



IEHP UM Subcommittee Approved Authorization Guideline			
Guideline	Liver Biopsy in Conjunction with Bariatric Surgery	Guideline #	UM SUR 05
		Original Effective Date	8/11/2010
Section	Surgery	Revision Date	11/14/2018

COVERAGE POLICY

IEHP does not cover routine liver biopsy in conjunction with bariatric surgery due to insufficient evidence that such practice alters the clinical management of non-alcoholic fatty liver disease (NAFLD) in obese individuals.

If a provider is concerned about a disease process in the liver the patient can be further assessed through laboratory analysis (*e.g.*, liver function tests), imaging studies (*e.g.*, ultrasound), and predictive scores/indices (*e.g.*, NAFLD Fibrosis Score, aminotransferase-to-platelet ratio index [APRI], Enhanced Liver Function [ELF] score, etc.), (Angulo, Hui, Marchesini, et al, 2007). Should these non-invasive modalities support the diagnosis of NAFLD or co-morbid metabolic syndrome in a bariatric surgery candidate, it is important to rule-out competing etiologies for liver disease (*e.g.*, viral infections, autoimmune processes, and alcohol use) prior to proceeding with an intraoperative liver biopsy (IOLB), (Chalasani, Younossi, Lavin, et al, 2012).

COVERAGE LIMITATIONS AND EXCLUSIONS

N/A

ADDITIONAL INFORMATION

Obesity is a topic of increasing public health concern in the United States, with over one-third of the population categorized as obese (*e.g.*, body mass index or BMI > 30). Obesity is linked to a number of chronic health conditions, including diabetes mellitus and heart disease, and has been associated with an increased mortality rate. However, the prevalence of the NAFLD spectrum – which encompasses simple steatosis, Non-Alcoholic Steatohepatitis (NASH), advanced fibrosis, and cirrhosis – in obese individuals has yet to be fully characterized. For this reason, some practitioners consider IOLB in conjunction with bariatric surgery to be a reasonable option for identifying disease in bariatric surgery candidates. However, since weight loss remains the best known treatment for NAFLD and bariatric surgery (presumably) will promote weight loss in obese patients regardless of their liver disease status, IOLB in conjunction with bariatric surgery does not appear to affect the clinical management of NAFLD. Additionally, information and recommendations related to post-surgical follow-up (including interval liver biopsy to monitor disease progression/regression) remain absent from current literature.

There have been several articles based on case series and cohort studies that appear in obesity surgery-related journals recommending IOLB in conjunction with bariatric surgery to distinguish NASH from NAFLD involving simple steatosis, (Dolce, Russo, et al, 2009; Kleiner, Berk, et al, 2014). However, no randomized clinical trials have compared outcomes between patients receiving IOLB and those receiving usual care. Furthermore, recent review articles have

concluded that the risk of IOLB does not warrant routine biopsy during bariatric surgery, (Barbois, Sandrine, Arvieux et al, 2017; Mahawar, Parmar, et al, 2016).

A recent review of the role of routine liver biopsy during bariatric surgery highlights the fact that while nearly a quarter of western world suffers from NAFLD, the role of screening is not well established (Mahawar, Parmar, et al, 2016). The authors reason that “if screening biopsies are not recommended for obese patients in general, it is hard to see how patients undergoing bariatric surgery would benefit from such biopsies.” Moreover, since “bariatric surgery actually alters the natural course of [NAFLD],” they conclude that the “existing scientific literature does not make a compelling case for routine liver biopsy with bariatric surgery.”

In another review it was noted that interoperative liver biopsy is still the gold standard for diagnosing the degree of NAFLD (Barbois, Arvieux, Leroy, et al 2017). Despite this, based on meta-analysis, only 25% of patients undergoing bariatric surgery have NASH which would require IOLB to confirm the diagnosis. Therefore, they conclude that the risk of routine IOLB to those who only have simple steatosis or no liver disease is unacceptable and they do not recommend routine IOLB. Alternatively, they propose that an algorithm of noninvasive tests needs to be developed and validated to determine who requires IOLB and those who do not.

CLINICAL/REGULATORY RESOURCE

Centers for Medicare and Medicaid Services (CMS) / Medi-Cal

CMS and Medi-Cal provide no specific policies addressing routine IOLB in conjunction with bariatric surgery.

MCG Medical Guidelines

MCG provides no specific guidelines addressing routine IOLB in conjunction with bariatric surgery.

The American Association of Clinical Endocrinologists (AACE), The Obesity Society, and the American Society for Metabolic and Bariatric Surgery (ASMBS) Clinical Practice Guidelines (March 2013)

The AACE, Obesity Society, and ASMBS have jointly issued a Grade D recommendation (*i.e.*, based on expert opinion because of lack of conclusive evidence) for liver biopsy in the perioperative evaluation of a bariatric surgery patient, indicating that “consideration can be made for liver biopsy at the time of surgery to document steatohepatitis and/or cirrhosis that may otherwise be unknown due to normal appearance and/or liver function tests.”

The American Association for the Study of Liver Diseases (AASLD), the American College of Gastroenterology (ACG), and the American Gastroenterological Association (AGA) Clinical Practice Guidelines (June 2012) and Practice Guidance (January 2018)

The AASLD, ACG, and AGA have jointly developed practice guidelines in 2012 and updated them with a guidance document in 2018. They have issued a Strength 1/Evidence B recommendation (e.g., strong, but further research may change confidence in the estimate of clinical effect) against routine screening for NAFLD in obesity clinics; a Strength 1/Evidence B recommendation indicating that the presence of the metabolic syndrome and the NAFLD Fibrosis Score may be used for identifying those at high risk for steatohepatitis and advanced

cirrhosis; and a Strength 1/Evidence B recommendation for the consideration of liver biopsy in individuals with suspected NAFLD in whom competing etiologies for hepatic steatosis and the presence and/or severity of co-existing chronic liver disease cannot be excluded without liver biopsy.

DEFINITION OF TERMS

N/A

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