



UM-CDG-043 Noninvasive Tests for Hepatic Fibrosis

Approved By:
Director, Health Services

Effective Date:
10/22/2025

This Policy applies to all SECUR affiliates, associates, and subsidiaries.

Approved by Courtney Gonzales, Director of Health Services on behalf of the Utilization Management Committee.

PURPOSE

This coverage determination guideline serves to address noninvasive tests for hepatic fibrosis. Chronic liver disease is an overarching term that includes numerous conditions that contribute to the progressive destruction of the liver and its tissue. Chronic liver disease encompasses both disease impacting liver cells (hepatocellular) and conditions that impact liver structures and function. Left untreated, chronic liver disease can result in multiple liver conditions including hepatic fibrosis, the excessive accumulation of fibrotic connective tissue resulting from prolonged inflammation and progressive scarring of the liver. Increased fibrosis causes corresponding increase in liver stiffness and reduces blood flow through the liver. This can lead to the hardening of tissue and death of liver cells. Liver biopsy is considered the optimal means of diagnosis. However, because it is invasive and there are risks for associated complications, noninvasive testing may be considered to reduce potential risk.

For SECUR Health Plan members, National Coverage Determinations (NCD) and Local Coverage Determinations (LCD) will be applied to requests when applicable. SECUR Health Plan Coverage Determination Guidelines (CDG) will be utilized in the absence of an appropriate NCD and/or LCD.

DEFINITIONS

Elastography: noninvasive imaging-based method for measuring liver stiffness using ultrasound and low frequency elastic waves.

Acoustic Radiation Forced Impulse (ARFI) Elastography: utilizes ultrasound to measure the tissue displacement that results when a high-intensity acoustic pulse (push pulse) is applied, providing single, one-dimensional measures of tissue elasticity. An alternate method may produce a two-dimensional B mode image.

Magnetic Resonance Elastography (MRE): uses wave propagation and tissue deformation analysis to assess changes to tissue viscoelasticity.

Shear Wave Elastography (SWE): ultrasound-based technique utilizing the propagation of shear waves to measure liver stiffness.

Real Time SWE (2D-SWE): uses ARFI technology to interrogate multiple areas of the liver in rapid succession producing 5,000 frames per second.

Point-SWE (pSWE): like real time SWE but only measures shear wave speeds through one small area of tissue.

Vibration Controlled Transient Elastography (VCTE)/Transient Elastography (TE): uses a single element ultrasound transducer with mechanical vibration source.

Spleen Stiffness Measurement: a technique that measures SSM along with liver stiffness using elastography.

Quantitative Magnetic Resonance for Analysis of Tissue Composition: uses multiparametric magnetic resonance imaging (mpMRI) to quantify liver tissue.

Enhanced Liver Fibrosis (ELF) Test: measures three markers: hyaluronic acid, tissue inhibitor of matrix metalloproteinase 1 (TIMP-1), and procollagen III amino-terminal peptide (PIIINP).

Fibrosis-4 Index (FIB-4): combines three serum markers, platelet count, AST, and alanine transaminase (ALT) with a person's age using a nonproprietary calculation. The score corresponds with the level of fibrosis present.

FibroMeter: measures platelet count, prothrombin index, ALT, AST, blood urea nitrogen (BUN), hyaluronic acid, and age, then uses a proprietary algorithm to assess the fibrosis score.

FibroSpect II: measures serum hyaluronic acid, TIMP-1, and alpha2-macroglobulin (A2M) using a proprietary algorithm to convert the data into the fibrosis score.

Fibrosure (FibroTest): measures several markers for liver fibrosis and uses a proprietary algorithm to determine severity.

ASH Fibrosure: assesses liver fibrosis in those with alcoholic liver disease.

HCV Fibrosure: uses six serum biomarkers, in addition to age and gender, to measure the degree of hepatic fibrosis and necroinflammation in those with HCV.

NASH FibroSure: is used in those with MASLD/NAFLD and includes the same ten serum markers utilized in the ASH Fibrosure test but utilizes a different algorithm to determine the degree of fibrosis.

ActiTest: refers to the addition of ALT to the various FibroSure algorithms.

HepaScore: measure four markers for liver fibrosis, bilirubin, GGT, hyaluronic acid, and A2M, and applies the results to a proprietary algorithm to determine the liver fibrosis score.

LiverFAST: uses ten biomarkers along with a proprietary algorithm to measure fibrosis and inflammatory activity.

NIS4: test designed to identify the presence of at-risk NASH.

OWLiver Test: combines twenty eight biomarkers from a blood sample and analyzes in two proprietary algorithms to determine liver status regarding fibrosis.

Artificial Intelligence Technologies: combine computer systems, databases, and advanced algorithms to imitate human abilities and is being investigated on its ability to detect hepatic fibrosis.

POLICY

SECUR Health Plan considers Fibrosis-4 Index (FIB-4 index) as medically necessary for the detection and staging of hepatic fibrosis.

Vibration Controlled Transient Elastography/Transient Elastography will be considered medically necessary when the following criteria are met:

1. Initial diagnosis and staging of hepatic fibrosis in members with chronic liver disease.
2. Follow up assessment in a member with a FIB-4 test result that is either inconclusive or greater than or equal to 1.3.
3. Follow up assessment for a member with FIB-4 test result that is less than 1.3 when one of more of the following risk factors are present:
 - Diagnosis of type II diabetes mellitus or pre-diabetes
 - Radiologic confirmation of hepatic steatosis
 - Two or more metabolic risk factors
4. Prior to the use of Hemgenix for the treatment of hemophilia B.
5. Prior to the use of Roctavian for the treatment of hemophilia A.
6. Treatment related evaluation for hepatic fibrosis in any of the following:
 - Annual monitoring for members undergoing treatment for HBV, or
 - Six months after successful completion of treatment in individuals with autoimmune hepatitis

And all the following:

- Testing for hepatic fibrosis has not been performed within the previous six months, and
- VCTE/TE performed no more than once every six months.

Magnetic resonance elastography will be considered medically necessary when the following are met:

1. Diagnosis of chronic liver disease, or
2. Follow up assessment for hepatic fibrosis in a member with a FIB-4 test result that is either inconclusive or greater than or equal to 1.3, or
3. Follow up assessment for hepatic fibrosis in a member with a FIB-4 test result that is less than 1.3 when one or more of the following risk factors are present:
 - Diagnosis of type II diabetes mellitus or pre-diabetes
 - Radiologic confirmation of hepatic steatosis
 - Two or more metabolic risk factorsAnd all the following:
 - Absence of contraindications to magnetic resonance imaging, and
 - Absence of documented moderate to severe hepatic iron overload, and
 - Successful testing for hepatic fibrosis has not been performed within the last six months, and
 - VCTE/TE is not available, inconclusive, or contraindicated due to clinical factors that would impact accuracy of the testing

SECUR Health Plan considers the following as not medically necessary:

1. Real time shear wave elastography
2. Spleen stiffness measurements
3. ARFI
4. Proprietary liver fibrosis serum panels such as ASH Fibrosure, ELF test, Fibrometer, Fibrospect, Fibrosure, FibroTest-ActiTest panel, HCV FibroSure, HepaScore, LiverFAST, NASH FibroSure, NIS4, and OWLiver
5. Magnetic resonance elastography
6. Quantitative magnetic resonance for analysis of tissue composition such as LiverMultiScan

For the above, there is insufficient evidence to determine these services are effective in determining hepatic fibrosis and therefore do not meet standard acceptable medical treatment.

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