Clinical Policy Title: Noninvasive assessment of hepatic fibrosis

Clinical Policy Number: 08.01.03

Effective Date: Oct. 1, 2014
Initial Review Date: June 18, 2014
Most Recent Review Date: August 17, 2017
Next Review Date: August 2018

Related policies:

CP# 01.01.01 Serum biomarkers for liver fibrosis in chronic hepatitis

ABOUT THIS POLICY: Select Health of South Carolina has developed clinical policies to assist with making coverage determinations. Select Health of South Carolina’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Select Health of South Carolina when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Select Health of South Carolina’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Select Health of South Carolina’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Select Health of South Carolina will update its clinical policies as necessary. Select Health of South Carolina’s clinical policies are not guarantees of payment.

Coverage policy

Select Health of South Carolina considers the use of transient elastography (FibroScan®, Echosens SA, Paris, France) and acoustic radiation force impulse (ARFI) imaging to be clinically proven and, therefore, medically necessary when ordered as part of an evaluation of hepatic pathology.

Treatment guidance for interpretation of noninvasive assessment of hepatic fibrosis is as follows:

- FibroScan® value of > 12.5 kilopascals has been associated with histologic cirrhosis.
- ARFI value of > 1.75 meters/second has been associated with histologic cirrhosis.
- The scatter of scores in non-cirrhotic liver disease makes the tests unreliable for correlation with Metavir Stage F3 or lower.

Select Health of South Carolina considers the use of magnetic resonance imaging (MRI), magnetic resonance elastography (MRE), computed tomography (CT), or hepatic chemistries such as FIBROSpect® (Prometheus Laboratories Inc., San Diego, California) to be investigational and, therefore, not medically necessary.

Limitations:
Transient elastography for determining the severity of portal hypertension is not medically necessary, as its diagnostic value has not been established for this use.

All other uses of liver elastography are not medically necessary.

**Alternative covered services:**

- Physician office visits.
- Liver biopsy.

**Background**

Liver fibrosis and chronic cirrhosis represent the pathological results of chronic liver injury. This may be the result of infection with one of the viral etiologies such as hepatitis B, C, or E or with toxins such as alcohol.

Hepatitis C virus (HCV) is a major cause of chronic liver disease, cirrhosis, and hepatocellular carcinoma (HCC). The Centers for Disease Control and Prevention (CDC) estimates that 2.7 to 3.9 million people in the United States have hepatitis C infection (CDC, 2017). Tice (2014) described the natural history of HCV infection as follows:

<table>
<thead>
<tr>
<th>Condition</th>
<th>Among 100 individuals with HCV (number of individuals)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remain asymptomatic</td>
<td>70 – 80</td>
</tr>
<tr>
<td>Develop chronic infection</td>
<td>75 – 85</td>
</tr>
<tr>
<td>Develop chronic liver disease</td>
<td>60 – 70</td>
</tr>
<tr>
<td>Develop symptoms</td>
<td>20 – 30</td>
</tr>
<tr>
<td>Develop cirrhosis over 20 to 30 years</td>
<td>5 – 20</td>
</tr>
<tr>
<td>Die from cirrhosis or liver cancers</td>
<td>1 – 5</td>
</tr>
</tbody>
</table>

The increased surveillance with the advent of effective oral therapies for HCV now makes this disease a major public health effort. In 2013, the U.S. Preventive Services Task Force recommended screening of adults born between 1945 and 1965 (Moyer, 2013). Because the majority of infected patients are asymptomatic and have low risk of disease progression, current treatment recommendations focus on proper patient selection, including those with advanced fibrosis or cirrhosis (i.e., Metavir Stage F3 or F4).

Liver biopsy is the standard for staging hepatic pathology but is associated with complications ranging from pain to perforation of internal organs. The American Association for the Study of Liver Diseases (AASLD) reports mortality in up to one in 10,000 liver biopsies (Rockey, 2009). Additionally, sampling errors may provide misinformation for care (Regev, 2002). 

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There are several noninvasive alternatives to liver biopsy, and most are rapidly evolving. Certain diseases can alter the elastic properties of the liver. Elastography induces a distortion in the tissue and observes the tissue’s response, from which the mechanical properties of the tissue can be mapped. Elastography has the advantage of depicting diffuse disease, which a biopsy can easily miss.

