Liver Biopsy

Policy Number: HS-261

Original Effective Date: 2/5/2015

Revised Date(s): 2/4/2016; 11/3/2016; 7/6/2017

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on www.wellcare.com. Guidelines are also available on the site by selecting the Provider tab, then “Tools” and “Clinical Guidelines”.

BACKGROUND

Liver biopsy is a fundamentally important tool in the management of patients with liver disease, important for diagnosis as well as staging of liver disease and its use is recommended until clearly superior methodologies are developed and validated (Recommendation Grading: Class IIB, Level C).1 According to the American Association for the Study of Liver Diseases (ASSLD), liver biopsy currently has three major roles: (1) for diagnosis, (2) for assessment of prognosis (disease staging), and/or (3) to assist in making therapeutic management decisions.1

- Percutaneous biopsy is the most common type and involves inserting a hollow needle through the abdomen into the liver.2 This method may be undertaken in one of three ways, namely palpation/percussion guided, image-guided, and real-time image-guided. A palpation/percussion-guided transthoracic approach, after infiltration of local anesthesia, is the classic percutaneous method (see also
Clinical Coverage Guideline


Percutaneous liver biopsy may be classified according to the site of entry of the biopsy needle, whether the biopsy is performed in a blind or guided manner, or whether the biopsy track is plugged after the procedure. Percutaneous liver biopsy has a small but inherent risk even in the most experienced hands, and it should therefore only be performed when the benefits of knowing the histology outweigh the risks to the patient (e.g., altering treatment or defining disease outcome). These benefits should be continually re-evaluated as new treatment options become available such as has occurred with the new antiviral therapies in viral hepatitis and in liver transplantation.

Acute hepatitis of unknown etiology, including possible drug-related hepatitis, has long been an indication for percutaneous liver biopsy, but liver biopsy in typical acute viral hepatitis is usually not necessary. The usefulness of liver biopsy in chronic viral hepatitis was once hotly debated; however, with the advent of new antiviral therapies...
there is no doubt of the value of histology in assessing those patients who will benefit from treatment and assessing their response to it. Patients with chronic hepatitis C virus infection as determined by a positive serum polymerase chain reaction test, who are being considered (and are otherwise candidates) for antiviral therapy should undergo liver biopsy. Liver biopsy should probably be undertaken even if the patient has normal aminotransferases as it has been reported that up to 50% of patients with active disease have a normal serum alanine aminotransferase.\(^3\)

**Radiological Considerations**

Sonography is often the first imaging procedure performed in the evaluation of individuals with suspected liver disease. Evaluation for biliary dilatation is always performed, because bile duct obstruction can cause abnormal liver test results, raising the suspicion of liver disease. Ultrasound is a useful but imperfect tool in evaluating diffuse liver disease. Sonography can show hepatomegaly, fatty infiltration of the liver, and cirrhosis, all with good but imperfect sensitivity and specificity. Sonography is of limited usefulness in acute hepatitis. Increased parenchymal echogenicity is a reliable criterion for diagnosing fatty liver. Cirrhosis can be diagnosed in the correct clinical setting when the following are present: a nodular liver surface, decreased right lobe–caudate lobe ratio, and indirect evidence of portal hypertension (collateral vessels and splenomegaly). Ultrasound plays an important role in the imaging of conditions and procedures common in patients with diffuse liver disease. The most common sonoanatomic finding in hepatitis is probably hepatomegaly. The so-called “starry night liver” pattern, increased periportal echoes coupled with decreased parenchymal echogenicity, is not useful clinically.\(^4,9\)

Ultrasound guided percutaneous liver biopsy is used extensively in the investigation of focal liver lesions; however, its use in diffuse liver disease is more controversial. It has been postulated that ultrasound guided biopsy should reduce complications. As the commonest cause of mortality is bleeding, it follows that the incidence of bleeding should be proportional to the incidence of hematoma formation. The rate of hematoma formation however is unaffected by the use of ultrasound guidance. The use of ultrasound to assist in liver biopsy for non-focal disease has been estimated to be cost effective in the U.S. if the additional cost of ultrasound is less than US$102.\(^3\)

The American College of Radiology (ACR), Society of Interventional Radiology (SIR), and Society for Pediatric Radiology (SPR) issued a joint guideline stating that the use of guided liver biopsy or fine needle aspiration in the diagnosis of hepatic tumors is the safest way of managing patients with liver disease.\(^4\)

Image-guided liver biopsy is recommended in certain clinical situations including in patients with known intrahepatic lesions (real-time imaging is strongly preferred) and in those with previous intra-abdominal surgery who may have adhesions. Image guided liver biopsy should also be considered in the following situations: patients with small livers that are difficult to percuss, obese patients, and patients with clinically evident ascites (Class I, Level C).\(^1\)

