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June 24, 2020

Institute for Clinical and Economic Review  
Two Liberty Square, Ninth Floor  
Boston, MA 02109

VIA Electronic Delivery

RE: Draft Evidence Report: Obeticholic Acid for the Treatment of Nonalcoholic Steatohepatitis with Fibrosis

Dear Sir or Madam:

On behalf of the more than 75,000 members of the Obesity Action Coalition (OAC), a National non-profit organization dedicated to giving a voice to the individual affected by the disease of obesity, we appreciate the opportunity to comment on the Institute for Clinical and Economic Review (ICER) draft evidence report entitled "Obeticholic Acid for the Treatment of Nonalcoholic Steatohepatitis (NASH) with Fibrosis."

Liver health can sometimes be overlooked in people with obesity, where cardiovascular and endocrinological complications take priority. However, the prevalence of nonalcoholic fatty liver disease (NAFLD) is higher in people with obesity compared with the general population, and up to one quarter of people affected by obesity with NAFLD go on to develop NASH. Obesity can also exacerbate genetic predisposition to fatty liver and fibrosis, increasing the risk of developing cirrhosis.

Weight-loss and weight management are often the first suggested treatment for NAFLD. However, weight loss is difficult to accomplish and sustain. A study found that 85% of people with NAFLD could not achieve and maintain a weight loss of 7-10% or more, which is the threshold to induce the highest rates of NASH resolution and fibrosis regression. The patients that did show success achieving the necessary weight loss utilized Intensive Behavioral Therapy (IBT), and many times still only were able to attain 7-10% at 6 months (usual peak for weight loss efforts) before regaining the weight back. In these cases, patients should have access to FDA-approved medications for chronic weight management/obesity to help them maintain their weight and manage their obesity.

If someone is unable to meet their weight-loss goals and they have a BMI greater than 35, bariatric surgery should be considered. This is particularly true for patients with NASH or fibrosis. Studies show that fatty liver disease improves after surgery a majority of the time, and about half of patients also see a decrease in inflammation.

While treating an individual's obesity can provide beneficial outcomes for those with NAFLD, ICER's modeling should not assume that obesity care and weight loss treatments are covered services under most health insurance plans and that such services are widely available. The unfortunate reality is that coverage for counseling, medications and surgery for obesity is either outright excluded or dramatically limited due to discriminatory benefit design and providers may not provide such services due to such coverage issues. Patients often face arbitrary hurdles to care such as waiting periods, higher copays and separate deductibles that increase their share of the treatment cost or discourage utilization.

#### **People First Language**

The OAC has identified many areas where weight bias penetrates today's society, such as media, entertainment, healthcare, employment, education and more. However, one of the most prevalent areas that the OAC is now tackling to eradicate weight bias and stigma is language. The OAC, along with other obesity-focused organizations in the community, are raising awareness of a new initiative titled People-First Language. Quite often, you will see news stories, articles and journal entries refer to an individual with obesity as "obese." By using "obese," we are dehumanizing individuals affected by this disease.

For these reasons, the OAC is disappointed regarding the lack of patient inclusive or people first language throughout the report. It is critical for ICER to put patients at the center of all of their assessments, and this should be abundantly clear in their choice of language throughout the report.

Again, we appreciate this opportunity to comment on ICER's draft evidence report and look forward to a continuing dialogue on ensuring patient access to the full continuum of care for both NASH and obesity.

Thank you,

A handwritten signature in black ink, appearing to read "Joe Nadglowski". The signature is stylized with a large, looped "N" and a trailing flourish.

Joseph Nadglowski, Jr., OAC President and CEO