The main elastographic methods for assessing liver fibrosis apply ultrasound (US) or MRI (Barr, 2016):

- **Transient elastography** applies US to track and quantify shear wave speed, which correlates with liver elasticity, to produce a one-dimensional image of tissue stiffness. In 2012, The U.S. Food and Drug Administration (FDA) granted 510(k) approval for use of FibroScan® as a commercially available transient elastography unit, citing the high degree of reliability of measurement (FDA, 2017). It can be used at the point of care.

- **ARFI** exploits the propagation of acoustic waves from a focused US beam to create a qualitative two-dimensional map of tissue stiffness. It can be used independently or as an add-on during liver US.

- **MRE** acquires a sequence of measurements of shear wave velocity to produce a color-scaled quantitative three-dimensional image depicting tissue stiffness in units of kilopascals. MRE can be an add-on in an abdominal MRI examination or an independent MRE-only examination. Unlike US-based elastography, MRE uses standardized shear wave driver systems, processing algorithms, and display conventions that allow for direct comparison between MRE systems.

**Searches**

Select Health of South Carolina searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality Guideline Clearinghouse and evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on July 6, 2017. Search terms were: “Elasticity Imaging Techniques (MeSH),” “noninvasive liver,” “imaging liver,” and “noninvasive hepatitis C.”

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.

- **Guidelines based on systematic reviews.**

- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**
Wilder (2014) and Foucher (2006) illustrate the importance of both the etiology of hepatic fibrosis and cirrhosis and differences in optimal elastography cutoffs used to define the stage of liver fibrosis when interpreting test results. Wilder (2014) pointed to the high degree of accuracy by FibroScan® for patients with cirrhosis but also a higher error rate at stages Metavir F2 or less. A compilation of reviews by Wilder (2014) and Foucher (2006) describe the following diagnostic characteristics for FibroScan®:

<table>
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<tr>
<td></td>
<td>Advanced fibrosis, Metavir ≥ F2 cutoff (kPa)</td>
<td>Cirrhosis, Metavir = F4 cutoff (kPa)</td>
</tr>
<tr>
<td></td>
<td>Sensitivity</td>
<td>Specificity</td>
</tr>
<tr>
<td>Hepatitis B virus (HBV)</td>
<td>≥7.2</td>
<td>0.74</td>
</tr>
<tr>
<td>HCV</td>
<td>≥7.1</td>
<td>0.68</td>
</tr>
<tr>
<td>HCV + HIV</td>
<td>7.2</td>
<td>0.88</td>
</tr>
<tr>
<td>Nonalcoholic steatohepatitis</td>
<td>7</td>
<td>0.76</td>
</tr>
<tr>
<td>Primary biliary cirrhosis</td>
<td>8.8</td>
<td>0.67</td>
</tr>
<tr>
<td>Alcoholic liver disease (from Foucher)</td>
<td>7.2</td>
<td>0.64</td>
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</table>

Policy updates:

Crossan (2015) reviewed the cost-effectiveness of treating patients in the absence of liver biopsy using a variety of statistical models and generally found FibroScan® to be the most cost-effective test. According to Moroşan (2014), liver biopsy provided the most valid information to avoid subjecting patients to inappropriate medication should they have mild disease.

In 2016, we identified four new systematic reviews and meta-analyses (Houot, 2016; Li, 2016; Liu, 2015; Singh, 2015), one systematic review update (Hayes, 2014 [updated 2015]) and two guideline updates (AASLD and Infectious Disease Society of America [IDSA], 2016; Terrault, 2016) for this policy. The systematic reviews and meta-analyses confirmed earlier findings that noninvasive tests, such as FibroScan® or ARFI, may be useful in ruling out cirrhosis, but are less accurate in predicting presence of significant fibrosis (F2 or higher) across a range of etiologies.

