Study		Significant Fibrosis (ie, Metavir Stages F2-F4)		Cirrhosis (ie, Metavir Stage F4)	
			83%) 75% (70% to 79%)		
Stebbing et al (2010)[54]	Multiple diseases	17/3066	NR 72% (71% to 72%) 82% (82% to 83%)	17/4052	NR 84% (84% to 85%) 95% (94% to 95%)
Talwalkar et al (2007)[55]	Multiple diseases	7/>1100	0.87 (0.83 to 0.91) 70% (67% to 73%) 84% (80% to 88%)	9/2083	0.96 (0.94 to 0.98) 87% (84% to 90%) 91% (89% to 92%)
Tsochatzis et al (2011)[56]	Multiple diseases	31/5919	NR 79% (74% to 82%) 78% (72% to 83%)	30/6530	NR 83% (79% to 86%) 89% (87% to 91%)
	HCV	14/NR	NR 78% (71% to 84%) 80% (71% to 86%)	11/NR	NR 83% (77% to 88%) 90% (87% to 93%)
	HBV	4/NR	NR 84% (67% to 93%) 78% (68% to 85%)	6/NR	NR 80% (61% to 91%) 86% (82% to 94%)
Tsochatzis et al (2014)[57]	HCV	37/NR	0.87 (0.83 to 0.90) 79% (74% to 84%) 83% (77% to 88%)	36/NR	0.96 (0.94 to 0.97) 89% (84% to 92%) 91% (89% to 93%)
	HBV	13/NR	0.83 (0.76 to 0.90) 71% (62% to 78%) 84% (74% to 91%)	13/NR	0.92 (0.89 to 0.96) 86% (79% to 91%) 85% (78% to 89%)
	NAFLD			4/NR	0.96 (0.94 to 0.99) 96% (83% to 99%) 89% (85% to 92%)
	ALD			6/NR	0.90 (0.87 to 0.94) 86% (76% to 92%) 83% (74% to 89%)
Xu et al (2015)[63]	HBV	14/2318	0.82 (0.78 to 0.86) NR NR	18/2996	0.91 (0.89 to 0.93) NR NR

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

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from RCTs.

There are currently no published studies that directly demonstrate the effect of transient elastography (eg, FibroScan) on patient outcomes.

FibroScan is used extensively in practice to make management decisions. In addition, FibroScan was used as an alternative to biopsy for to diagnose fibrosis or cirrhosis to establish trial eligibility in several trials (ION-1,-3; VALENCE; ASTRAL-2, -3, -4) that confirmed the efficacy of HCV treatments.[14-19] For example, in the VALENCE trial, cirrhosis could be defined by liver biopsy or a confirmatory FibroTest or FibroScan result at 12.5 kPa or greater. In VALENCE, FibroScan was used to determine cirrhosis in 74% of the participants.

Section Summary: Transient Elastography (FibroScan)

Transient elastography (FibroScan) is the most widely validated of the noninvasive methods. FibroScan has been studied in populations with viral hepatitis, NAFLD, and ALD. FibroScan validation studies have suggested that it can provide good detection of significant fibrosis and good-to-excellent detection of cirrhosis compared with liver biopsy for HCV and HBV. There are limited data on NAFLD and ALD. There are no established or validated cutoffs, and the quality of the validation studies was generally not high. Failures of the test are not uncommon, particularly for those with high body mass index; however, failures were frequently missed in analyses of the validation studies. Newer more sensitive probes may lessen this limitation. There is no direct evidence that FibroScan improves health outcomes. However, FibroScan has been used as an alternative to biopsy to diagnose fibrosis or cirrhosis to establish trial eligibility in several RCTs that established the efficacy of HCV treatments.

Other Noninvasive Imaging

The following noninvasive imaging types are evaluated in this section: magnetic resonance elastography (MRE), ARFI imaging (eg, Acuson S2000), and real-time tissue elastography (RTE; eg, HI VISION Preirus).

