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August 12, 2024

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

Dear Dr. Agrawal:

On behalf of patients living with liver disease, Global Liver Institute is deeply concerned that Anthem, Inc. is advancing adverse coverage approval criteria 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. 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.

Anthem's coverage approval criteria state, "Documentation is provided that individual has histological evidence of NASH/MASH based on liver biopsy."[1] Yet, there was no opportunity for patients to be consulted in the process regarding Anthem's criteria, despite its consequences for denying or delaying access to needed medication. We cannot find any information on the evidentiary basis for this decision, 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.[2,3] It is well understood among clinicians the limited tissue sample from a biopsy can render false or misleading results.[4]

We ask Anthem for the removal of the biopsy requirement as an approval criterion for any approved medication 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.

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[1] Anthem Formulary: see https://client.formularynavigator.com/Search.aspx?siteCode=0442274318&targetScreen=3&drugBrandListBaseKey=rezdiffra%2Boral%2Btablet%2B80%2Bmg&drugId=226829

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

[3] 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.

[4] EASL-ALEH Clinical Practice Guidelines: Non-invasive tests for evaluation of liver disease severity and prognosis, Journal of Hepatology, Vol 63, Issue 1,2015, 237-264,ISSN 0168-8278, https://doi.org/10.1016/j.jhep.2015.04.006.

Resmetirom (Rezdiffra™) was approved by the FDA on March 14, 2024[5] 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.

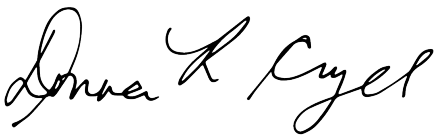
We want to emphasize that the FDA specifically did *not* recommend or require a liver biopsy when prescribing this medication. This decision reflected the FDA's responsiveness to the voices of patients from Global Liver Institute's Externally-Led, Patient-Focused Drug Development Meeting in 2022[6] and 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, Anthem has chosen to create unnecessary roadblocks under the current criteria 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 Anthem 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

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

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

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.