Noninvasive Imaging Techniques for the Evaluation and Monitoring of Patients with Chronic Liver Disease

Effective: July 7, 2017

Next Review: May 2018
Last Review: June 2017

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Options for non-invasive monitoring of liver fibrosis include specialized imaging with ultrasound or magnetic resonance imaging (MRI). These techniques are being evaluated as a substitute for biopsy in the screening, evaluation, and monitoring of patients with chronic liver disease.

MEDICAL POLICY CRITERIA

Note: This policy does not address transient elastography (FibroScan®), which may be considered medically necessary.

The following noninvasive imaging techniques are considered investigational for the evaluation and monitoring of patients with chronic liver disease:

A. Magnetic resonance elastography;
B. Acoustic radiation force impulse imaging (ARFI; e.g., Acuson S2000);
C. Real-time tissue elastography

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.
BACKGROUND

BIOPSY FOR CHRONIC LIVER DISEASE

The diagnosis of non-neoplastic liver disease is often made from needle biopsy samples. In addition to establishing a disease etiology, liver biopsy can determine the degree of inflammation present and can stage the degree of fibrosis. The degree of inflammation and fibrosis may be assessed by different scoring schemes. Most of these scoring schemes grade inflammation from 0-4 (with 0 being no or minimal inflammation and 4 being severe) and fibrosis from 0-4 (with 0 being no fibrosis and 4 cirrhosis). There are several limitations to liver biopsy, including its invasive nature, small tissue sample size, and subjective grading system. Regarding small tissue sample size, liver fibrosis can be patchy and thus missed on a biopsy sample, which includes only 0.002% of the liver tissue. A noninvasive alternative to liver biopsy would be particularly helpful, both to initially assess patients and then as a monitoring tool to assess response to therapy.

Noninvasive Imaging

Noninvasive imaging technologies to detect liver fibrosis or cirrhosis among patients with chronic liver disease are being evaluated as an alternative to liver biopsy. For individuals who have chronic liver disease who receive transient elastography (FibroScan®), the evidence includes many systematic reviews of more than 50 observational studies (>10,000 patients). Relevant outcomes are test accuracy and validity, morbid events, and treatment-related morbidity. FibroScan® has been studied in populations with viral hepatitis, nonalcoholic fatty liver disease (NAFLD), and alcoholic liver disease (ALD). There are varying cutoffs for positivity. Failures of the test are not uncommon, particularly for those with high body mass index, but were frequently not captured in analyses of the validation studies. Given these limitations and the imperfect reference standard, it is difficult to interpret performance characteristics. However, for the purposes of deciding whether a patient has severe fibrosis or cirrhosis, the FibroScan® results provide data sufficiently useful to determine therapy. Specifically, FibroScan® has been used as an alternative to biopsy to establish eligibility regarding presence of fibrosis or cirrhosis in several randomized controlled trials (RCTs) that showed the efficacy of hepatitis C virus (HCV) treatments, which in turn demonstrated that the test can identify patients who would benefit from therapy. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Other noninvasive imaging technologies include magnetic resonance elastography (MRE), acoustic radiation force impulse imaging (ARFI; e.g., Acuson S2000™), and real-time tissue elastography (RTE; e.g., HI VISION Preirus). Noninvasive imaging tests have been used in combination with multi-analyte serum tests, such as FibroTest® (known as FibroSure® in the US) with FibroScan®.

Acoustic Radiation Force Impulse Elastography (AFRI) uses an ultrasound probe to produce an acoustic “push” pulse, which generates shear waves that propagate in tissue to assess liver stiffness. ARFI elastography evaluates the wave propagation speed to assess liver stiffness. The faster the shear wave speed, the harder the object. AFRI technologies include Virtual Touch™ Quantification and Siemens Acuson S2000™ system. ARFI elastography can be performed at the same time as a liver sonographic evaluation, even in patients with a
Magnetic Resonance Elastography (MRE) uses a driver to generate 60-Hz mechanical waves on the patient’s chest well. The magnetic resonance imaging (MRI) equipment creates elastograms by processing the acquired images of propagating shear waves in the liver using an inversion algorithm. These elastograms represent the shear stiffness as a pixel value in kilopascals. MRE has several advantages over ultrasound elastography, including: (1) analyzing larger liver volumes; (2) analyzing liver volumes of obese patients or patients with ascites; and precise analysis of viscoelasticity using a 3-dimensional displacement vector.

