhosis is the most common reason for liver

transplantation, and 20 percent of individuals with NASH/MASH progress to advanced fibrosis and cirrhosis caused by NASH/MASH. The long-term implications of obesity for increased incidence of NASH/MASH, and therefore liver cancer and liver failure leading to transplantation, is a cost and a burden that is imminently preventable by preventing and treating obesity.

Including a consumer perspective on insurers' Pharmacy & Therapeutics (P&T) Committees, as proposed, is a step in the right direction for providing additional insight into the practical use of therapies and effect on quality-of-life outcomes. Additionally, we urge the final requirements to include a patient representative that brings a focus on the patient experience of care to the P&T committee, in addition to a consumer perspective. Also, as modeled by the Food and Drug Administration,[1] the P&T committee process should engage impacted patients with lived experience and the organizations that represent them as advisors to P&T committees with requirements to ensure that their perspectives, i.e. outcomes that matter to patients, are key considerations in payer decisions. If liver disease patients had a stronger voice in formulary decisions, P&T committees would better understand the value of different treatments and medications for liver disease patients, as well as the implications of treatment for co-existing conditions that may improve health for patients and reduce costly adverse events for payers. Unfortunately, P&T committees rely heavily on third party contractors providing recommendations for formularies that are based on value assessments and other studies that fail to capture outcomes that matter to patients and the broad scope of benefits that a treatment may have for co-existing conditions.

Therefore, we strongly support the comments provided to CMS from OCAN. It is imperative to cover obesity treatments to address not only obesity but the associated challenges with liver disease and other related conditions. With patients engaged in coverage decisions made by payers, such as in formulary decisions made by P&T committees, better health, including liver health, is achievable.

Sincerely,

Donna R. Cryer, JD
President & CEO
Global Liver Institute

[1] https://www.fda.gov/patients/learn-about-fda-patient-engagement/fda-patient-engagement-overview

About Global Liver Institute

Global Liver Institute (GLI) was built to solve the problems that matter to liver patients, equipping advocates to improve the lives of individuals and families impacted by liver disease. GLI promotes innovation, encourages collaboration, and supports the scaling of optimal approaches to help eradicate liver diseases. GLI believes liver health must take its place on the global public health agenda commensurate with the prevalence and impact of liver illness. GLI is the only patient-created, patient-driven nonprofit organization tackling liver health and all liver disease holistically, operating globally. Follow GLI on Facebook, Instagram, LinkedIn, and YouTube.