


# MEDICAL POLICY – 2.01.536

## Noninvasive Tests for Hepatic Fibrosis

Ref. Policy: PA-101		RELATED MEDICAL POLICIES: None
Effective Date:	Apr. 1, 2025	
Last Revised:	Mar. 24, 2025	
Replaces:	N/A	

Select a hyperlink below to be directed to that section.

- [POLICY CRITERIA](#) | [CODING](#) | [RELATED INFORMATION](#) | [REFERENCES](#) | [HISTORY](#)

 Clicking this icon returns you to the hyperlinks menu above.

### Introduction

Liver fibrosis is a process where healthy liver tissue is replaced by scar tissue from repeated injury or inflammation. It can be caused by diseases like hepatitis. The scar tissue causes stiffness in the liver and can lead to more serious liver disease. Certain noninvasive tests can be used to detect and monitor liver fibrosis. These include blood tests and imaging studies that use ultrasound and magnetic resonance imaging. This policy describes when noninvasive testing for liver fibrosis may be considered medically necessary.

**Note:** The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

### Policy Coverage Criteria

Service	Medical Necessity
<ul style="list-style-type: none"> <li><b>Enhanced Liver Fibrosis (ELF) Test</b></li> </ul>	<p><b>Enhanced Liver Fibrosis (ELF) Test and Fibro Test (FT) - Acti Test/HCV - Fibrosure may be considered medically necessary</b></p>

Service	Medical Necessity
<ul style="list-style-type: none"> <li><b>Fibro Test (FT) - Acti Test/HCV- Fibrosure</b></li> </ul>	<p><b>for the detection and prognosis of liver fibrosis in persons with chronic liver diseases when the following criteria are met:</b></p> <ul style="list-style-type: none"> <li>To evaluate hepatic fibrosis in chronic hepatitis C individuals</li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>To diagnose fibrosis in carriers of chronic hepatitis B virus</li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>Evaluating fibrosis in patients suffering from metabolic conditions (nonalcoholic fatty liver disease) and patients who consume excess alcohol</li> </ul> <ul style="list-style-type: none"> <li>To evaluate hepatic fibrosis in co-infected HIV carriers</li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>To provide access to new-generation non-interferon treatment for hepatitis</li> </ul> <p><b>Performance of Fibro Test (FT) - Acti Test/HCV- Fibrosure test more than twice per year or within 6 months following a liver biopsy or transient elastography is considered not medically necessary.</b></p> <ul style="list-style-type: none"> <li>The advice of a liver disease specialist should be sought for interpretation in chronic states in which the components of the test could be modified, such as chronic hemolysis, particularly in individuals with a cardiac valvular prosthesis; Gilbert disease; protease inhibitors used in HIV treatment, which can increase unconjugated bilirubin (Indinavir, Atazanavir); or gamma glutamyltransferase (GGT) and alanine aminotransferase (Ritonavir).</li> </ul> <p><b>Fibro Test (FT) - Acti Test/HCV- Fibrosure is considered investigational for all other indications.</b></p> <p><b>Note:</b> See <a href="#">Related Information</a> below for <a href="#">Limitations</a></p>
<p><b>Magnetic Resonance Elastography</b></p>	<p><b>Magnetic resonance elastography may be considered medically necessary for metabolic dysfunction-associated steatohepatitis (MASH), and hepatic fibrosis or cirrhosis is known or suspected.</b></p>



Service	Medical Necessity
	<p><b>Magnetic resonance elastography is investigational for:</b></p> <ul style="list-style-type: none"> <li>• Distinguishing hepatic cirrhosis from non-cirrhosis in persons with hepatitis C or other chronic liver diseases</li> <li>• All other indications (e.g., prediction of ascites in persons with chronic liver disease)</li> </ul>
<p><b>Transient Elastography (TE) (e.g., FibroScan)</b></p>	<p><b>Transient Elastography (TE) (e.g., FibroScan) may be considered medically necessary for the following indications:</b></p> <ul style="list-style-type: none"> <li>• Initial assessment of fibrosis of individuals with a diagnosis with hepatitis C</li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>• Follow-up assessment of fibrosis of individuals with a diagnosis of hepatitis C and previously documented F0, F1, or F2 per <b>METAVIR</b> staging guidelines</li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>• Assessment of advanced fibrosis (F2 or greater) versus minimal or no fibrosis (F1 or F0)</li> </ul> <p><b>TE (e.g., FibroScan) is considered not medically necessary when any of the following is present:</b></p> <ul style="list-style-type: none"> <li>• The individual has a BMI of &lt;19 kg/m<sup>2</sup> or &gt;30 kg/m<sup>2</sup></li> <li>• Focal lesions within the liver (e.g., tumor)</li> <li>• Acute liver injury</li> <li>• Previously documented liver fibrosis of F3 or F4</li> <li>• The individual is pregnant</li> <li>• Alanine transaminase (ALT) level five or more times the upper limit of normal (55 units per liter )</li> <li>• Implanted metal device (e.g., pacemaker, automated implantable cardioverter defibrillator (AICD), or any other implantable defibrillators)</li> <li>• TE performed within the previous 12 months</li> <li>• Liver biopsy performed within the previous six months</li> </ul> <p><b>TE is considered investigational for all other indications.</b></p>



