



INLAND EMPIRE HEALTH PLAN

IEHP UM Subcommittee Approved Authorization Guidelines
Elastography

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.

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.

California Department of Health Care Services (DHCS):

Treatment Policy for the Management of Chronic Hepatitis C - Effective July 1, 2015 ⁽¹⁾.

DHCS accepts the use of Fibroscan (elastography) in the identification of candidates for the treatment of hepatitis C.

Any of the following clinical states identify candidates for treatment:

- Evidence of Stage 2 or greater hepatic fibrosis/cirrhosis including one of the following:
Liver biopsy confirming a METAVIR score F2 or greater;
- Transient elastography (Fibroscan®) score greater than or equal to 7.5 kPa; OR
FibroSure® score of greater than or equal to 0.48; OR APRI score greater than 0.7 OR
FIB-4 greater than 3.25.

Medical Review Criteria Guidelines for Managing Care (Apollo):

The Apollo Medical Guidelines state services are to be medically reasonable and necessary to "...improve [a] physical functional impairment. They should follow national standards for medical care as evidenced by the medical literature. ⁽²⁾

10801 Sixth St, Rancho Cucamonga, CA 91730
Tel (909) 890-2000 Fax (909) 890-2003
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Similarly, “Experimental and investigational treatment services are any procedure, study, test, drug, equipment, device or facility that have not been objectively tested or are still undergoing study/testing (Phase I, II or III trials), and generally not accepted as safe and effective therapy based on well designed clinical trials that have been published in peer-reviewed literature.”⁽³⁾

Aetna⁽⁴⁾:

Aetna considers transient elastography (e.g., FibroScan) medically necessary for distinguishing hepatic cirrhosis from noncirrhosis in persons with hepatitis C or other chronic liver diseases. Performance of transient elastography more than twice per year is considered not medically necessary. Performance of transient elastography within six months following a liver biopsy is considered not medically necessary. Transient elastography is considered experimental and investigational for all other indications.

U.S. National Library of Medicine⁽⁵⁾:

Roulot, D; Costes , J-L; Warzocha , U; *et al.* **Transient Elastography as a Screening Tool for Liver Fibrosis and Cirrhosis in a Community-based Population Aged Over 45 Years.** *Gut.* 2011;60(7):977-984⁽⁶⁾

LSM proved to be a useful and specific procedure to screen for cirrhosis in the general population and to detect undiagnosed chronic liver disease in apparently healthy subjects.

Kirk, G; Astemborski, J; Mehta, S; et al. **Assessment of Liver Fibrosis by Transient Elastography in Persons with Hepatitis C Virus Infection or HIV–Hepatitis C Virus Coinfection.** *Clin Infect Dis.* (2009) 48 (7): 963-972.⁽⁷⁾

For most HCV-infected persons, fibrosis stage predicted by elastography is similar to that predicted by examination of a biopsy specimen. Elastography-based measurement of liver stiffness holds promise to expand liver disease screening and monitoring, particularly among injection drug users.

Up To Date:

Dietrich, C; **Noninvasive assessment of hepatic fibrosis: Ultrasound-based elastography; Literature review current through: Jun 2015. | This topic last updated: Mar 18, 2015.**⁽⁸⁾

Disadvantages of liver biopsy include the fact that it is invasive, it is associated with rare but serious complications, and it can only sample a small portion of the liver parenchyma, making it susceptible to sampling variation. To overcome these problems, alternative noninvasive methods such as ultrasound-based elastography have been developed to assess hepatic fibrosis (table 1). (See 'Role of ultrasound-based elastography' above and "Noninvasive assessment of hepatic fibrosis: Overview of serologic and radiographic tests".)

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While ultrasound-based elastography is primarily used to assess hepatic fibrosis, it can also be used to predict complications in patients with cirrhosis. However, it is not in widespread use in the United States, where liver biopsy remains the standard for assessing hepatic fibrosis. Ultrasound-based elastography has been studied for the evaluation of focal liver lesions, but because of limitations such as limited depth of penetration, it is not recommended for this application

Background:

“Liver biopsy has long been the gold standard to stage fibrosis in the liver. In particular, liver biopsy 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. The disadvantages of biopsy are that it is an invasive test, it requires the patient to be hospitalized for half a day, it is expensive, and it is associated with certain risks, such as pain and bleeding. (While bleeding due to liver biopsy is uncommon, it poses a significant risk when it occurs.) In addition, 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 overstaging or understaging of fibrosis; sampling error may occur in up to 25-30% of liver biopsies. Another limitation of liver biopsy is that different pathologists can interpret the same sample differently, which can result in discrepancies in liver disease staging.

Given these limitations and patients’ desire to avoid invasive testing, researchers have done much work over the past 10 years to develop noninvasive tests that can measure liver fibrosis. Fibroscan is one such test, and it offers several advantages compared to liver biopsy. Because Fibroscan is a noninvasive test, it can be performed at the point of care, there is no pain, and sedation is not required. Also, the test takes only 5—7 minutes to perform, it is significantly less expensive than liver biopsy, and it has not been associated with any side effects. Finally, the results of the test are instantaneous, so clinicians can use them to make decisions during patients’ visits.”⁽⁹⁾

Effective Date: *August 12, 2015*

Reviewed Annually: *November 9, 2016*

Revised:

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2. 2013 Apollo Medical Review Criteria For Managed Care – “Medical Necessity - What is it?”
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Devices/Clinical Trials – Coverage/Non-coverage

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5. U.S. National Library of Medicine
<http://www.ncbi.nlm.nih.gov/pubmed/21068129>
6. Roulot, D; Costes , J-L; Warzocha , U; et al. Transient Elastography as a Screening Tool for Liver Fibrosis and Cirrhosis in a Community-based Population Aged Over 45 Years. *Gut*. 2011;60(7):977-984
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