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June 4, 2024

Dr. Shereef Elnahal
Under Secretary for Health
Veterans Health Administration
U.S. Department of Veterans Affairs
810 Vermont Ave., NW
Washington, DC 20420

Dear Dr. Elnahal:

On behalf of veterans and patients living with liver disease, the undersigned organizations are writing to express our deep concern that the U.S. Department of Veterans Affairs (VA) is advancing adverse Criteria for Use of a new medication to treat Nonalcoholic Steatohepatitis (NASH), also known as Metabolic Dysfunction-associated Steatohepatitis (MASH), to include biopsy, contrary to the label from the Food and Drug Administration and clinical guidelines. We are also concerned that the VA's recommendation on lifestyle interventions will further delay access to care.

Despite many of our strong relationships with the VA, there was no opportunity for patients to be consulted in the process regarding criteria that may deny them access to needed medication. While the VA states its "recommendations are based on medical evidence, clinician input, and expert opinion," we cannot find any information on the evidentiary basis for this decision, nor is it supported by existing clinical guidelines.

We ask the VA for the removal of the VA Pharmacy Benefits Management Services and National Formulary Committee's recommendation of biopsy as a Criteria for Use for any approved medication for NASH/MASH.

As background, Resmetirom (Rezdiffra™) was approved by the FDA on March 14, 2024[1] and celebrated by patients. 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. As noted by the FDA, approximately 6-8 million people in the U.S. currently have NASH with moderate to advanced

[1] https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-patients-liver-scarring-due-fatty-liver-disease

liver scarring. NASH/MASH is the fastest-growing cause of cirrhosis, liver cancer, and liver transplant. With researchers anticipating 27 million cases of NASH/MASH in the U.S. by 2030, this drug is another tool to treat a stage of this serious, progressive disease.

We want to emphasize that the FDA intentionally 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[2] 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, veterans will face significant hurdles in accessing the drug under the current criteria that calls for a biopsy.

As drafted by the VA Pharmacy Benefits Management Services and National Formulary Committee, a liver biopsy is one of the inclusion criteria, all of which must be met.[3] The Criteria for Use state support for cost-effective use of the drug, yet even the Institute for Clinical and Economic Review (ICER), the VA's partner in formulary decisions that conducts cost-effectiveness analyses, did not recommend the use of a biopsy. ICER stated that "access to liver biopsy is limited by the number of hepatologists, and clinical experts do not believe that it is reasonable to require liver biopsy prior to beginning therapy" and concluded "liver biopsy should not be universally required for diagnosis."

Additionally, we ask the VA for the removal of the recommendation of six months of comprehensive lifestyle intervention as a Criteria for Use.

In addition to our deep opposition to the requirement for biopsy, our community also has concerns about the requirement of six months or greater of "comprehensive lifestyle intervention" before beginning treatment. While lifestyle interventions may be an effective part of a comprehensive treatment approach that potentially includes FDA-approved treatments where appropriate and prescribed, they should not be promoted in payer decisions as a barrier to overcome to qualify for treatment, which only serves to delay care and advance the liver disease.

We are requesting due process to formally appeal these decisions. As the VA's Criteria for Use document states, "The content of the document is dynamic and will be revised as new information becomes available." Therefore, we welcome guidance from the VA on how to ensure this additional information is considered by the Pharmacy Benefits Management Services and National Formulary Committee so that it reflects the science and ensures veterans receive access to care. We also look forward to transparency related to the evidentiary basis for these decisions.

Please reach out to Jeff McIntyre, GLI Vice President for Liver Health Programs, for additional information at jmcintyre@globalliver.org.

Sincerely,

American College of Occupational and Environmental Medicine

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[2] https://globalliver.org/wp-content/uploads/2022/07/FINAL_NASH_EL_PFDD_REPORT.pdf

[3] https://www.va.gov/formularyadvisor/DOC_PDF/CFU_Resmetirom_REZDIFFRA_in_Metabolic_Dysfunction-associated_Steatohepatitis_Criteria_Apr_2024.pdf

Community Liver Alliance
Fatty Liver Foundation
Global Liver Institute
Liver Health Foundation
Mid South Liver Alliance
NASH kNOWledge
Northeast Ohio Liver Alliance
Obesity Action Coalition
Preventive Cardiovascular Nurses Association

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cc:
Chairman Jon Tester, Senate Veterans Affairs Committee
Ranking Member Jerry Moran, Senate Veterans Affairs Committee
Chairman Mike Bost, House Veterans Affairs Committee
Ranking Member Mark Takano, House Veterans Affairs Committee

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.