**American Association for the Study of Liver Diseases\(^7\)**

Highlights from the AASLD recommendations reflect guidelines that are intended to be flexible, in contrast to standards of care, which are inflexible policies to be followed in every case. Specific recommendations are based on relevant published information. Recommendation highlights include:

**Focal Disease and Mass Lesions**

- Liver biopsy should be considered in patients in whom diagnosis is in question, and when knowledge of a specific diagnosis is likely to alter the management plan (Class I, Level B).
- Liver histology is an important adjunct in the management of patients with known liver disease, particularly in situations where (prognostic) information about fibrosis stage may guide subsequent treatment; the decision to perform liver biopsy in these situations should be closely tied to consideration of the risks and benefits of the procedure (Class I, Level B).

**Complications**

- Those performing liver biopsy must be cognizant of multiple potential complications (including death) that may occur after liver biopsy and discuss these appropriately with their patients beforehand (Class I, Level C).
- Platelet transfusion should be considered when levels are less than 50,000-60,000/mL (this applies whether one is attempting biopsy transcutaneously or transvenously) (Class I, Level C).
• Use of prophylactic or rescue strategies (e.g., plasma, fibrinolysis inhibitors, recombinant factors) should be considered in specific situations, although their effectiveness remains to be established (Class IIa, Level C).
• In patients with renal failure or on hemodialysis, desmopressin (DDAVP) may be considered, although its use appears to be unnecessary in patients on stable dialysis regimens (Class IIa, Level B).
• Patients on chronic hemodialysis should be well dialyzed prior to liver biopsy, and heparin should be avoided if at all possible (Class I, Level C).

Pathological Considerations

• Because diagnosis, grading, and staging of non-neoplastic, diffuse parenchymal liver disease is dependent on an adequate sized biopsy, a biopsy of at least 2-3 cm in length and 16-gauge in caliber is recommended (Class I, Level C).
• It is recommended that if applicable, the presence of fewer than 11 complete portal tracts be noted in the pathology report, with recognition that diagnosis, grading, and staging may be incorrect due to an insufficient sample size (Class I, Level C).
• If cirrhosis is suspected, a cutting rather than a suction needle is recommended (Class I, Level B).
• In clinical practice, use of a simple (e.g., Metavir or Batts-Ludwig) rather than complex (e.g., Ishak) scoring system is recommended (Class I, Level C).
• Liver biopsy is currently a fundamentally important tool in the management of patients with liver disease, important for diagnosis as well as staging of liver disease and its use is recommended until clearly superior methodologies are developed and validated (Class IIB, Level C).

Pre-Biopsy

The AASLD recommends the following as part of the pre-biopsy testing:¹

• Prior to performance of liver biopsy, patients should be educated about their liver disease and about investigations other than liver biopsy (if any) that may also provide diagnostic and prognostic information (Class I, Level C).
• Prior to performance of liver biopsy, patients must be carefully informed about the procedure itself including alternatives (as above), risks, benefits, and limitations; written informed consent should be obtained (Class I, Level C).

Providers should consider the following medication recommendations:¹

• Antiplatelet medications should be discontinued several to 10 days before liver biopsy, although there is uncertainty surrounding the need for their discontinuation. Management of specific compounds should be handled on a case-by-case basis, taking into account their clinical indications, as well as the potential bleeding risk associated with their use in the setting of liver biopsy (Class I, Level C).
• Anticoagulant medications should be discontinued prior to liver biopsy. Warfarin should generally be discontinued at least 5 days prior to liver biopsy. Heparin and related products should be discontinued 12-24 hours prior to biopsy. In all patients, the risk of discontinuing anticoagulant medications must be weighed against the (potential) risk of bleeding during/after liver biopsy (Class I, Level C).
• Antiplatelet therapy may be restarted 48-72 hours after liver biopsy (Class I, Level C).
• Warfarin may be restarted the day following liver biopsy (Class I, Level C).