Service	Investigational
<b>Detection or monitoring of hepatic fibrosis in persons with hepatitis C or other chronic liver diseases</b>	<p><b>The following are considered investigational for the detection or monitoring of hepatic fibrosis in persons with hepatitis C or other chronic liver diseases (e.g., NAFLD) (not an all- inclusive list):</b></p> <ul style="list-style-type: none"> <li>• Acoustic Radiation Forced Impulse (ARFI)</li> <li>• Hepatic Artery Resistive Index</li> <li>• Serum Marker Tests including: <ul style="list-style-type: none"> <li>○ Angiotensin converting enzyme</li> <li>○ FibroMAX</li> <li>○ FibroSpect</li> <li>○ HepaScore</li> <li>○ LIVERFAST</li> <li>○ Micro-fibrillar associated glycoprotein 4 (MFAP4)</li> <li>○ MicroRNA-21</li> <li>○ miR-29a and miR-122</li> <li>○ miRNA-221 and miRNA-222</li> <li>○ NASH FibroSure</li> <li>○ Plasma cytokeratin-18</li> <li>○ Signal-induced proliferation associated 1 like 1 (SIPA1L1)</li> </ul> </li> </ul>

## Coding

Code	Description
<b>CPT</b>	
76981	Ultrasound, elastography; parenchyma (e.g., organ)
76982	Ultrasound, elastography; first target lesion
76983	Ultrasound, elastography; each additional target lesion (List separately in addition to code for primary procedure)
81517	Liver disease, analysis of 3 biomarkers (hyaluronic acid [HA], procollagen III amino terminal peptide [PIIINP], tissue inhibitor of metalloproteinase 1 [TIMP-1]), using immunoassays, utilizing serum, prognostic algorithm reported as a risk score and risk of liver fibrosis and liver-related clinical events within 5 years
81596	Infectious disease, chronic hepatitis C virus (HCV) infection, six biochemical assays (ALT, A2-macroglobulin, apolipoprotein A-1, total bilirubin, GGT, and haptoglobin)



Code	Description
	utilizing serum, prognostic algorithm reported as scores for fibrosis and necroinflammatory activity in liver (Fibro Test (FT) - Acti Test/HCV- Fibrosure)
91200	Liver elastography, mechanically induced shear wave (e.g., vibration), without imaging, with interpretation and report

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

## Related Information

### Limitations

Clinical factors that could affect the assessment of hepatic fibrosis in the following noninvasive tests include:

- ELF
  - Gastrectomy – increases HA
  - Extra-hepatic fibrosing conditions – conditions such as interstitial lung disease can increase collagen markers
- FibroTest
  - Active alcohol use – increases GGT
  - Inflammatory condition – increased A2M levels and falsely elevated FibroTest
  - Hemolysis – decreases haptoglobin levels and increases total bilirubin
  - Gilbert syndrome and other cholestatic diseases – increased total bilirubin
  - Acute sickle cell crisis – related to hemolysis
- MRE
  - Ascites - large amounts can lead to test failure
  - Iron overload – affects T2 signaling leading to test failure
- TE



- Narrow interstitial space
- Ascites – affects transmission of vibration and mechanical signals
- Moderate to severe steatosis – causes overestimate fibrosis
- Chronic kidney disease – hemofiltration can result in lower stiffness in those with baseline fluid overload
- Acute sickle cell crisis – acute vaso-occlusive crisis increases liver stiffness

## Tests

- Enhanced Liver Fibrosis (ELF) Test: measures three direct markers of fibrosis: hyaluronic acid (HA), N-terminal propeptide of procollagen type III (PIIINP), and tissue inhibitor of metalloproteinase 1 (TIMP-1)
- Fibro Test (FT) - Acti Test/HCV- FibroSure: consists of five standard biochemical markers (alfa2-macroglobulin (A2M), apolipoprotein A1, haptoglobin, gamma-glutamyltransferase GGT, and total bilirubin)