Clinical Context and Test Purpose

The purpose of noninvasive testing in individuals with chronic liver disease is to detect liver fibrosis so that patients can avoid the potential adverse events of an invasive liver biopsy and receive appropriate treatment. The degree of liver fibrosis is an important factor in determining the appropriate approach for managing patients with liver disease (eg, hepatitis, ALD, NAFLD).

The question addressed in this portion of the evidence review is: Does the use of noninvasive imaging other than transient elastography for detecting liver fibrosis improve the net health outcome in patients with chronic liver disease?

The following PICOTS were used to select literature to inform this review.

Patients
The relevant population of interest is individuals with chronic liver disease.

Interventions
The tests being considered are noninvasive radiologic methods other than transient elastography for liver fibrosis measurement (eg, MRE, ARFI imaging, RTE).

Comparators
The following tests and practices are currently being used to diagnose chronic liver disease: liver biopsy, other noninvasive radiologic methods, and multianalyte serum assays.

Outcomes
The general outcomes of interest are test validity, morbid events, and treatment-related morbidity.

Timing
Follow-up over months to years is of interest for the relevant outcomes.

Setting
Patients are actively managed by gastroenterologists and other specialists in an outpatient setting.

Study Selection Criteria
For the evaluation of clinical validity of this test, studies that meet the eligibility criteria are outlined in indication 1.

ARFI Imaging

Clinically Valid
A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Tables 4 and 5 summarize the characteristics and results of systematic reviews that have assessed the diagnostic accuracy of ARFI imaging.

Table 4. Characteristics of Systematic Reviews Assessing Acoustic Radiation Force Impulse Imaging

Study	Dates	Studies	N	Population
Bota et al	To May 2012	6	518	Chronic hepatitis

Study	Dates	Studies	N	Population
(2013)[44]				
Crossan et al (2015)[5]	1998 to Apr 2012	4	Not reported	Hepatitis C virus
Guo et al (2015)[64]	To Jun 2013	15	2128	Multiple diseases
Hu et al (2017)[65]	To Jul 2014	fz7	723	Nonalcoholic fatty liver disease
Jiang et al (2018)[59]	To Dec 2017	9	982	Nonalcoholic fatty liver disease
Liu et al (2015)[66]	To Apr 2016	23	2691	Chronic hepatitis B or C
Nierhoff et al (2013)[67]	2007 to Feb 2012	36	3951	Multiple diseases

Table 5. Results of Systematic Reviews Assessing the Diagnostic Accuracy of Acoustic Radiation Force Impulse Imaging

Study	Population	Significant Fibrosis (ie, Metavir Stages F2-F4)		Cirrhosis (ie, Metavir Stage F4)	
		Studies / Sample Size	AUROC (95% CI) Sensitivity (95% CI) Specificity (95% CI)	Studies / Sample Size	AUROC (95% CI) Sensitivity (95% CI) Specificity (95% CI)
Bota et al (2013)[44]	Chronic hepatitis	6/518	0.88 (0.83 to 0.93) NR NR		0.92 (0.87 to 0.98) NR NR
Crossan et al (2015)[5]	HCV	4/NR	NR 85% (69% to 94%) 89% (72% to 97%)		
Guo et al (2015)[64]	Multiple diseases	13/NR	NR 76% (73% to 78%) 80% (77% to 83%)	14/NR	NR 88% (84% to 91%) 80% (81% to 84%)
Hu et al (2017)[65]	HBV, HCV	15/NR	88% (85% to 91%) 75% (69% to 78%) 85% (81% to 89%)		
Jiang et al (2018)[59]	NAFLD	6/NR	0.86 (0.83 to 0.89) 70% (59% to 79%) 84% (79% to 88%)	7/NR	0.95 (0.93 to 0.97) 89% (60% to 98%) 91% (82% to 95%)
Liu et al (2015)[66]	NAFLD	7/723	NR 80% (76% to 84%) 85% (81% to 89%)		
Nierhoff et al (2013)[67]	Multiple diseases	26/NR	0.83 (0.80 to 0.86)	27/NR	0.91 (0.89 to 0.93)

Study	Population	Significant Fibrosis (ie, Metavir Stages F2-F4)	Cirrhosis (ie, Metavir Stage F4)
		NR	NR
		NR	NR

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

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from RCTs.

