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Global Liver Institute 100 M Street SE Suite 750 Washington, DC 20003

⋈ info@globalliver.org
∰ globalliver.org

January 17, 2025

Honorable Chiquita Brooks-LaSure Administrator, Centers for Medicare & Medicaid Services Department of Health and Human Services 7500 Security Boulevard Baltimore, MD 21244-1850

Submitted via electronic submission

Re: Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (CMS-4208-P)

Dear Administrator Brooks-LaSure:

The Global Liver Institute (GLI) appreciates the opportunity to provide comments to CMS on the Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly.

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 coexisting conditions such as obesity.

Overview of Comments

GLI was very pleased to see CMS take the step of expanding coverage for anti-obesity medications when used to treat obesity in the Medicare Part D and Medicaid programs. This is a seminal step to ensuring Americans living with obesity are able to access the care they need. We strongly agree with CMS's proposal to identify obesity as a chronic disease and cover obesity medications, an important step towards curbing our nation's chronic disease epidemic and making America healthy again.

Rising obesity prevalence and the looming epidemic of NASH/MASH are costly.

The prevalence of obesity in the United States has risen in recent years, paralleling rising rates in liver diseases such as nonalcoholic fatty liver disease (NAFLD), also known as metabolic dysfunction-associated steatotic liver disease (MASLD), and its advanced form, nonalcoholic steatohepatitis (NASH), also known as metabolic dysfunction-associated steatohepatitis (MASH), having a negative impact on our nation's health and economy. The financial burden of obesity is exacerbated by the costs associated with NASH/MASH, 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.²

Coverage for anti-obesity medications will reduce obesity prevalence and address the looming epidemic of NASH/MASH.

The prevalence of obesity among individuals over age 60 is 42.8%, similar to the level among younger and middle-aged adults. The prevalence of severe obesity among those over age 60 is 5.8%, contributing to higher rates of liver disease, including NAFLD/MASLD and NASH/MASH. By 2030, more than 20% of the population will be 65 years of age or older, up from 15% today, underscoring the importance of addressing obesity among older Americans as a tactic for preventing co-existing conditions such as liver disease and eventually liver cancer. According to a study published in The Lancet, 213 million American adults are expected to have overweight or obesity by 2050 in the absence of any major policy changes.³ Obesity is a progressive disease; without treatment, Medicare beneficiaries with overweight or obesity risk further health deterioration and an increased likelihood of co-existing conditions such as liver disease, liver cancer, diabetes, and end stage renal disease. In fact, estimates show that up to 90% of patients with obesity have NAFLD/MASLD. Additionally, people with severe obesity have a 48% higher risk of physical injury, including falls, which contributes to higher costs and mortality rates.

Coverage for obesity medication is particularly important to the liver community when considering the strong connection between obesity and related health issues such as NAFLD/MASLD and its advanced form, NASH/MASH. With over 148 million people worldwide having the more advanced disease of NASH/MASH, and the prevalence of obesity expected to rise, expanding access to effective treatments is crucial. Research has closely linked the presence of NASH/MASH to metabolic comorbidities such as obesity and diabetes, concluding that these conditions typically go hand-in-hand. Without treatment, it's projected that 1 in 4 individuals will be obese by 2035,⁴ most of whom will also experience a form of liver disease.⁵ Changing the trajectory of these numbers is essential and requires comprehensive and evidence-based approaches to obesity disease care.

To put it simply, obesity is a treatable chronic disease and providing coverage for medications to treat it will help reduce both obesity and its many co-existing conditions.

Coverage for anti-obesity medications will help address chronic illness in underserved rural populations.

Obesity has a disproportionate impact on individuals that already struggle to access care. Obesity, like liver disease, is significantly more prevalent among rural adult populations than urban ones. Adults living in the most rural counties have a 34.7% obesity prevalence compared to a 29%

¹ https://aasldpubs.onlinelibrary.wiley.com/doi/pdf/10.1002/hep.30254

² <u>https://pmc.ncbi.nlm.nih.gov/articles/PMC9300564/</u>

³ https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(24)01548-4/fulltext

⁴ <u>https://www.worldobesityday.org/</u>

⁵ https://aasldpubs.onlinelibrary.wiley.com/doi/10.1002/hep.28431

prevalence for those living in metropolitan counties.⁶ Rural Americans already often lack accessible health care, which exacerbates this problem. Coverage of highly effective anti-obesity medications is one tool to address this issue.

Supporting coverage of obesity drugs will ultimately save the Medicare program money, reducing chronic disease and mitigating the need for liver transplants.

As we look to save money and ensure the Medicare and Medicaid programs are sustainable, CMS' decision to cover anti-obesity medication in the Medicare Part D and Medicaid programs will save the system money. A study conducted by the University of Southern California Schaeffer Center estimates that coverage for anti-obesity treatments could generate approximately \$175 billion in cost offsets to Medicare in the first 10 years alone, and, by 30 years, cost offsets could increase to \$700 billion.⁷ These savings would be a result of reduced health care spending and reduced disability if all Americans were able to access effective obesity treatments.

In reality, these savings will be higher, as this study did not consider rising rates of people with obesity and liver disease resulting in rising numbers of liver transplant candidates due to their NASH/MASH or associated hepatocellular carcinoma.⁸ Chronic liver failure due to cirrhosis is the most common reason for liver transplantation and 20% of individuals with NASH/MASH progress to advanced fibrosis and cirrhosis.⁹ Additionally, 12% of those with NASH/MASH will go on to have liver cancer.¹⁰ Addressing obesity early is a crucial and effective way to mitigate this devastating outcome for patients.

Conclusion

In conclusion, GLI is supportive of CMS's proposal to provide coverage of anti-obesity medications and feels strongly that this proposal should be finalized. GLI stands ready to be a resource to CMS. If you have any questions or would like to discuss these comments, please reach out to Jeff McIntyre, GLI Vice President for Liver Health Programs at jmcintyre@globalliver.org.

Sincerely,

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

⁶ <u>https://norc.org/content/dam/norc-</u> org/pdfs/Adult%20Obesity%20in%20Rural%20America_Final%20White%20Paper.pdf

⁷ <u>https://healthpolicy.usc.edu/research/benefits-of-medicare-coverage-for-weight-loss-drugs/</u>

⁸ https://pubmed.ncbi.nlm.nih.gov/31652761/

⁹ https://pubmed.ncbi.nlm.nih.gov/31520407/

¹⁰ <u>https://www.cancer.gov/news-events/cancer-currents-blog/2022/spectrin-fatty-liver-disease-liver-cancer</u>

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.