Real-Time Tissue Elastography (RTE), also known as real-time strain elastography, is a type of strain elastography which uses a combined autocorrelation method to measure tissue strain causes by manual compression or a person’s heartbeat. The relative tissue strain is displayed on conventional color B mode ultrasound images in real time. Hitachi manufactures the RTE devices, including one called HI VISION Preirus. The challenge is to identify a region of interest while avoiding areas likely to introduce artifacts, such as large blood vessels, the area near the ribs, and the surface of the liver. Areas of low strain increase as fibrosis progresses and strain distribution becomes more complex. Various subjective and quantitative methods have been developed to evaluate the results. RTE can be performed in patients with ascites or inflammation. This technology does not perform as well in severely obese individuals.

**LIVER DISEASE**

**Hepatitis C**

Infection with the hepatitis C virus can lead to permanent liver damage. Liver biopsy is typically recommended prior to the initiation of antiviral therapy. Repeat biopsies may be performed to monitor fibrosis progression. Liver biopsies are analyzed according to a histologic scoring system; the most commonly used one for hepatitis C is the METAIRV scoring system, which scores the presence and degree of inflammatory activity and fibrosis. The fibrosis is graded from F0-F4, with a METAIRV score of F0 signifying no fibrosis and F4 signifying cirrhosis (which is defined as the presence throughout the liver of fibrous septa that subdivide the liver parenchyma into nodules and represents the final and irreversible form of disease). The stage of fibrosis is the most important single predictor of morbidity and mortality in patients with hepatitis C. Biopsies for hepatitis C are also evaluated according to the degree of inflammation present, referred to as the grade or activity level. For example, the METAIRV system includes scores for necroinflammatory activity ranging from A0 to A3 (A0=no activity, A1=minimal activity, A2=moderate activity, A3=severe activity.)

**Hepatitis B**

Most people who become infected with hepatitis B virus (HBV) recover fully, but a small portion will develop chronic HBV, which can lead to permanent liver damage. As with HCV, identification of liver fibrosis is needed to determine timing and management of treatment, and liver biopsy is the criterion standard for staging fibrosis. The grading of fibrosis in HBV also uses the Metavir system.

**Alcoholic Liver Disease**

Alcoholic liver disease (ALD) is the leading cause of liver disease in most Western countries. Histologic features of ALD usually include steatosis, alcoholic steatohepatitis (ASH), hepatocyte necrosis, Mallory bodies (tangled proteins seen in degenerating hepatocytes), a
large polymorphonuclear inflammatory infiltrate, and, with continued alcohol abuse, fibrosis and possibly cirrhosis. The grading of fibrosis is similar to the scoring system used in hepatitis C. The commonly used Laënnec scoring system uses grades 0-4, with 4 being cirrhosis.

Nonalcoholic Fatty Liver Disease

Nonalcoholic fatty liver disease (NAFLD) is defined as a condition that pathologically resembles ALD but occurs in patients who are not heavy users of alcohol. It may be associated with a variety of conditions, including obesity, diabetes, and dyslipidemia. The characteristic feature of NAFLD is steatosis. At the benign end of the spectrum of the disease, there is usually no appreciable inflammation, hepatocyte death, or fibrosis. In contrast, nonalcoholic steatohepatitis (NASH), which shows overlapping histologic features with ALD, is an intermediate form of liver damage, and liver biopsy may show steatosis, Mallory bodies, focal inflammation, and degenerating hepatocytes. NASH can progress to fibrosis and cirrhosis. A variety of histological scoring systems have been used to evaluate NAFLD. The NAFLD activity score (NAS) system for NASH includes scores for steatosis (0-3), lobular inflammation (0-3), and ballooning (0-2). Cases with scores of 5 or greater are considered NASH, while cases with scores of 3 and 4 are considered borderline (probable or possible) NASH. The grading of fibrosis is similar to the scoring system used in hepatitis C. The commonly used Laënnec scoring system uses grades 0-4, with 4 being cirrhosis.

REGULATORY STATUS

In November 2008, Acuson S2000™ Virtual Touch (Siemens AG, Erlanger, Germany), which provides acoustic radiation force impulse imaging, was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process (K072786).

In August 2009, AIXPLORER® Ultrasound System (SuperSonic Imagine, Aix en Provence, France), which provides shear wave elastography, was cleared for marketing by FDA through the 510(k) process (K091970).

