IEHP UM Subcommittee Approved Authorization Guidelines

Liver Biopsy in Conjunction with Bariatric Surgery

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, s/he can further assess the patient 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.). 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).

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.

Apollo Managed Care:
Apollo 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): 2

The AASLD, ACG, and AGA have jointly 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 have been excluded.

The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) and the American Society for Metabolic and Bariatric Surgery (ASMBS) Clinical Practice Guidelines (March 2008): 4

SAGES and the Clinical Issues Committee of the ASMBS have jointly issued the following recommendation for liver biopsy as a part of the preoperative evaluation for bariatric surgery: “The liver may be assessed by hepatic profile and ultrasound. In cases of suspected cirrhosis, biopsy may be indicated.”

Aetna Policy Statement (May 2016): 5

Aetna considers routine liver biopsy for bariatric surgery not medically necessary in the absence of signs or symptoms of liver disease (e.g., elevated liver enzymes, enlarged liver).

CIGNA Policy Statement (May 2016): 6

CIGNA does not cover ANY of the following performed in conjunction with a bariatric surgery because each is considered not medically necessary:

- Cholecystectomy in the absence of signs or symptoms of gallbladder disease
- Liver biopsy in the absence of signs or symptoms of liver disease (e.g., elevated liver enzymes, enlarged liver)
- Herniorrhaphy for an asymptomatic hiatal hernia
- Routine vena cava filter placement for individuals not at high risk for venous thromboembolism (VTE)

Premera Blue Cross Policy Statement (April 2016): 7

Premera Blue Cross indicates that routine liver biopsy during obesity surgery is considered not medically necessary in the absence of pre-surgery clinical suspicion of liver disease. However, a liver biopsy during surgery may be performed to help identify the cause of:

- Persistent abnormal liver enzymes
- Unexplained jaundice
- A liver abnormality found on ultrasound, CT scan or nuclear scan
- Unexplained enlargement of the liver
Clinical Studies:

According to an ECRI Institute search of PubMed, the Cochrane Library, and other medical databases for studies related to IOLB in conjunction with bariatric surgery, there were six nonrandomized/comparison studies, five diagnostic cohort studies, and one retrospective review published between January 1, 2011 and April 22, 2016. Overall, the studies included in the ECRI Institute report demonstrate that IOLB may help identify the burden of NAFLD in patients undergoing bariatric surgery; however, it is unclear to what extent IOLB impacts post-surgical management if histological examination confirms the diagnosis of NAFLD.8

A number of the studies included in the ECRI Institute report examined the predictive accuracy of noninvasive testing (including serum markers and imaging modalities) when compared to biopsy-proven NAFLD in bariatric surgery patients. In a nonrandomized study by de Cleva et al. in 2015, the APRI was a reasonable predictor of advanced liver disease in an evaluation of 131 bariatric surgery patients.9 In a nonrandomized study by Karlas et al. in 2015, the ELF score correctly classified biopsy-proven cases of fibrosis in 87.5% of patients with liver disease comprising the study cohort of 41 participants.10 Alternately, the NAFLD Fibrosis Score was found to be a sub-optimal predictor of fibrosis in 225 patients undergoing bariatric surgery according to a 2014 nonrandomized study by Simo et al.11 The utility of evaluating serum triglycerides, liver function tests, and imaging studies was inconclusive, as some studies found these diagnostic tests to be efficient and effective predictive markers for NAFLD in obese individuals, while others did not.12-17

Several articles based on case series and cohort studies that appear in obesity surgery-related journals recommend IOLB in conjunction with bariatric surgery in order to distinguish non-alcoholic steatohepatitis (NASH) from NAFLD involving simple steatosis.18-23 However, no randomized clinical trials have compared outcomes between patients receiving IOLB and those receiving usual care. Furthermore, some authors note the controversial role of IOLB (especially in conjunction with bariatric surgery), pointing out that the primary reason to perform an IOLB during non-bariatric abdominal surgery is to identify NAFLD so that the patient can then be referred for bariatric surgery to aid in weight loss as a treatment for the liver disease.18 That said, the most recent Cochrane Systematic Review on the topic concluded that there is insufficient evidence to recommend for or against bariatric surgery as a treatment for NAFLD due to a lack of randomized controlled trials, though most prospective and retrospective cohort studies evaluating the effects of bariatric surgery on NAFLD have shown beneficial effects.19

In a recent review of the role of routine liver biopsy during bariatric surgery, Mahawar KK et al. highlight the fact that while nearly a quarter of western world suffers from NAFLD, the role of screening is not well established.24 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.”24 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.”24
**Background:**

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, 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.

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**Bibliography:**

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