

Medica Coverage Policy



Policy Name:	Elastography – Mayo Medical Plan Only
Effective Date:	1/15/2024

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member’s plan document for other specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.

NOTE: THIS POLICY APPLIES TO MAYO MEDICAL PLAN (MMP) MEMBERS.

NOTE: For all other medica members, Medica is using clinical criteria developed by Carelon, a utilization management (UM) program third-party vendor, to assist in administering magnetic resonance elastography. See also Medica Coverage Policy, *Sacroiliac Joint Fusion, Open*.

Coverage Policy

Ultrasound transient elastography (e.g. FibroScan) for diagnosing and monitoring liver fibrosis or cirrhosis in individuals with chronic liver disease (e.g., cirrhosis, hepatitis C, nonalcoholic fatty liver disease) is **COVERED**.

Ultrasound transient elastography (e.g., FibroScan) is investigative and unproven and therefore **NOT COVERED** for ALL OTHER liver disease and ALL non-liver disease (i.e., breast, thyroid, prostate) indications. There is insufficient reliable evidence in the form of high-quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

Magnetic resonance elastography is **COVERED** for diagnosing and monitoring:

- a. Liver fibrosis or cirrhosis in individuals with chronic liver disease, when ultrasound transient elastography is unavailable, contraindicated, or results are indeterminate
- b. Nonalcoholic fatty liver disease, known or suspected.

Magnetic resonance elastography is investigative and unproven and therefore **NOT COVERED** for ALL OTHER liver disease and ALL non-liver disease (i.e., breast, thyroid, prostate) indications. There is insufficient reliable evidence in the form of high-quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

Other modalities of elastography (e.g., acoustic radiation force impulse imaging (ARFI), two-dimensional shear wave (SWE) elastography) are investigative and unproven and therefore **NOT COVERED** for all indications. There is insufficient reliable evidence in the form of high-quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

Note: See also related Medica coverage policy, *Biochemical Biomarker Panels for Assessing Hepatitis-Associated Liver Disease*.

Note: See also related Medica coverage policy, *Genetic Testing: Gastroenterologic Disorders (Non-Cancerous)*, for biochemical biomarker panel use in management of non-hepatitis associated non-cancerous liver disease.

Description

Elastography is a noninvasive method for measuring stiffness or elasticity of organs and other structures in the body. Elastography uses low frequency vibrations during an ultrasound or MRI to measure organ stiffness (or elasticity). Ultrasound elastography is also known as vibration-controlled transient elastography (VCTE) or ultrasound transient elastography (TE).

Elastography is most commonly used to assess the liver, but new areas are emerging such as breast, kidney, thyroid, prostate, and muscles/tendons. Causes of liver disease include, but are not limited to alcohol use, nonalcoholic fatty liver disease, viral hepatitis (A, B, C), and autoimmune disorders. The technology is based on the principle that malignant tissue is harder than benign tissue. Ultrasound (US) or magnetic resonance imaging (MRI) measures how quickly these vibrations move through the organ. For example, liver disease may cause a buildup of scar tissue (fibrosis), which causes tissue stiffness. Elastography may be used as a non-invasive alternative to measure stiffness in place of a standard liver biopsy. Elastography is used to aid in the clinical diagnosis and management of solid tissue disease.

FDA Approval

FibroScan® Family of Products (Echosens) received initial FDA approval 04/05/2013 with subsequent approvals for additional models.

Magnetic resonance elastography (MRE) is a procedure and, therefore, not subject to FDA regulation. However, any medical devices, drugs, biologics, or tests used as part of this procedure may be subject to FDA regulation. FDA clearance of devices:

- MR Elastography (FDA 510(k) approval # K140666; June 2014)
- MR-Touch Option (FDA 510(k) approval # K083421; July 2009)

Acoustic Radiation Force Impulse (ARFI): FDA clearance of devices:

- Siemens Acuson S2000/S3000 Diagnostic U/S system (FDA 510(k) approval #: K130739; 2013)
- Philips EPIQ Diagnostic U/S System (FDA 510(k) approval #: K160807, K182857; 2016, 2018)

SonixTouch Ultrasound Imaging System received 510(k) marketing clearance by the FDA in October 2008.

Prior Authorization

Prior authorization is not required. However, services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial may result if criteria are not met.

Coding Considerations

Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT Codes:

- 76391 – Magnetic resonance (eg, vibration elastography)
- 76981 – Ultrasound, elastography; parenchyma (eg, organ)
- 76982 – Ultrasound, elastography; first target lesion
- 76983 – Ultrasound, elastography; each additional target lesion (list separately in addition to code for primary procedure)
- 91200 – Liver elastography, mechanically induced shear wave (eg, vibration), without imaging, with interpretation and report

Original Effective Date: 9/14/2020
Re-Review Date(s): 7/21/2021
11/15/2023
5/01/2024 – Administrative update; policy applies to Mayo Medical Plan members only

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