In June 2010, Hitachi HI VISION Preirus Diagnostic Ultrasound Scantier (Hitachi Medical Systems America, Twinsburg, OH), which provides real-time tissue elastography, was cleared for marketing by FDA through the 510(k) process (K093466). FDA product code: IYO.

EVIDENCE SUMMARY

Validation of the clinical use of any diagnostic test focuses on three main principles:

1. Analytic validity of the test;
2. Clinical validity of the test (i.e., sensitivity, specificity, and positive and negative predictive values in relevant populations of patients and compared to the gold standard); and
3. Clinical utility of the test (i.e., how the results of the diagnostic test will be used to improve the management of the patient).

Due to the large number of primary studies published on this topic, this evidence review focuses on systematic reviews when available. The validation of multiple noninvasive tests will be assessed individually in the following sections.

LIVER BIOPSY IS AN IMPERFECT REFERENCE STANDARD
As mentioned in the Background, liver biopsy is an imperfect reference standard. There is a high rate of sampling error in biopsy, which can lead to underdiagnosis of liver disease.[1,2] This will bias estimates of performance characteristics of the noninvasive tests to which it is compared and must be considered in apprising the body of evidence. Mehta et al estimated that, under the best scenario where sensitivity and specificity of liver biopsy are 90% and the prevalence of significant disease (Metavir ≥ F2) is 40%, even a perfect alternative marker would have calculated area under the receiver operating characteristic (AUROC) curve of 0.90.[3] Therefore, effectiveness of alternative technologies may be underestimated. In fact, when the accuracy of biopsy is presumed to be 80%, a comparative technology with an AUROC curve of 0.76 may actually have an AUROC curve of 0.93 to 0.99 for diagnosing true disease.

Although options exist for performing systematic reviews with imperfect reference standards,[4] the majority of available reviews on this topic did not use any correction for the imperfect reference.

ACOUSTIC RADIATION FORCE IMPULSE IMAGING

Analytic Validity

Piscaglia et al (2011) demonstrated that the interoperator reproducibility of ARFI was high ($r=0.874$) in a study of 133 patients with chronic liver disease, and the method was feasible for all patients enrolled.[5] Other measures of technical performance were not found.

Clinical Validity

The systematic reviews in Tables 1 and 2 have reported on diagnostic accuracy of ARFI.

Table 1. Acoustic Radiation Force Impulse Imaging Systematic Review Characteristics

<table>
<thead>
<tr>
<th>Study (Year)</th>
<th>Dates</th>
<th>Studies</th>
<th>N</th>
<th>Population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guo et al (2015)[9]</td>
<td>Up to Jun 2013</td>
<td>15</td>
<td>2128</td>
<td>Multiple diseases</td>
</tr>
<tr>
<td>Liu et al (2015)[10]</td>
<td>Up to Jul 2014</td>
<td>7</td>
<td>723</td>
<td>Nonalcoholic fatty liver disease</td>
</tr>
</tbody>
</table>

Table 2. Acoustic Radiation Force Impulse Imaging Systematic Reviews of Diagnostic Accuracy

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Significant Fibrosis (ie, Metavir Stages F2-F4)</th>
<th>Cirrhosis (ie, Metavir Stage F4)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Studies/ Sample Size</td>
<td>AUROC (95% CI) Sensitivity (95% CI) Specificity (95% CI)</td>
<td>Studies/ Sample Size</td>
</tr>
<tr>
<td>Nierhoff et al (2013)</td>
<td>Multiple diseases</td>
<td>26/NR</td>
<td>0.83 (0.80 to 0.86)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>27/NR</td>
</tr>
<tr>
<td>Study</td>
<td>Population</td>
<td>Significant Fibrosis (ie, Metavir Stages F2-F4)</td>
<td>Cirrhosis (ie, Metavir Stage F4)</td>
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<tr>
<td>---------------------</td>
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<td>-----------------------------------------------</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>AUROC (95% CI) Sensitivity (95% CI) Specificity (95% CI)</td>
<td>Studies/ Sample Size</td>
</tr>
<tr>
<td>Bota et al (2013)</td>
<td>Chronic hepatitis</td>
<td>6/518</td>
<td>0.88 (0.83 to 0.93) NR NR</td>
</tr>
<tr>
<td>Crossan et al (2015)</td>
<td>HCV</td>
<td>4/NR</td>
<td>NR 85% (69% to 94%) 89% (72% to 97%)</td>
</tr>
<tr>
<td>Guo et al (2015)</td>
<td>Multiple diseases</td>
<td>13/NR</td>
<td>NR 76% (73% to 78%) 80% (77% to 83%)</td>
</tr>
<tr>
<td>Liu et al (2016)</td>
<td>NAFLD</td>
<td>7/723</td>
<td>NR 80% (76% to 84%) 85% (81% to 89%)</td>
</tr>
</tbody>
</table>

AUROC: area under the receiver operating characteristic curve; CI: confidence interval; HCV: hepatitis C virus; NAFLD: nonalcoholic fatty liver disease; NR: not reported.

