

**Obeticholic Acid for the Treatment of Nonalcoholic Steatohepatitis:  
Comparative Clinical Effectiveness and Value**

***Summary of Public Comments Received on Initial Draft Report and ICER Response***

The Institute for Clinical and Economic Review (ICER) values the opportunity to receive and respond to public comment on its work products by interested stakeholders. There was one set of stakeholder comments submitted in response to the initial draft ICER report on obeticholic acid (OCA) for the treatment of nonalcoholic steatohepatitis (NASH) that was posted on May 25, 2016. Below is a summary of the comments received as well as responses from the ICER team and its research collaborators, including any major changes made to the report.

The one set of comments received consider the report to be premature, considering the ongoing Phase III trial (REGENERATE) and the lack of a current labeled indication for OCA in NASH. The comment also raises concerns that patients with advanced fibrosis might be dissuaded from enrolling in this trial based on the findings of our report.

While we recognize that the only current labeled indication for OCA is in primary biliary cholangitis, we received input from several clinical experts that there is significant interest in exploring off-label use of OCA in NASH given its significance as a clinical problem in the US and the current lack of effective treatments for the condition. We also note in the report that the results of our analyses of both comparative clinical effectiveness and comparative value should be considered preliminary, and that both components of this appraisal will be updated when data from REGENERATE become available.