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

Chain of Evidence

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

Because the clinical validity of ARFI imaging has not been established, a chain of evidence supporting the clinical utility of this test for this population cannot be constructed.

Subsection Summary: ARFI Imaging

The use of ARFI imaging has been evaluated in viral hepatitis and NAFLD. Moreover, many have noted that ARFI imaging has potential advantages over FibroScan—it can be implemented on a standard ultrasound machine, may be more applicable for assessing complications such as ascites and may be more applicable in obese patients. ARFI imaging appears to have similar diagnostic accuracy to FibroScan, but there are fewer data available on performance characteristics. Validation studies have used varying cutoffs for positivity.

Magnetic Resonance Elastography

Clinically Valid

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Tables 6 and 7 summarize the characteristics and results of systematic reviews that have assessed the diagnostic accuracy of MRE. MRE has been studied primarily in hepatitis and NAFLD.

Table 6. Characteristics of Systematic Reviews Assessing Magnetic Resonance Elastography

Study	Dates	Studies	N	Population
Crossan et al (2015)[5]	1998 to Apr 2012	3	Not reported	Chronic liver disease
Guo et al (2015)[64]	To Jun 2013	11	982	Multiple diseases
Singh et al (2015)[68]	2003 to Sep 2013	12	697	Chronic liver disease
Singh et al (2016)[69]	To Oct 2014	9	232	Nonalcoholic fatty liver disease

Table 7. Results of Systematic Reviews Assessing the Diagnostic Accuracy of Magnetic Resonance Elastography

Study		Significant Fibrosis (ie, Stages F2-F4)		Cirrhosis (ie, Stage F4)	
	Population	Studies/ Sample Size	AUROC (95% CI) Sensitivity (95% CI) Specificity (95% CI)	Studies/ Sample Size	AUROC (95% CI) Sensitivity (95% CI) Specificity (95% CI)
Crossan et al (2015)[5]	Chronic liver disease	3/NR	NR 94% (13% to 100%) 92% (72% to 98%)		
Guo et al (2015)[64]	Multiple diseases	9/NR	NR 87% (84% to 90%) 94% (91% to 97%)		NR 93% (88% to 96%) 91% (88% to 93%)
Singh et al (2015)[68]	Chronic hepatitis	12/697	0.84 (0.76 to 0.92) 73% (NR) 79% (NR)	12/697	0.92 (0.90 to 0.94) 91% (NR) 81% (NR)
Singh et al (2016)[69]	NAFLD	9/232	0.87 (0.82 to 0.93) 79% (76% to 90%) 81% (72% to 91%)	9/232	0.91 (0.76 to 0.95) 88% (82% to 100%) 87% (77% to 97%)

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

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from RCTS.

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

Chain of Evidence

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

Because the clinical validity of MRE has not been established, a chain of evidence supporting the clinical utility of this test for this population cannot be constructed.

Subsection Summary: Magnetic Resonance Elastography

MRE has a high success rate and is highly reproducible across operators and time. The diagnostic accuracy also appears to be high. In particular, MRE has high diagnostic accuracy for detection of fibrosis in NAFLD, independent of body mass index and degree of inflammation. However, further validation is needed to determine standard cutoffs and confirm performance characteristics because confidence intervals for estimates are wide. MRE is not widely available.

Real-Time Tissue Elastography (HI VISION 15 Preirus)

Clinically Valid

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Kobayashi et al (2015) published results of a meta-analysis assessing RTE for staging liver fibrosis.[70] They selected 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%) 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, respectively. 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.