Grading System for Recommendations

<table>
<thead>
<tr>
<th>Classification</th>
<th>Conditions for which there is evidence and/or general agreement that a given diagnostic evaluation, procedure or treatment is beneficial, useful, and effective</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I</td>
<td>Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a diagnostic evaluation, procedure, or treatment</td>
</tr>
<tr>
<td>Class IIa</td>
<td>Usefulness/efficacy is less well established by evidence/opinion</td>
</tr>
<tr>
<td>Class IIb</td>
<td>Conditions for which there is evidence and/or general agreement that a diagnostic evaluation/procedure/treatment is not useful/effective and in some cases may be harmful</td>
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</tbody>
</table>
Liver biopsy is considered medically necessary when diagnosing and treating liver disease. The member must meet at least one of the following:

1. **Percutaneous Liver Biopsy**
   - Percutaneous liver biopsy is considered medically necessary for any of the following:
     - Evaluation of abnormal liver test results, if all other workup is unrevealing
     - Confirmation of diagnosis and prognostication
     - Determination of stage of fibrosis and grade of inflammation for chronic hepatitis B and hepatitis C
     - Evaluation of autoimmune hepatitis
     - Evaluation of a liver mass that does not exhibit typical imaging features of hepatocellular carcinoma (HCC)
     - Quantitative estimation of iron in hemochromatosis
     - Quantitative estimation of copper in Wilson disease
     - Estimation of the severity of alcoholic liver disease
     - Evaluation of suspected drug toxicity or drug reactions
     - Evaluation of the suitability of a donor liver for transplantation
     - Diagnosis and staging of nonalcoholic fatty liver disease (NAFLD) / nonalcoholic steatohepatitis (NASH)
     - Evaluation of unexplained jaundice
     - Diagnosis of cholestatic liver disease
     - Evaluation of infiltrative or granulomatous disorders
     - Evaluation of liver injury from immunosuppressive agents (methotrexate)
     - Follow-up evaluation while on antiviral treatment for chronic hepatitis C (rare)
     - Monitoring of disease activity of autoimmune hepatitis during treatment (may assist in determining if therapy can be discontinued)
     - Following a case of liver transplantation to evaluate and manage rejection
     - Diagnosis of acute cellular rejection
     - Diagnosis of chronic rejection
     - Diagnosis of recurrent hepatitis C
     - Diagnosis of post-transplant lymphoproliferative disorder
     - Diagnosis of cytomegalovirus (CMV) hepatitis
     - Protocol biopsies to monitor for fibrosis or inflammation (particularly in patients who received liver transplants to treat liver failure in chronic hepatitis C)

Contraindications of percutaneous liver biopsy include:

- Uncooperative patient
- Inability to identify a suitable biopsy site by either percussion or ultrasonographic guidance
- Prolonged (>1.5) international normalized ratio (INR)
- Decreased platelet count (< 60,000/mm3) (thrombocytopenia)
- Bleeding diathesis (e.g., hemophilia)
- Recent use (within the last 7 days) of aspirin or nonsteroidal anti-inflammatory drugs (NSAID) or...
antiplatelet class of medications
- Unavailability of blood products for transfusion
- Difficult body habitus of patient (transjugular route preferred), including morbid obesity of patient
- Ascites
- No backup support available from surgery or interventional radiology in case of a complication
- Suspected hemangioma or hepatic echinococcal cysts
- Abdominal wall infection over the identified biopsy site
- Infection in the right pleural cavity or below the right hemidiaphragm
- Bowel overlying biopsy site (on ultrasound or other abdominal imaging)

Plugged liver biopsy is considered medically necessary as an alternative method to a transvenous approach for members with prolonged PT and reduced platelet counts.

Computed Tomography (CT) needle biopsy of the liver is considered medically necessary when there is inadequate visualization of a target lesion by ultrasound. Image-guided liver biopsy is recommended in certain clinical situations including in patients with known intrahepatic lesions (real-time imaging is strongly preferred) and in those with previous intra-abdominal surgery who may have adhesions. Image guided liver biopsy should also be considered in the following situations: patients with small livers that are difficult to percuss, obese patients, and patients with clinically evident ascites (Class I, Level C).¹

2. **Transvenous (Transjugular or Transfemoral)**

Transvenous (transjugular or transfemoral) liver biopsy is considered medically necessary for members with diffuse liver disease and meet one or more of the following:²
- Deranged coagulation; OR,
- Massive ascites; OR,
- Liver abnormalities such as peliosis hepatitis; OR,
- In combination with transjugular intrahepatic portosystemic shunt (TIPSS) or venography; OR,
- Any other contraindication for percutaneous biopsy; OR,
- Failed percutaneous biopsy; OR,
- Morbid obesity

Contraindications of transvenous liver biopsy include:²
- When no specific contraindications exist, but attempts should be made to correct coagulation derangements before proceeding.
- Lack of venous access is a limitation for this procedure.
- Note that this technique should not be used in assessing focal liver lesions.

3. **Laparoscopic or Open Surgical**

Laparoscopic (or open surgical) liver biopsy is considered medically necessary for members needing a liver biopsy that are already undergoing Laparoscopy or open Laparotomy for a separate but medically necessary reason.

