# Cohere Medicare Advantage Policy - Magnetic Resonance (MR) Elastography

*Clinical Guidelines for Medical Necessity Review*

**Version:** 1
**Effective Date:** October 17, 2024

# Important Notices

## Notices & Disclaimers:

**GUIDELINES ARE SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION-MAKING OF END USERS.**

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## Other Notices:



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## Guideline Information:

**Specialty Area:** Diagnostic Imaging
**Guideline Name:** Cohere Medicare Advantage Policy - Magnetic Resonance (MR) Elastography

**Date of last literature review**: 10/15/2024
**Document last updated:** 10/16/2024
**Type:** [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17yo)

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# Medical Necessity Criteria

***Service: Magnetic Resonance (MR) Elastography***

## Benefit Category

Not applicable.

## Related CMS Documents

Please refer to the CMS Medicare Coverage Database for the most current applicable CMS National Coverage.[1-2]

- There are no applicable NCDs and/or LCDs for MR Elastography.

## Recommended Clinical Approach

Magnetic resonance elastography (MRE) is a non-invasive imaging technique that measures the mechanical properties of tissues, particularly stiffness, which can indicate the presence of fibrosis and other pathologies. This technique is primarily used in the assessment of liver diseases, but it also has applications in diagnosing conditions affecting the brain, muscles, and other organs. MRE provides a quantitative measure of tissue elasticity, which is valuable in evaluating the extent of disease, monitoring disease progression, and guiding treatment decisions.[3]

The clinical journey leading to MRE typically starts with the detection of risk factors or symptoms suggestive of liver fibrosis, such as elevated liver enzymes or clinical signs of chronic liver disease. Initial imaging studies like ultrasound or CT may indicate abnormalities, prompting further evaluation with MRE to assess the degree of fibrosis. MRE is particularly useful in patients for whom a liver biopsy is contraindicated or who require a non-invasive method to monitor treatment response over time.[4]

MRE is a valuable tool in tumor diagnosis by measuring tissue stiffness across various cancers. MRE can detect changes in tissue stiffness before clinical symptoms appear, making it essential for early tumor detection, treatment planning, and assessing resistance to chemoradiotherapy.[5]

## Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of MR Elastography. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- There is a risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- A potential exists for allergic reactions to contrast material, if used in the study. The MRI department staff will monitor the patient for an allergic reaction and treat as recommended by a physician.[6-7]
- Use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.[6-7]
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is uncertain risk for MR imaging in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.[8]
- There is a risk of increased healthcare costs and complications from the inappropriate use of additional interventions.[9]

The clinical benefits of using these criteria include:

- MRE is a safe, non-invasive alternative to liver biopsy to detect and stage liver fibrosis. One study included patients with chronic hepatitis B, chronic hepatitis C, metabolic dysfunction-associated steatotic liver disease, autoimmune liver disease, or iron overload. The success rate following MRE was 98%. For patients that required additional evaluation, a biopsy was still recommended for 22% of the patients. Of this percentage, 12.5% MRE showed minimal fibrosis, and biopsy allowed for

further evaluation (e.g., steatohepatitis, to identify the origin of abnormal transaminase levels.[3-4,10]
- Technology advances have demonstrated the precision of MRE as well as the use of biomarkers to differentiate various diagnoses (e.g., fibrosis vs inflammation or hepatic venous congestion).[11]
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

## Medical Necessity Criteria

### Indications

➔ **Magnetic resonance elastography (MRE)** is considered appropriate if **ANY** of the following is **TRUE**[3-5,10]:
- ◆ The patient has metabolic dysfunction-associated steatotic liver disease (MASLD), and hepatic fibrosis or cirrhosis known or suspected; **OR**
- ◆ **ALL** of the following are **TRUE**:
  - The patient has a chronic liver disease (e.g., chronic hepatitis C virus infection, chronic hepatitis B virus infection) and hepatic fibrosis or cirrhosis is known or suspected; **AND**
  - Ultrasound elastography cannot be performed or is nondiagnostic; **OR**
- ◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
  - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**

- One-time clarifying follow-up of a prior indeterminate finding; **OR**
- In the absence of change in symptoms, there is an established need for monitoring which would influence management.

### Non-Indications

➔ **Magnetic resonance elastography (MRE)** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**
- ◆ The patient has metallic clips on vascular aneurysms; **OR**
- ◆ Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
- ◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern.

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.
**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

## Level of Care Criteria

Inpatient or Outpatient

## Procedure Codes (CPT/HCPCS)

| CPT/HCPCS Code | Code Description |
|---|---|
| 75565 | Cardiac magnetic resonance imaging for velocity flow mapping (List separately in addition to code for primary procedure) |
| 76391 | Magnetic resonance (eg, vibration) elastography |

**Disclaimer:** G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

# Medical Evidence

Feuille et al. (2024) analyzed clinical situations where magnetic resonance elastography (MRE) of the liver is indicated. A total of 96 MRE exams and respective follow-ups were included over 14 months. The primary indication for all MREs was non-invasive assessment of liver fibrosis, with one additional indication identified in every case. Liver biopsy decreased after MRE however, when liver biopsy was indicated, the patient was very likely to undergo the procedure. MRE is a safe alternative for patients however, rare but serious risks may occur.[4]

Yang et al. (2021) review the advances of MRE as a non-invasive method to diagnose tumors. Tissue stiffness due to pathological changes may be visible sooner with MRE than with other imaging modalities. MRE is often utilized for tumors of the brain, breast, colon, gallbladder, liver, prostate, and uterus. Early detection of tumor changes and resistance to chemoradiotherapy are noted benefits of MRE.[5]

Venkatesh et al. (2013) review the utilization of MRE of the liver. While adequate to detect and stage liver fibrosis, its use is for additional applications. The authors note that future research is needed to improve three-dimensional imaging quality and resolution to aid in characterizing liver lesions and fibrosis. MRE also shows promise for evaluating patient response to antifibrotic treatments.[3]

The diagnostic performance of MRE for advanced (≥ F3) fibrosis is excellent, with most studies reporting greater than 80% sensitivity and greater than 90% specificity.[5]

In a large meta-analysis by Singh et al including 12 studies and 697 individual patients with different chronic liver diseases from Europe and the United States, the area under the receiver operating characteristic curve values for discriminating any (≥ F1), significant (≥ F2), or advanced fibrosis (≥ F3) or cirrhosis (≥ F4) were 0.84, 0.88, 0.93, and 0.92, respectively.[10]

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# Clinical Guideline Revision History/Information

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| **Review History** | | |
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