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June 16, 2025

Dr. Lisa Harris, M.D. Senior Vice President, Corporate Medical Director Excellus BCBS 165 Court Street Rochester New York 14647

Dear Dr. Harris:

On August 19, 2024, Global Liver Institute shared with you a request to cover an FDA-approved treatment of Nonalcoholic Steatohepatitis (NASH), also known as Metabolic Dysfunction-associated Steatohepatitis (MASH), consistent with 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, Resmiteron is the only drug approved for the treatment of this condition. We remain concerned that Excellus Pharmacy Management Drug Policy now claims that an FDA-approved treatment is "has not been medically proven to be effective,"² ignoring its approval by the FDA and its clearly labeled indication for adults with NASH/MASH with moderate to advanced liver fibrosis. There was no opportunity for patients to be consulted in the process regarding this policy, despite its consequences for denying access to needed medication. The flawed evidentiary basis for this decision provided by Excellus fails to recognize that the drug is both approved by FDA and is supported by existing clinical guidelines. Today, more than 80% of patients with commercial insurance are covered for treatment of NASH/MASH, as well as Tricare for active-duty military and their families.

We are disappointed that our prior request for due process to formally appeal and reverse this decision has been met with no

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.000000000001112

² https://provider.excellusbcbs.com/documents/d/global/rezdiffra-resmetirom-policy-pdf#:~:text=POLICY:%20Commercial/Essential/Child,positive%20effect%20on%20health%20outcomes.

response from Excellus BCBS. We welcome guidance on how to advance reconsideration of the policy so it reflects the science and ensures patients receive timely access to care.

Please reach out to Alyssa Davenport at <u>adavenport@globalliver.org</u> for additional information.

Sincerely,

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Larry R. Holden President & Chief Executive Officer Global Liver Institute

About Global Liver Institute

Global Liver Institute (GLI) is a 501(c)3 nonprofit organization founded in the belief that liver health must take its place on the global public health agenda commensurate with the prevalence and impact of liver illness. GLI promotes innovation, encourages collaboration, and supports the scaling of optimal approaches to help eradicate liver diseases. Operating globally, GLI is committed to solving the problems that matter to liver patients and equipping advocates to improve the lives of individuals and families impacted by liver disease. GLI holds Platinum Transparency with Candid/GuideStar, is a member of the National Health Council and NORD, and serves as a Healthy People 2030 Champion. Follow GLI on Facebook, Instagram, LinkedIn, and YouTube or visit www.globalliver.org.

