

Current Effective Date: 5/1/25

Status: Approved

Reviewed by Medical Policy Subcommittee: 5/1/25

Reviewed Dates: 1/8/25

INSTRUCTIONS FOR USE DISCLAIMER:

SummaCare posts policies relating to coverage and medical necessity issues to assist members and providers in administering member benefits. These policies do not constitute a contract or agreement between SummaCare and any member or provider. The policies are guidelines only and are intended to assist members and providers with coverage issues. SummaCare is not a health care provider, does not provide or assist with health care services or treatment, and does not make guarantees as to the effectiveness of treatment administered by providers. The treatment of members is the sole responsibility of the treating provider, who is not an employee of SummaCare, but is an independent contractor in private practice. The policies posted to this site may be updated and are subject to change without prior notice to members or providers.

Medical policies in conjunction with other nationally recognized standards of care are used to make medical coverage decisions.

Elastography Policy

Indication/Usage:

Noninvasive imaging technologies to detect liver fibrosis or cirrhosis for individuals with chronic liver disease are being performed as alternatives to liver biopsy

Transient Elastography

Transient elastography (TE, FibroScan) produces a low frequency wave inducing an elastic shear wave that propagates throughout the liver. Ultrasound tracks the wave to produce a one dimensional image liver stiffness. Increases in liver fibrosis also increase liver stiffness and resistance of liver blood flow. Transient elastography does not perform as well in individuals with ascites, higher body mass index, or narrow intercostal margins. TE is used to measure fibrosis, unlike liver biopsy, it will not provide

information on necroinflammatory activity and steatosis, nor is it accurate during acute hepatitis or hepatitis exacerbations.

Magnetic Resonance Elastography

Magnetic resonance elastography (MRE) involves a pulse sequence sensitive to the transmission of waves through the tissue producing a color-scaled, quantitative, three-dimensional image. MRE has the advantages to analyze larger liver volumes, analyze liver volumes of obese patients or patients with ascites; and analyze viscoelasticity using a 3-dimensional displacement vector.

Acoustic Radiation Force Impulse

Acoustic radiation force impulse (ARFI) elastography is a noninvasive method for detecting and staging hepatic fibrosis. ARFI involves a ultrasound beam creating a two dimensional image. This creates a 'push' technique inside the tissue using the acoustic radiation force from a focused ultrasound beam. Softer tissue is more easily pushed than stiffer tissue, thus creating a map a tissue stiffness and can be performed on individuals with a significant amount of ascites.

Shear Wave Elasticity

Shear wave elasticity (SWE) measures the shear waves produced from focus beams of ultrasound energy from conventional transducers producing movement within the tissue. Providing a 2- dimensional map of tissue elasticity or stiffness.

Real-time Tissue Elastography

Real-time tissue elastography (RTE) evaluates reproducible differences in ultrasound signals that result from compression of tissues and uses color Doppler to generate an image of tissue movement in response to the external vibrations. RTE can be performed in patients with ascites or inflammation but does not work well in members with severe obesity.

Medical Indications for Authorization

Commercial and Medicare Members

1. SummaCare considers these forms of transient elastography (FibroScan) (Acoustic Radiation Force Impulse, Shear Wave Elasticity, Real-time Tissue, Elastography) medically necessary when the following criteria is met
 - a. To detect or stage advanced hepatic (liver) fibrosis and cirrhosis in an individual with hepatitis B, hepatitis C, chronic alcoholic liver disease and/or all other chronic liver diseases.
 - b. TE can only be performed every 6 months.
 - c. TE can't be performed within six months following a liver biopsy.
2. SummaCare considers Magnetic resonance elastography (MRE) medically necessary to diagnose and/or manage advanced hepatic fibrosis or cirrhosis when the following criteria is met.
 - a. Members with nonalcoholic fatty liver disease **or** with other established chronic liver diseases when ultrasound elastography can't be performed or is not diagnostic.

- b. MRE can only be performed every 6 months.
- c. MRE can't be performed within six months following a liver biopsy.

