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August 19, 2024

Mr. Joe Lastinger
President, Health Alliance Medical Plan
290 E. John Carpenter Freeway
Irving, TX 75062-2710

Dear Mr. Lastinger:

On behalf of patients living with liver disease, Global Liver Institute is deeply concerned to learn that Health Alliance Medical Plan has excluded from coverage 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 and clinical guidelines. Attached to this letter is a petition signed by over 50 patient advocates and organizations calling on private payers to cover NASH/MASH treatment without biopsy.

Health Alliance Medical Plan listed Rezdiffra among medications that lack "clinical benefit," ignoring its recent approval by the FDA and its clearly labeled indication for adults with NASH with moderate to advanced liver fibrosis.[1] There was no opportunity for patients to be consulted in the process regarding this policy, despite its consequences for denying access to needed medication. We cannot find any information on the evidentiary basis for this decision, nor is it supported by existing clinical guidelines.

We ask Health Alliance Medical Plan to cover FDA-approved medications for NASH/MASH.

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.

Resmetirom (Rezdiffra™) was approved by the FDA on March 14, 2024[2] 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, now available to more than 50 percent of commercial lives

[1] https://www.healthalliance.org/documents/policy/3138P
[2] FDA Press Announcement: see https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-patients-liver-scarring-due-fatty-liver-disease

covered by health insurance in the U.S, with less than 5 percent of those covered being required a biopsy for diagnosis.

This new medication met the FDA's high bar for accelerated approval by achieving two primary trial endpoints: fibrosis improvement and NASH resolution. In addition to approving the medication for NASH patients, 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[3] and the impact of the Beyond the Biopsy™ collaborative, as well as clinical guidelines. We had hoped this approval would give patients and healthcare providers a long-awaited tool to change the trajectory of their chronic liver disease.

Yet, contrary to the science, Health Alliance Medical Plan has chosen to deny patients access to the first medication to address the unmet needs of NASH/MASH patients, inserting itself between the patient and the physician. 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 Health Alliance Medical Plan 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.

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

Sincerely,

Donna R. Cryer, JD
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.

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