Liver biopsy as an add-on procedure is considered medically necessary for any of the following:³
- Evaluation of abnormal liver test results, if all other workup is unrevealing
- Confirmation of diagnosis and prognostication
- Determination of stage of fibrosis and grade of inflammation for chronic hepatitis B and hepatitis C
- Evaluation of autoimmune hepatitis
- Evaluation of a liver mass that does not exhibit typical imaging features of hepatocellular carcinoma (HCC)
- Quantitative estimation of iron in hemochromatosis
• Quantitative estimation of copper in Wilson disease
• Estimation of the severity of alcoholic liver disease
• Evaluation of suspected drug toxicity or drug reactions
• Evaluation of the suitability of a donor liver for transplantation
• Diagnosis and staging of nonalcoholic fatty liver disease (NAFLD) / nonalcoholic steatohepatitis (NASH)
• Evaluation of unexplained jaundice
• Diagnosis of cholestatic liver disease
• Evaluation of infiltrative or granulomatous disorders
• Evaluation of liver injury from immunosuppressive agents (methotrexate)
• Follow-up evaluation while on antiviral treatment for chronic hepatitis C (rare)
• Monitoring of disease activity of autoimmune hepatitis during treatment (may assist in determining if therapy can be discontinued)
• Following a case of liver transplantation to evaluate and manage rejection
• Diagnosis of acute cellular rejection
• Diagnosis of chronic rejection
• Diagnosis of recurrent hepatitis C
• Diagnosis of post-transplant lymphoproliferative disorder
• Diagnosis of cytomegalovirus (CMV) hepatitis
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Place of Service

Outpatient. The following guidelines reflect the American Gastroenterological Association’s position statement on outpatient percutaneous liver biopsy.6,8

• The patient must be able to easily return to the hospital where the procedure was performed within 30 minutes of developing any adverse symptoms.
• A reliable individual must be available to stay with the patient during the first night after the liver biopsy and provide care and transportation to the hospital, if necessary.
• The patient should not have any preexisting serious medical problems that might increase the risk of complications from the biopsy. Such problems may include encephalopathy, ascites, liver failure with severe jaundice, significant extrahepatic obstruction, significant coagulopathies, or serious comorbidities such as severe congestive heart failure. Also, patients should not be very old, very young, or so anxious that they require sedation.
• The facility where the biopsy is to be performed should have an approved laboratory, blood banking unit, easy access to an inpatient bed, and personnel to monitor the patient for 6 hours after the biopsy.

Inpatient. The patient should be hospitalized after biopsy if any evidence exists of bleeding, bile leak, pneumothorax, or other organ puncture. Hospitalization is suggested if the patient’s pain requires more than 1 dose of an analgesic in the first 4 hours after the biopsy.

Discharge. Post liver biopsy observation should continue for six hours and if at the end of this period there have been no complications then the Member may be discharged. The Member should, however, have a responsible person to stay with on the first post-biopsy night and should be able to return to hospital within 30 minutes should the need arise.3

CODING

CPT Codes
47000  Percutaneous needle biopsy of liver
47001  Percutaneous needle biopsy of liver, when done for indicated purpose at time of other major procedure (list separately in addition to code for primary procedure)
LIVER BIOPSY

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47100   Biopsy of liver, wedge
47379   Unlisted laparoscopic procedure, liver (for biopsy performed during a laparoscopic procedure)

HCPCS Codes – No applicable codes.

Covered ICD-10 Codes – This list may not be all inclusive
B18.0   Chronic viral hepatitis B with delta-agent
B18.1   Chronic viral hepatitis B without delta-agent
B18.2   Chronic viral hepatitis C
B25.0 – B25.9  Cytomegaloviral disease
D47.Z1  Post-transplant lymphoproliferative disorder (PTLD)
E83.00 – E83.09  Disorders of copper metabolism
E83.118 Other hemochromatosis
E83.119  Hemochromatosis, unspecified
K70.0 – K70.9  Alcoholic liver disease
K73.0 – K73.9  Chronic hepatitis, not elsewhere classified
K74.0 – K74.69  Fibrosis and cirrhosis of liver
K75.4  Autoimmune hepatitis
K75.81  Nonalcoholic steatohepatitis (NASH)
K76.0  Fatty (change of) liver, not elsewhere classified
K76.89  Other specified diseases of liver
K76.9  Liver disease, unspecified
K77  Liver disorders in diseases classified elsewhere
R17  Unspecified jaundice
R94.5  Abnormal results of liver function studies

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

REFERENCES


MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

Date       Action
7/6/2017       • Approved by MPC. No changes.
11/3/2016       • Approved by MPC. Inclusion of medical necessity reason list from percutaneous biopsy to the section for liver biopsy during another procedure.
2/4/2016       • Approved by MPC. Coding changes only.
2/5/2015       • Approved by MPC. New.

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