Hong et al (2014) reported on the results of a meta-analysis evaluating RTE for staging fibrosis in multiple diseases.[71] 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 in the included studies: Liver Fibrosis Index (LFI), Elasticity Index, elastic ratio 1 (ER1), and elastic ratio 2. 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 elastic ratio 2 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 elastic ratio 2, 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 Elasticity Index were not performed due to insufficient data.

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from RCTs.

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

Chain of Evidence

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

Because the clinical validity of RTE has not been established, a chain of evidence supporting the clinical utility of this test for this population cannot be constructed.

Subsection Summary: Real-Time Tissue Elastography

RTE has been evaluated in multiple diseases with varying scoring methods and cutoffs. Although data are limited, the accuracy of RTE appears to be similar to FibroScan for the evaluation of significant liver fibrosis, but less accurate for the evaluation of cirrhosis. However, there was evidence of publication bias in the systematic review and the diagnostic accuracy may be overestimated.

Section Summary: Noninvasive Radiological Methods Other Than Transient Elastography

The available studies have suggested that other radiologic methods (AFRI, MRE, RTE) may have similar performance for detecting significant fibrosis or cirrhosis. However, the studies frequently included varying cutoffs not prespecified or validated. Given these limitations and the imperfect reference standard, it is difficult to interpret performance characteristics. There is no direct evidence that other noninvasive radiologic methods improve health outcomes and an indirect chain cannot be constructed due to the lack of sufficient evidence on clinical validity.

Summary of Evidence

Multianalyte Serum Assays

For individuals who have chronic liver disease who receive FibroSURE serum panels, the evidence includes systematic reviews of more than 30 observational studies (>5000 patients). Relevant outcomes are test validity, morbid events, and treatment-related morbidity. FibroSURE has been studied in populations with viral

hepatitis, nonalcoholic fatty liver disease, and alcoholic liver disease. There are established cutoffs, although they were not consistently used in 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, FibroSURE results provide data sufficiently useful to determine therapy. Specifically, FibroSURE has been used as an alternative to biopsy to establish eligibility regarding the presence of fibrosis or cirrhosis in several randomized controlled trials that showed the efficacy of hepatitis C virus treatments, which in turn demonstrated 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.

For individuals who have chronic liver disease who receive multianalyte serum assays for liver function assessment other than FibroSURE, the evidence includes systematic reviews of observational studies. Relevant outcomes are test validity, morbid events, and treatment-related morbidity. Studies have frequently included varying cutoffs, some of which were standardized and others not validated. Given these limitations and the imperfect reference standard, it is difficult to interpret performance characteristics. There is no direct evidence that other multianalyte serum assays improve health outcomes; further, it is not possible to construct a chain of evidence for clinical utility due to the lack of sufficient evidence on clinical validity. The evidence is insufficient to determine the effects of the technology on health outcomes.

Noninvasive Imaging

For individuals who have chronic liver disease who receive transient elastography, the evidence includes many systematic reviews of more than 50 observational studies (>10,000 patients). Relevant outcomes are test validity, morbid events, and treatment-related morbidity. Transient elastography (FibroScan) has been studied in populations with viral hepatitis, nonalcoholic fatty liver disease, and alcoholic liver disease. There are varying cutoffs for positivity. Failures of the test are not uncommon, particularly for those with high body mass index, but these failures often went undetected in analyses of the validation studies. Given these limitations and the imperfect reference standard, it can be 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. In fact, FibroScan has been used as an alternative to biopsy to establish eligibility regarding the presence of fibrosis or cirrhosis in the participants of several randomized controlled trials. These trials showed the efficacy of hepatitis C virus 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.