**Clinical Utility**

There are currently no published studies that directly demonstrate effect on patient outcomes of ARFI.

**MAGNETIC RESONANCE ELASTOGRAPHY**

**Analytic Validity**

A phase 1 study examined the interobserver agreement between 2 pathologists who assessed with MRE using biopsy results from 103 patients with chronic hepatitis B and C.[11] The intraclass correlation coefficient (ICC) was very high at 0.99 (95% CI, 0.98 to 1.00). For the same patients, the ICC for these 2 pathologists using Metavir was 0.91 (95% CI, 0.86 to 0.94; difference with 23 MRE, p<0.001). In a second phase 1 study of 110 patients and 10 normative volunteers, the ICC for 2 raters was 0.993 for MRE. The absolute differences in elasticity assigned by the 2 raters were less than 0.8 kPa for more than 95% of the subjects. Twenty-one patients had also undergone liver biopsy. Shi et al (2014) demonstrated that, in 22 healthy volunteers liver, MRE had good short and mid-term (within 6 mo) repeatability.[12] Venkatesh et al (2014) showed that liver stiffness measurements on MRE performed 4 to 6 weeks apart in a study of 41 healthy Asian volunteers had an ICC of 0.9 (95% CI, 0.78 to 0.96) and a within-subject coefficient of variation of 2.2% to 11.4%.[13] Yin et al (2016) retrospectively analyzed 1377 consecutive MRE examinations performed between 2007 and 2010 for patients with various chronic liver diseases.[14] MRE had a success rate of 94% and highly reproducible measurements (r=0.972, p<0.001). BMI was not associated with success.
Clinical Validity

The systematic reviews in Tables 3 and 4 summarize the diagnostic accuracy of MRE. MRE has been studied primarily in hepatitis and NAFLD.

Table 3. Magnetic Resonance Elastography Systematic Review Characteristics

<table>
<thead>
<tr>
<th>Study (Year)</th>
<th>Dates</th>
<th>Studies</th>
<th>N</th>
<th>Population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crossan et al (2015)</td>
<td>1998 to Apr 2012</td>
<td>3</td>
<td>Not reported</td>
<td>Chronic liver disease</td>
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<tr>
<td>Singh et al (2015)</td>
<td>2003 to Sep 2013</td>
<td>12</td>
<td>697</td>
<td>Chronic liver disease</td>
</tr>
<tr>
<td>Singh et al (2016)</td>
<td>Up to Oct 2014</td>
<td>9</td>
<td>232</td>
<td>Nonalcoholic fatty liver disease</td>
</tr>
</tbody>
</table>

Table 4. Magnetic Resonance Elastography Systematic Reviews of Diagnostic Accuracy

<table>
<thead>
<tr>
<th>Study (Year)</th>
<th>Population</th>
<th>Studies/ Sample Size</th>
<th>AUROC (95% CI)</th>
<th>Sensitivity (95% CI)</th>
<th>Specificity (95% CI)</th>
<th>Studies/ Sample Size</th>
<th>AUROC (95% CI)</th>
<th>Sensitivity (95% CI)</th>
<th>Specificity (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crossan et al (2015)</td>
<td>Chronic liver disease</td>
<td>3/NR</td>
<td>NR</td>
<td>94% (13% to 100%)</td>
<td>92% (72% to 98%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Guo et al (2015)</td>
<td>Multiple diseases</td>
<td>9/NR</td>
<td>NR</td>
<td>87% (84% to 90%)</td>
<td>94% (91% to 97%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Singh et al (2015)</td>
<td>Chronic hepatitis</td>
<td>12/697</td>
<td>0.84 (0.76 to 0.92)</td>
<td>73% (NR)</td>
<td>79% (NR)</td>
<td>12/697</td>
<td>0.92 (0.90 to 0.94)</td>
<td>91% (NR)</td>
<td>81% (NR)</td>
</tr>
<tr>
<td>Singh et al (2016)</td>
<td>NAFLD</td>
<td>9/232</td>
<td>0.87 (0.82 to 0.93)</td>
<td>79% (76% to 90%)</td>
<td>81% (72% to 91%)</td>
<td>9/232</td>
<td>0.91 (0.76 to 0.95)</td>
<td>88% (82% to 100%)</td>
<td>87% (77% to 97%)</td>
</tr>
</tbody>
</table>

AUROC: area under the receiver operating characteristic curve; CI: confidence interval; NAFLD: nonalcoholic fatty liver disease; NR: not reported.