## Transient elastography (TE):

METAVIR Scoring System	
Activity Grade	
A0	No activity
A1	Mild activity
A2	Moderate activity
A3	Severe activity
Fibrosis Stage	
F0	No fibrosis
F1	Fibrous portal expansion (mild fibrosis)
F2	Few bridges or septa (moderate fibrosis)
F3	Numerous bridges or septa (severe fibrosis)
F4	Cirrhosis



## References

1. Berzigotti, A., Tsochatzis, E., Boursier, J., Castera, L., Cazzagon, N., Friedrich-Rust, M., Petta, S., & Thiele, M. (2021). EASL Clinical Practice Guidelines on non-invasive tests for evaluation of liver disease severity and prognosis – 2021 update. *Journal of Hepatology*, 75(3), 659–689. [EASL Clinical Practice Guidelines on non-invasive tests for evaluation of liver disease severity and prognosis - 2021 update - PubMed](#). Accessed February 26, 2025.
2. Bojanic, K., Bogojevic, M. S., Vukadin, S., Sikora, R., Ivanac, G., Lucic, N. R., Smolic, M., Tabll, A. A., Wu, G. Y., & Smolic, R. (2023). Noninvasive Fibrosis Assessment in Chronic Hepatitis C Infection: An Update. In *Journal of Clinical and Translational Hepatology* (Vol. 11, Issue 5, pp. 1228–1238). Xia and He Publishing Inc. <https://doi.org/10.14218/JCTH.2022.00365>. Accessed February 26, 2025.
3. Tamaki, N., Kurosaki, M., Huang, D. Q., & Loomba, R. (2022). Noninvasive assessment of liver fibrosis and its clinical significance in nonalcoholic fatty liver disease. In *Hepatology Research* (Vol. 52, Issue 6, pp. 497–507). John Wiley and Sons Inc. <https://doi.org/10.1111/hepr.13764>. Accessed February 26, 2025.
4. Sterling, R. K., Duarte-Rojo, A., Patel, K., Asrani, S. K., Alsawas, M., Dranoff, J. A., Fiel, M. I., Murad, M. H., Leung, D. H., Levine, D., Taddei, T. H., Taouli, B., & Rockey, D. C. (2024). AASLD Practice Guideline on imaging-based noninvasive liver disease assessment of hepatic fibrosis and steatosis. *Hepatology*. <https://doi.org/10.1097/HEP.0000000000000843>. Accessed February 26, 2025.
5. Curry, M. P., & Afdhal, N. H. (2024, January 12). Noninvasive assessment of hepatic fibrosis: Overview of serologic tests and imaging examinations [Updated 2024 January 12]. Wolters Kluwer - UpToDate. <https://www.uptodate.com/contents/noninvasive-assessment-of-hepatic-fibrosis-overview-of-serologic-tests-and-imaging-examinations#H61007147>. Accessed February 26, 2025.
6. Krishna, M. (2021). Histological Grading and Staging of Chronic Hepatitis. In *Clinical Liver Disease* (Vol. 17, Issue 4, pp. 222–226). John Wiley and Sons Inc. <https://doi.org/10.1002/cld.1014>

## History

Date	Comments
09/16/19	New policy, approved August 13, 2019, effective January 1, 2020. Transient Elastography (TE) (e.g., FibroScan) may be considered medically necessary for the indications listed in this policy; otherwise, considered investigational.
11/01/20	Annual Review, approved October 22, 2020. No changes to policy statement, references updated.
05/01/21	Annual Review, approved April 1, 2021. No changes to policy statement, references updated. Added CPT codes 76981, 76982 and 76983.
02/01/22	Annual Review, approved January 24, 2022. Title changed from “Transient Elastography” to “Noninvasive Tests for Hepatic Fibrosis”. Added Medically Necessary criteria for non-invasive blood tests: considered medically necessary for the detection



Date	Comments
	and prognosis of liver fibrosis in persons with chronic liver diseases and criteria for Magnetic Resonance Elastography. References updated. Added CPT codes 0014M and 81596.
01/01/23	Interim Review, approved December 12, 2022. No changes to policy statement, references updated. Changed the wording from "patient" to "individual" throughout the policy for standardization.
01/01/24	Annual Review, approved December 11, 2023. Formatting changes made to policy statement table to clarify that criteria applies to both the Enhanced Liver Fibrosis (ELF) Test and the Fibro Test (FT) - Acti Test/HCV – FibroSure; policy statements unchanged.
03/01/24	Coding update. Removed termed code 0014M and added CPT code 81517.
12/01/24	Annual Review, approved November 25, 2024. No changes to policy statement, references updated.
04/01/25	Annual Review, approved March 24, 2025. Minor update to policy statement wording. References updated.

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2025 Premera All Rights Reserved.

**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy only applies to Individual Plans.