For individuals who have chronic liver disease who receive noninvasive radiologic methods other than transient elastography for liver fibrosis measurement, the evidence includes systematic reviews of observational studies. Relevant outcomes

are test validity, morbid events, and treatment-related morbidity. Other radiologic methods (eg, magnetic resonance elastography, real-time transient elastography, acoustic radiation force impulse imaging) may have similar performance for detecting significant fibrosis or cirrhosis. Studies have frequently included varying cutoffs not prespecified or validated. Given these limitations and the imperfect reference standard, it is difficult to interpret performance characteristics. There is no direct evidence that other noninvasive radiologic methods improve health outcomes; further, it is not possible to construct a chain of evidence for clinical utility due to the lack of sufficient evidence on clinical validity. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 3 physician specialty societies and 3 academic medical centers while this review was under review in 2015 Most reviewers considered noninvasive techniques for the evaluation and monitoring of chronic liver disease to be investigational, both individually and in combination.

Practice Guidelines and Position Statements

Nonalcoholic Fatty Liver Disease

American Gastroenterological Association et al

The practice guidelines on the diagnosis and management of nonalcoholic fatty liver disease (NAFLD), developed by the American Gastroenterological Association, the American Association for the Study of Liver Diseases, and the American College of Gastroenterology (2018) stated that "NFS [NAFLD fibrosis score] or FIB-4 [Fibrosis-4] index are clinically useful tools for identifying NAFLD patients with higher likelihood of having bridging fibrosis (stage 3) or cirrhosis (stage 4)."[72] It also cited VCTE [vibration-controlled transient elastography] and MRE [magnetic resonance elastography] as "clinically useful tools for identifying advanced fibrosis in patients with NAFLD."

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (NICE; 2016) published guidance on the assessment and management of NAFLD.[73] The guidance did not reference elastography or multianalyte assays with algorithmic analyses. The guidance recommended the enhanced liver fibrosis test to test for advanced liver fibrosis.

American College of Gastroenterology Institute

The American College of Gastroenterology Institute (2017) published guidelines on the role of elastography in chronic liver disease. The guidelines indicated that, in adults with NAFLD, VCTE has the better diagnostic performance for diagnosing cirrhosis than the aspartate aminotransferase to platelet ratio index and Fibrosis-4 (very low quality of evidence).[74] Moreover, the guidelines stated that, in adults with NAFLD, magnetic resonance–guided elastography has little or no increased diagnostic accuracy for identifying cirrhosis compared with VCTE in patients who have cirrhosis, and has higher diagnostic accuracy than VCTE in patients who do not have cirrhosis (very low quality of evidence).

Hepatitis B and C Viruses

National Institute for Health and Care Excellence

NICE (2013) published guidance on the management and treatment of patients with hepatitis B.[75] The guidance recommended offering transient elastography as the initial test in adults diagnosed with chronic hepatitis B, to inform the antiviral treatment decision (see Table 8).

Table 8. Antiviral Treatment Recommendations by Transient Elasticity Score

Transient Elasticity Score	Antiviral Treatment
>11 kPa	Offer antiviral treatment
6-10 kPa	Offer liver biopsy to confirm fibrosis level prior to offering antiviral treatment
<6 kPa plus abnormal (ALT)	Offer liver biopsy to confirm fibrosis level prior to offering antiviral treatment
<6 plus normal ALT	Do not offer antiviral treatment

ALT: alanine aminotransferase.

As of September 2016, NICE had placed a pause on the development of the guidance on hepatitis C, citing instability and costs in the availability of treatments for the condition.

American Association for the Study of Liver Diseases and Infectious Diseases Society of America

The American Association for the Study of Liver Diseases and Infectious Diseases Society of America (2018) guidelines for testing, managing, and treating hepatitis C virus (HCV) recommended that, for counseling and pretreatment assessment purposes, the following should be completed:

> "Evaluation for advanced fibrosis using liver biopsy, imaging, and/or noninvasive markers is recommended in all persons with HCV infection to facilitate an appropriate decision regarding HCV treatment strategy and determine the need for initiating additional measures for the management of cirrhosis (eg, hepatocellular carcinoma screening).
> Rating: Class I, Level A [evidence and/or general agreement; data derived from multiple randomized trials, or meta-analyses]"[76]

The guidelines noted that there are several noninvasive tests to stage the degree of fibrosis in patients with hepatitis C. Tests included indirect serum biomarkers, direct serum biomarkers, and vibration-controlled liver elastography. The guidelines asserted that no single method is recognized to have high accuracy alone and careful interpretation of these tests is required.