Clinical Utility

There are currently no published studies that directly demonstrate the effect on patient outcomes of MRE.

REAL-TIME TISSUE ELASTOGRAPHY (HI VISION 15 PREIRUS)

Analytic Validity

In a study of 70 hospitalized patients with HCV, RTE was performed at 4 liver locations by 2 independent observers. The elastic ratio (ratio of the value in the intrahepatic venous small vessels divided by the value in the hepatic parenchyma) was highly correlated between the 2 examiners ($R^2=0.869$, $p<.001$) and consistent across liver locations ($\kappa=0.835$, ICC=0.966). Other measures of technical performance were not found.

Clinical Validity
In 2014, Hong et al reported results of a meta-analysis RTE for staging fibrosis in multiple diseases.[18] Thirteen studies (total N=1347 patients) published between April 2000 and April 2014 that used liver biopsy or transient elastography as the reference standard were included. Different quantitative methods were used to measure liver stiffness: Liver Fibrosis Index (LFI), Elasticity Index (EI), elastic ratio 1 (ER1), and elastic ratio 2 (ER2) in the included studies. For predicting significant fibrosis (stage ≥ F2), the pooled sensitivities for LFI and ER1 were 78% (95% CI, 70% to 84%) and 86% (95% CI, 80% to 90%), respectively. The specificities were 63% (95% CI, 46% to 78%) and 89% (95% CI, 83% to 94%) and the AUROCs were 0.79 (95% CI, 0.75 to 0.82) and 0.94 (95% CI, 0.92 to 0.96) respectively. For predicting cirrhosis (stage F4), the pooled sensitivities of LFI, ER1, and ER2 were 79% (95% CI, 61% to 91%), 96% (95% CI, 87% to 99%), and 79% (95% CI, 61% to 91%), respectively. The specificities were 88% (95% CI, 81% to 93%) for LFI, 89% (95% CI, 83% to 93%) for ER1, and 88% (95% CI, 81% to 93%) for ER2, and the AUROCs were 0.85 (95% CI, 0.81 to 0.87), 0.93 (95% CI, 0.94 to 0.98), and 0.92 (95% CI NR), respectively. Pooled estimates for EI were not performed due to insufficient data.

Kobayashi et al published results of a meta-analysis of RTE for staging liver fibrosis in 2015.[19] They included 15 studies (total N=1626 patients) published through December 2013, including patients with multiple liver diseases and healthy adults. A bivariate random-effects model was used to estimate summary sensitivity and specificity. The summary AUROC, sensitivity, and specificity were 0.69 (precision NR), 79% (95% CI, 75% to 83%) and 76% (95% CI, 68% to 82%), respectively, for detection of significant fibrosis (stage ≥ F2) and 0.72 (precision NR), 74% (95% CI, 63% to 82%), and 84% (95% CI, 79% to 88%) for detection of cirrhosis. Reviewers found evidence of heterogeneity due to differences in study populations, scoring methods, and cutoffs for positivity. They also found evidence of publication bias based on funnel plot asymmetry.

**Clinical Utility**

There are currently no published studies that directly demonstrate the effect on patient outcomes of RTE.

**COMBINED USE OF MULTIANALYTE ASSAYS AND NONINVASIVE IMAGING**

The combined use of multianalyte assays with algorithmic analyses and noninvasive imaging has been considered for evaluating fibrosis in patients with chronic liver disease. Few studies have evaluated the incremental accuracy of the combined use of tests.

One such algorithm was described by Castera et al (2010) and is called the Bordeaux algorithm.[20] It is a synchronous test of FibroTest and FibroScan that was developed in patients with HCV. The algorithm states that if FibroScan <7.1 kPa and FibroTest ≤0.48 then fibrosis stage is F0 or F1. If FibroScan ≥7.1 and FibroTest >0.48, then fibrosis stage is ≥F2. If there is disagreement between the 2 tests then a biopsy is performed. Crossan et al (2015) found 1 study describing the performance characteristics of the Bordeaux algorithm in HCV for detecting significant (stage ≥F2) fibrosis.[8] Summary sensitivity and specificity were 88% (95% CI, 85% to 91%) and 89% (95% CI, 85% to 92%), respectively. For detecting cirrhosis, summary sensitivity and specificity from 1 study were 87% (95% CI, 80% to 92%) and 95% (95% CI, 93% to 96%), respectively.

