



IEHP UM Subcommittee Approved Authorization Guideline			
Guideline	Elastography	Guideline #	UM DIA 08
		Original Effective Date	8/12/2015
Section	Diagnostic	Revision Date	8/17/2023

COVERAGE POLICY

Based on a review of the currently available literature, IEHP considers the use of Elastography (e.g. Fibroscan) medically necessary for distinguishing hepatic cirrhosis from non-cirrhosis in persons with hepatitis C or other chronic liver diseases.

COVERAGE LIMITATIONS AND EXCLUSIONS

Limitations:

1. Elastography done more than twice in one year is not considered medically necessary.
2. Performing elastography within 6 months of a liver biopsy is not considered medically necessary.
3. The IEHP UM Subcommittee considers this procedure experimental and investigational for any other condition.

ADDITIONAL INFORMATION

Liver biopsy is considered the gold standard for diagnosis and management of chronic liver disease. It has been used to evaluate patients with viral hepatitis (particularly those with hepatitis B virus [HBV] or hepatitis C virus [HCV] infection), to stage disease, and to determine whether treatment should be pursued. However, it is an invasive procedure that may result in complications, such as possible pain and bleeding. A liver biopsy samples only a very small piece of the liver, which can lead to incorrect staging if this sample is not representative of the rest of the liver. Thus, liver biopsy can lead to sampling error, which may result in either over-staging or under-staging of fibrosis; sampling error may occur in up to 25-30% of liver biopsies. Non-invasive hepatic fibrosis tests have been introduced as an alternative.

Elastography offers several advantages compared to a liver biopsy. It is non-invasive, performed at the point of care, is painless and takes 5-7 minutes to perform. Results of the test are instantaneous and can be used to make decisions during the patient's visit.

CLINICAL/REGULATORY RESOURCE

Medicare does not discuss this type of medical imaging. Medi-Cal has a policy that mirrors our own guideline and establishes frequency limitations and diagnoses necessary to have this done. MCG addresses the use of magnetic resonance elastography and vibration-controlled transient elastography (VCTE) ultrasound for chronic liver disease. Both procedures are indicated for the need to assess for advanced fibrosis or cirrhosis but does not address frequency limits or mention of use with other organs.

Apollo addresses limitations of VCTE but does not address frequency limits or use of VCTE with other organs.

An Aetna Clinical Policy Bulletin contains frequency recommendations for this procedure. Performance of transient elastography (FibroScan, Fibrosure) more than twice per year is not considered medically necessary. Performance of transient elastography within 6 months following a liver biopsy is not considered medically necessary. Transient elastography is considered experimental and investigational for all other indications.

DEFINITION OF TERMS

Elastography is a type of ultrasonography that takes advantage of the changed elasticity of soft tissues resulting from pathological or physiological processes. Fibrosis associated with chronic liver diseases causes the liver to become stiffer than normal tissues. Elastography can be used to differentiate affected from normal tissue (Sigrist, et al, 2017).

REFERENCES

1. Apollo Medical Review Criteria Guidelines for Managing Care 21st edition, 2022. RAD 200 Elastography. Accessed 8/17/2023.
2. Aetna Clinical Policy Bulletin 0690 Noninvasive Tests for Hepatic Fibrosis. Accessed 8/17/2023. https://www.aetna.com/cpb/medical/data/600_699/0690.html
3. California Department of Health Care Services (DHCS). Treatment Policy for the Management of Chronic Hepatitis C Updated and Effective December 9, 2021. Accessed 8/17/2023. <https://www.dhcs.ca.gov/Pages/HepatitisC.aspx>
4. MCG Health 25th edition, 2021. A-1012 Hepatic Elastography, MR. Accessed 8/17/2023.
5. MCG Health 25th edition, 2021. A-1013 Hepatic Vibration-Controlled Transient Elastography (VCTE) Ultrasound. Accessed 8/17/2023.
6. Sigrist RMS, Liau J, Kaffas AE, Chammas MC, Willmann JK. Ultrasound Elastography: Review of Techniques and Clinical Applications. *Theranostics*. 2017;7(5):1303-1329. Published 2017 Mar 7. doi:10.7150/thno.18650
7. <https://files.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/part2/medne.pdf>. Accessed 8, 17, 2023.

DISCLAIMER

IEHP Clinical Authorization Guidelines (CAG) are developed to assist in administering plan benefits, they do not constitute a description of plan benefits. The Clinical Authorization Guidelines (CAG) express IEHP's determination of whether certain services or supplies are medically necessary, experimental and investigational, or cosmetic. IEHP has reached these conclusions based upon a review of currently available clinical information (including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). IEHP makes no representations and accepts no liability with respect to the content of any external information cited or relied upon in the Clinical Authorization Guidelines (CAG). IEHP expressly and solely reserves the right to revise the Clinical Authorization Guidelines (CAG), as clinical information changes.