American College of Gastroenterology Institute

Guidelines published by the American College of Gastroenterology Institute (2017) on the role of elastography in chronic liver disease indicated that, in adults with chronic hepatitis B virus and HCV, VCTE has better diagnostic performance for diagnosing cirrhosis than the aminotransferase to platelet ratio index and Fibrosis-4 (moderate quality of evidence for HCV, low quality of evidence for hepatitis B virus).[74] In addition, the guidelines stated that, in adults with HCV, magnetic resonance–guided elastography has little or no increased diagnostic accuracy for identifying cirrhosis compared with VCTE in patients who have cirrhosis, and has lower diagnostic accuracy than VCTE in patients who do not have cirrhosis (very low quality of evidence).

Chronic Liver Disease

American College of Radiology

The American College of Radiology (2017) appropriateness criteria rated 1-dimensional transient elastography as a 7 (usually appropriate) for the diagnosis of liver fibrosis in patients with chronic liver disease.[77] The criteria noted, "This procedure is less reliable in diagnosing liver fibrosis and cirrhosis in patients with obesity or ascites."

European Association for the Study of Liver Disease et al

The European Association for the Study of Liver Disease and the Asociacion Latinoamericana para el Estudio del Higado (2015) convened a panel of experts to develop clinical practice guidelines on the use of noninvasive tests to evaluate liver disease severity and prognosis.[78] The publication summarized the advantages and disadvantages of noninvasive techniques (serum biomarkers, imaging techniques). Table 9 summarized the joint recommendations for serum biomarkers and transient elastography.

Table 9. Recommendations for Serum Biomarkers and Transient Elastography

Biomarkers	QOE	SOR
"Serum biomarkers can be used in clinical practice due to high applicability (>95%) and good reproducibility."	High	Strong
"TE can be considered the non-invasive standard for the measure of LS"	High	Strong
"Serum biomarkers are well-validated for chronic viral hepatitis.... They are less well-validated for NAFLD not validated in other chronic kidney diseases."	High	Strong
"For the diagnosis of significant fibrosis a combination of tests with concordance may provide the highest diagnostic accuracy"	High	Weak
"All HCV patients should be screened to exclude cirrhosis by TE	High	Strong

[or]… serum biomarkers….”		
“Non-invasive assessment including serum biomarkers or TE can be used as first line procedure for the identification of patients at low risk of severe fibrosis/cirrhosis”	High	Strong
“Follow-up assessment by either serum biomarkers or TE for progression of liver fibrosis should be used for NAFLD patients at a 3 year interval”	Moderate	Strong

HCV: hepatitis C virus; LS: liver stiffness; NAFLD: nonalcoholic fatty liver disease; QOE: quality of evidence; SOR: strength of recommendation; TE: transient elastography.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 10.

Table 10. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Unpublished			
NCT01789008	Interest of Transient Elastography in the Determination of Advanced Fibrosis in Alcoholic Liver Disease in Alcoholic Patients in Weaning.	300	Aug 2017 (completed)
NCT02569567	Applicability, Reliability and Accuracy for Staging Hepatic Fibrosis: Comparison of Smart-Shear Wave Elastography and Transient Elastography	105	Jun 2016 (unknown)

NCT: national clinical trial.