Combination approaches using ARFI and routine serum biomarkers to evaluate and predict significant fibrosis and cirrhosis in patients with chronic hepatitis B have also been proposed.[21,22]
There is insufficient evidence to determine the incremental benefit of combining multianalyte assays with noninvasive imaging and its effects on health outcomes cannot be determined.

**PRACTICE GUIDELINE SUMMARY**

**AMERICAN ASSOCIATION FOR THE STUDY OF LIVER DISEASES (AASLD), THE AMERICAN COLLEGE OF GASTROENTEROLOGY (ACG), AND THE AMERICAN GASTROENTEROLOGICAL ASSOCIATION (AGA)**

The 2012 AASLD/ACG/AGA practice guideline on the Diagnosis and Management of Non-Alcoholic Fatty Liver Disease (NAFLD) delineates when subsequent biopsy is recommended following unsuspected hepatic steatosis detected on imaging (strong and high to moderate recommendations).[23] For steatohepatitis and advanced fibrosis, the guideline specifies that imaging tests are not a reliable method of measurement in NAFLD patients.

**AMERICAN ASSOCIATION FOR THE STUDY OF LIVER DISEASES (AASLD) AND THE INFECTIOUS DISEASES SOCIETY OF AMERICA (IDSA)**

The 2016 AASLD/IDSA Guidance on Hepatitis recommends evaluation for advanced fibrosis in those with current (active) HCV infection.[24] Evaluation includes using liver biopsy, imaging, and/or noninvasive markers to facilitate an appropriate decision regarding HCV treatment strategy and to determine the need for initiating additional measures for the management of cirrhosis (eg, hepatocellular carcinoma screening). This recommendation has a rating of Class I: Conditions for which there is evidence and/or general agreement that a given diagnostic evaluation, procedure, or treatment is beneficial, useful, and effective; and Level A: Data derived from multiple randomized clinical trials, meta-analyses, or equivalent.

**DEPARTMENT OF VETERANS AFFAIRS (VA) AND THE NATIONAL VIRAL HEPATITIS PROGRAM IN THE OFFICE OF PATIENT CARE SERVICES**

The VA and National Viral Hepatitis Program in the Office of Patient Care Services treatment considerations (2016) for chronic hepatitis C virus infection state that cirrhosis can be diagnosed by a variety of non-invasive means; liver biopsy should be reserved for situations in which the risks and limitations of the procedure are outweighed by the benefits of obtaining information via this technique.[25] There is no recommendation for imaging, specifically. A comment states vibration-controlled transient elastography and ARFI with values of >12.5 kilopascals and >1.75 meters/section, respectively, have been associated with histologic cirrhosis, however, cutoff values vary by the population studied.

**UNITED STATES PREVENTIVE SERVICES TASK FORCE (USPSTF)**

The USPSTF June 2013 Hepatitis C: Screening Final Recommendation Statement specifies there is adequate evidence that various noninvasive tests have good to very good diagnostic accuracy in diagnosing fibrosis or cirrhosis.[26] However, a research gap exists with regard to the clinical utility of “noninvasive” assessment of cirrhosis and fibrosis; patient populations may vary from those who were enrolled in trial cohorts. Imaging tests are not specifically mentioned in the recommendation.
SUMMARY

There is not enough research to show magnetic resonance elastography (MRE), acoustic radiation force impulse imaging (ARFI), or real-time tissue elastography (RTE) improves health outcomes for people with chronic liver disease. Therefore, MRE, ARFI, and RTE are considered investigational for the evaluation and monitoring of patient with chronic liver disease.

REFERENCES


25. Chronic Hepatitis C Virus (HCV) Infection: Treatment Considerations from the Department of Veterans Affairs National Hepatitis C Resource Center Program and the


<table>
<thead>
<tr>
<th>Codes</th>
<th>Number</th>
<th>Description</th>
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<tr>
<td>CPT</td>
<td>91200</td>
<td>Liver elastography, mechanically induced shear wave (eg, vibration), without imaging, with interpretation and report</td>
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Date of Origin: May 2015