There are currently no NCD or LCD for Elastography for hepatic fibrosis per

CPT Codes

76981 Ultrasound, elastography; parenchyma (eg, organ)

91200 Liver elastography, mechanically induced shear wave (eg, vibration), without imaging, with interpretation and report

Limitations

The following procedures are considered experimental, investigational, or unproven because the effectiveness of these approaches has not been established:

- Any other ultrasound elastography techniques of the liver not listed above
- Acoustic radiation forced impulse (ARFI) and magnetic resonance elastography (MRE) for distinguishing hepatic cirrhosis from non-cirrhosis in persons with hepatitis C and other chronic liver diseases
- TC for members with ascites

Coverage Decisions

Coverage decisions made per CMS Guidelines, Hayes Research and industry standards research

Plans Covered By This Policy

Commercial and Medicare

Self-funded Commercial groups refer to plan document for coverage

Sources Reviewed

Abe K, Takahashi A, Imaizumi H, et al. Utility of magnetic resonance elastography for predicting ascites in patients with chronic liver disease. J Gastroenterol Hepatol. 2018; 33(3):733-740.

American Association for the Study of Liver Diseases, Infectious Disease Society of American Recommendations for Managing, and Treating Hepatitis C, March 21, 2014. A

Besutti G, Valenti L, Ligabue G, et al. Accuracy of imaging methods for steatohepatitis diagnosis in nonalcoholic fatty liver disease patients: A systematic review. *Liver Int.* 2019; 39(8):1521-1534.

Bi J, Liu L, Qin T, et al. Comparison of magnetic resonance elastography and transient elastography in the diagnosis of hepatic fibrosis: A systematic review and meta-analysis. *Ann Palliat Med.* 2021; 10(8):8692-8700.

Cai C, Song X, Chen X, et al. Transient Elastography in Alcoholic Liver Disease and Nonalcoholic Fatty Liver Disease: A Systemic Review and Meta-Analysis. *Can J Gastroenterol Hepatol.* 2021; 2021: 8859338.

Chon YE, Choi EH, Song KJ, et al. Performance of transient elastography for the staging of liver fibrosis in patients with chronic hepatitis B: a meta-analysis. *PLoS One.* 2012; 7(9):e44930.

CMS <https://www.cms.gov/medicare-coverage-database/search.aspx>

Crossan c, Tsochatatzid EA, Longworth L, Gurusamy K, Rodriguez-Peralvarez M, Mantzoukis K, O'Brien J, Thalassinou E, Papastergiou V, Burroughs A. Cost-effectiveness of noninvasive methods for assessment and monitoring of liver fibrosis and cirrhosis with chronic liver disease: systematic review and economic evaluation. *Health Technol Assess.* 2015 Jan; 19(9):1-409, v-vi

Friedrich-Rust M, Lupsor M, de Knecht R, Dries V, Buggisch P, Gebel M, Maier B, Herrmann E, Sagir A, Zachoval R, Shi Y, Schneider MD, Badea R, Rifai K, Poynard T, Zeusem S, Sarrasin C. Point shear wave elastography by acoustic radiation force impulse quantification in comparison to transient elastography for the noninvasive assessment of liver fibrosis in chronic hepatitis C; A prospective international multicenter study.

Ultraschall Med. 2015 Jun; 36(3):239-247.

Hayes, Inc. Noninvasive assessment of hepatic fibrosis: ultrasound-based elastography. Oct 2017

Kobayashi K, Nakao H, Nishiyama T, et al. Diagnostic accuracy of real-time tissue elastography for the staging of liver fibrosis: A meta-analysis. *Eur Radiol.* 2015; 25(1):230-238.

Lichtinghagen R, Bahr MJ. Noninvasive diagnosis of fibrosis in chronic liver disease. *Expert Rev Mol Diagn.* Sep 2004;4(5):715-726.

Myers RP, et al. Feasibility and diagnostic performance of the FibroScan XL probe for liver stiffness measurement in overweight and obese patients. *Hepatology* 55.1 (2012): 199-208

Naveau S, Raynard B, Ratziu V, et al. Biomarkers for the prediction of liver fibrosis in patients with chronic alcoholic liver disease. *Clin Gastroenterol Hepatol.* Feb 2005; 3(2):167-174.

Tsochatzis EA, Gurusamy KS, Ntaoula S, et al. Elastography for the diagnosis of severity of fibrosis in chronic liver disease: a meta-analysis of diagnostic accuracy. *J Hepatol.* Apr 2011; 54(4):650-659.

Wilder J, Patel K. The clinical utility of FibroScan® as a noninvasive diagnostic test for liver disease. Med Devices (Auckl). 2014 May 3; 7:107-14

Xu XY, Wang WS, Zhang QM, et al. Performance of common imaging techniques vs serum biomarkers in assessing fibrosis in patients with chronic hepatitis B: A systematic review and metaanalysis. World J Clin Cases. Aug 06 2019; 7(15): 2022-2037.