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Billing Coding/Physician Documentation Information

0001M Infectious disease, HCV, six biochemical assays (ALT, A2-macroglobulin, apolipoprotein A-1, total bilirubin, GGT, and haptoglobin) utilizing serum, prognostic algorithm reported as scores for fibrosis and necroinflammatory activity in liver (Code deleted 1/1/2019)

0002M Liver disease, ten biochemical assays (ALT, A2-macroglobulin, apolipoprotein A-1, total bilirubin, GGT, haptoglobin, AST, glucose, total cholesterol and triglycerides) utilizing serum, prognostic algorithm reported as quantitative scores for fibrosis, steatosis and alcoholic steatohepatitis (ASH)

0003M Liver disease, ten biochemical assays (ALT, A2-macroglobulin, apolipoprotein A-1, total bilirubin, GGT, haptoglobin, AST, glucose, total cholesterol and triglycerides) utilizing serum, prognostic algorithm reported as quantitative scores for fibrosis, steatosis and nonalcoholic steatohepatitis (NASH)

0346T Ultrasound, elastography (List separately in addition to code for primary procedure) (Code deleted 1/1/2019)

76391 Magnetic resonance (eg, vibration) elastography (New code 1/1/2019)

76981 Ultrasound, elastography; parenchyma (eg, organ) (New code 1/1/2019)

76982 Ultrasound, elastography; first target lesion (New code 1/1/2019)
76983 Ultrasound, elastography; each additional target lesion (List separately in addition to code for primary procedure) (New code 1/1/2019)
81596 Infectious disease, chronic hepatitis C virus (HCV) infection, six biochemical assays (ALT, A2-macroglobulin, apolipoprotein A-1, total bilirubin, GGT, and haptoglobin) utilizing serum, prognostic algorithm reported as scores for fibrosis and necroinflammatory activity in liver (New code 1/1/2019)
84999 Unlisted chemistry procedure
83520 Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; quantitative, not otherwise specified
83883 Nephelometry, each analyte not elsewhere specified
91200 Liver elastography, mechanically induced shear wave (eg, vibration), without imaging, with interpretation and report

ICD-10 Codes

B18.X Chronic viral hepatitis Code Range
B19.X Unspecified viral hepatitis Code Range
K70.0-K77 Liver diseases code range (fibrosis is K74.0)

There are specific CPT MAAA codes for the 3 FibroSURE™ tests performed by LabCorp:

HCV FibroSURE™, LabCorp
0001M - Infectious disease, HCV, 6 biochemical assays (ALT, α_2-macroglobulin, apolipoprotein A1, total bilirubin, GGT, and haptoglobin) utilizing serum, prognostic algorithm reported as scores for fibrosis and necroinflammatory activity in liver

ASH FibroSURE™, LabCorp
0002M - Liver disease, 10 biochemical assays (ALT, α_2-macroglobulin, apolipoprotein A1, total bilirubin, GGT, haptoglobin, AST, glucose, total cholesterol and triglycerides) utilizing serum, prognostic algorithm reported as quantitative scores for fibrosis, steatosis, and alcoholic steatohepatitis (ASH)

NASH FibroSURE™, LabCorp
0003M - Liver disease, 10 biochemical assays (ALT, α_2-macroglobulin, apolipoprotein A1, total bilirubin, GGT, haptoglobin, AST, glucose, total cholesterol and triglycerides) utilizing serum, prognostic algorithm reported as quantitative scores for fibrosis, steatosis, and nonalcoholic steatohepatitis (NASH)

There are no specific CPT codes that represent FIBROSpect as a whole. At this time, it may be reported using the unlisted chemistry procedure code 84999 or with the codes for each component test. There is no specific CPT code for the use of the associated proprietary algorithm for FIBROSpect. An example of possible coding would be:

hyaluronic acid [CPT 83520 – Immunoassay, analyte, quantitative; not otherwise specified]
tissue inhibitor of metalloproteinase (TIMP-1) [CPT 83520 – Immunoassay, analyte, quantitative; not otherwise specified]
α_2-macroglobulin [CPT 83883 – Nephelometry, each analyte not elsewhere specified]

There is a specific CPT code for elastography:

91200 Liver elastography, mechanically induced shear wave (eg, vibration), without imaging, with interpretation and report

This policy does not address standard imaging with ultrasound or magnetic resonance imaging.

Additional Policy Key Words

N/A

Policy Implementation/Update Information

2/2017 New Policy. Considered Medically Necessary when criteria is met.
2/2018 No policy statement changes.
2/2019 No policy statement changes.