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May 8, 2025

Dr. Shantanu Agrawal
Chief Health Officer
Elevance Health, Inc.
220 Virginia Avenue
Indianapolis, IN 46204

Dear Dr. Shantanu Agrawal:

On August 19, 2024, Global Liver Institute shared with you a request to remove the biopsy requirement as an approval criterion for FDA-approved treatment of Nonalcoholic Steatohepatitis (NASH), also known as Metabolic Dysfunction-associated Steatohepatitis (MASH), which is contrary to the label from the Food and Drug Administration (FDA) and clinical guidelines.¹ The petition is now signed by over 60 patient advocates and organizations calling on private payers to cover NASH/MASH treatment without biopsy.

With FDA approval, healthcare practitioners should be empowered to prescribe treatment to their patients consistent with clinical guidelines and best available evidence without unnecessary delays. At this time, Resmitemon is the only drug approved for the treatment of this condition. Any current or future FDA-approved medication for fatty liver disease should not require diagnosis with a liver biopsy if it is not required as part of FDA's approval or supported by clinical guidance.

We would also note that around 95% of covered patients in the United States are not subjected to such a policy. Tricare does not subject this policy onto active-duty military and their families. And where this policy does exist, patients and providers are united in their opposition to it.²

We are disappointed that our request for due process to formally appeal and reverse this decision has been met with no response from Anthem or CaredonRx. We welcome guidance on how to advance reconsideration of the policy so it reflects the science and ensures patients receive timely access to care. We also look forward to transparency related to the evidentiary basis for these decisions.

¹ Chen, Vincent L.1; Morgan, Timothy R.2,3; Rotman, Yaron4; Patton, Heather M.5,6; Cusi, Kenneth7; Kanwal, Fasiha8,9,10; Kim, W. Ray11. Resmetirom therapy for metabolic dysfunction-associated steatotic liver disease: October 2024 updates to AASLD Practice Guidance. *Hepatology* 81(1):p 312-320, January 2025. | DOI: 10.1097/HEP.0000000000001112

² <https://globalliver.org/wp-content/uploads/2025/03/GLI-AASLD-VA-Biopsy-Requirement-Joint-letter-03032025.pdf>

Please reach out to Alyssa Davenport, Policy Director, at adavenport@globalliver.org for additional information.

Sincerely,



Larry Holden
President & CEO
Global Liver Institute

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](#).

