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May 7, 2025

Dr. Heather O'Toole, M.D.
Vice President & Chief Medical Officer
Select Health
5381 S Green St.
Murray, UT 84123

Dear Dr. O'Toole:

On behalf of patients living with liver disease, Global Liver Institute is deeply concerned to learn that Select Health of Utah is advancing an adverse policy requiring a biopsy for coverage of a new medication to treat Nonalcoholic Steatohepatitis (NASH), also known as Metabolic Dysfunction-associated Steatohepatitis (MASH), contrary to the label from the Food and Drug Administration (FDA) and clinical guidelines.[1] Attached to this letter is a petition signed by over 60 patient advocates and organizations calling on private payers to cover NASH/MASH treatment without biopsy.

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. In limited circumstances where a biopsy requirement exists, patients and providers are united in their opposition to it.[2]

The step therapy policy advanced by Select Health, including that a member must have a biopsy to diagnose NASH/MASH before qualifying for treatment, provided no opportunity for patients to be consulted in its development, despite its consequences for denying or delaying access to needed medication. We cannot find any information on the evidentiary basis for the policy, nor is it supported by existing clinical guidelines. Biopsies have known risks and should only be used when it has been determined that the information intended to be gained substantially outweighs the known risks, particularly given the availability of several types of non-invasive diagnostic options.[3,4] It is well understood among clinicians the limited tissue sample from a biopsy can render false or misleading results.[5]

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[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

[3] Rockey, Don, MD "Liver Biopsy: Proceed With Caution," AHRQ, August 21, 2014 https://psnet.ahrq.gov/web-mm/liver-biopsy-proceed-caution

[4] NIDDK on risk of biopsy including bleeding and pain, https://www.niddk.nih.gov/health-information/diagnostic-tests/liver-biopsy#:~:text=Internal%20bleeding%20is%20a%20serious,pressure%2C%20and%20a%20fast%20heartbeat.

[5] EASL-ALEH Clinical Practice Guidelines: Non-invasive tests for evaluation of liver disease severity and

We ask Select Health for the removal of step therapy requirements, including the need for a biopsy-confirmed diagnosis.

Recent years have seen the development of promising new therapies for NASH/MASH. These therapies target various aspects of the disease process, including inflammation, fibrosis and bile acid regulation. New treatments offer the potential to slow or even reverse disease progression. Step therapy requirements will only delay care and subject patients to more risks.

Resmetirom (Rezdiffra™) was approved by the FDA on March 14, 2024[6] and celebrated by patients as the first and currently only treatment for NASH/MASH. It was approved for the treatment of adults with noncirrhotic NASH with moderate to advanced liver fibrosis, in conjunction with diet and exercise. This breakthrough followed years of NASH patient-led, multi-stakeholder advocacy and partnership with researchers in both drug and diagnostic development. The hope of the NASH/MASH and larger liver health community is that this successful approval and the robust and diverse pipeline of therapies to follow will open a new era of care options for people living with fatty liver disease. This drug is another tool to treat a stage of this serious, progressive disease.

We want to emphasize that the FDA specifically did *not* recommend or require a liver biopsy when prescribing this medication. This decision reflected the FDA's responsiveness to the voices of patients from Global Liver Institute's Externally-Led, Patient-Focused Drug Development Meeting in 2022[7] and the impact of the Beyond the Biopsy™ collaborative. We had hoped this approval would give patients and healthcare providers a long-awaited tool to change the trajectory of their chronic liver disease.

Instead, we understand that Select Health has chosen to create unnecessary roadblocks by requiring a biopsy, inserting itself between the patient and the physician and delaying needed care for patients. Given the risks and pain associated with biopsies, some patients may never get access if they choose not to expose themselves to an invasive and expensive biopsy, leading to poor outcomes and driving up costs in the healthcare system. Additionally, for those that choose to proceed with a biopsy, the delay in care could be devastating. As you are aware, biopsies are not routinely done on patients. It requires a separately scheduled appointment, a 1-2 week timeframe for analysis by a laboratory, and the added administrative burden associated with prior authorization only after receipt of the biopsy results – adding weeks or months to a patients' suffering and advancement of disease. These hurdles are even more burdensome for patients in rural areas and those already facing health inequities.

We are requesting due process to formally appeal and reverse this decision. We welcome guidance on how to ensure this additional information is considered by Select Health and urge a revised policy that 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.

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prognosis, Journal of Hepatology, Vol 63, Issue 1,2015, 237-264,ISSN 0168-8278, https://doi.org/10.1016/j.jhep.2015.04.006.

[6] FDA Press Announcement: see https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-patients-liver-scarring-due-fatty-liver-disease

[7] GLI PFDD Report: see https://globalliver.org/wp-content/uploads/2022/07/FINAL_NASH_EL_PFDD_REPORT.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.