Current guidelines recommend that all persons with HCV or HBV infection undergo an evaluation for advanced fibrosis using liver biopsy or noninvasive techniques to facilitate an appropriate decision regarding treatment strategy and management of cirrhosis (AASLD and IDSA, 2017; Terrault, 2016). While none of the noninvasive tests is as diagnostic as liver biopsy, transient elastography is a reliable and easily repeated tool for following the progression of liver fibrosis toward cirrhosis.
Insufficient, low-quality evidence supports MRE for measuring liver stiffness as a surrogate marker of liver
disease and fibrosis. The evidence suggests moderate diagnostic performance that improves with disease
severity, but prospective studies are needed to confirm these findings before wide application (Singh,
2015). These new findings would not alter the conclusions of the initial policy; therefore, no policy changes
are warranted.

In 2017, we added three systematic reviews/meta-analyses (Kim, 2017; Njei, 2016; Singh, 2016) and
professional guidance from the Society of Radiologists in Ultrasound (SRU; Barr, 2016) and the North
American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHN; Vos, 2017) to the
policy. Portal hypertension is a consequence of chronic liver disease, and its severity is associated with a
poor prognosis. Invasive measurement of the hepatic venous pressure gradient (HVPG) is used to
determine severity. Kim (2017) found transient elastography could be a reliable noninvasive alternative to
the HVPG for diagnosing the severity of portal hypertension, but the results require confirmation in
prospective research before more widespread clinical application.

In patients with HIV-HCV coinfection, transient elastography is highly accurate for detecting cirrhosis but
less accurate for detecting less severe fibrosis (Njei, 2016). Studies of transient elastography generally
exclude persons with a mean body mass index (BMI) greater than 30 kg/m², but Singh (2016) found neither
BMI nor inflammation affected the high diagnostic performance of MRE in persons with NAFLD.

Nonetheless, the current evidence base for MRE is less established than that of transient elastography and
ARFI. It consists of retrospective studies, has a high potential for spectrum and referral bias, and lacks
established cutoffs for classifying disease severity, which could lower its diagnostic performance in other
populations.

Noninvasive detection of liver fibrosis is particularly appealing for children, but the limitations in the
evidence base for all modalities of elastography are magnified in this population. The need for larger
prospective studies representing a spectrum of disease severity calls for cautious use in pediatric
populations (Vos, 2017). The SRU support noninvasive measurement of liver fibrosis using transient
elastography, ARFI, or MRE to distinguish patients with no or minimal (METAVIR stages F0 and F1) fibrosis
who could avoid liver biopsy and unnecessary treatment from patients with severe fibrosis or cirrhosis who
would require additional follow up and treatment (Barr, 2016). These results are consistent with previous
findings, and no policy changes are warranted.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Comments, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kim (2017)</td>
<td><strong>Key points:</strong></td>
</tr>
</tbody>
</table>
| Transient elastography versus HVPG for diagnosing portal hypertension (PH) | • Systematic review and meta-analysis of eight studies (1,356 total patients).  
• Overall quality: low with inconsistent patient characteristics, cirrhosis etiologies, and diagnostic thresholds.  
• For the detection of PH (HVPG ≥6 mmHg), Se 0.88 (95% confidence interval [CI] 0.86 to 0.90) and Sp 0.74 (95% CI 0.67 to 0.81). |
<table>
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<tr>
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<tbody>
<tr>
<td><strong>For clinically significant PH (HVPG ≥10 mmHg), Se 0.85 (95% CI 0.63 to 0.97) and Sp 0.71 (95% CI 0.50 to 0.93).</strong>&lt;br&gt;<strong>High correlation between transient elastography and HVPG (0.75, 95% CI 0.65 to 0.82, P&lt;0.0001).</strong>&lt;br&gt;<strong>Promising but additional rigorous research is needed.</strong></td>
<td></td>
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<tr>
<td>Vos (2017) for NASPGHAN Guideline: diagnosis and treatment of NAFLD in children</td>
<td><strong>Key points:</strong>&lt;br&gt;- ARFI, transient elastography, and MRE are mostly assessed in adults; pediatric literature is characterized by small sample size, and particularly small numbers of patients with clinically significant fibrosis (≥ F2).&lt;br&gt;- Research needed to determine optimal cut-points and track fibrosis over time in children.</td>
</tr>
<tr>
<td>Barr (2016) for the SRU Consensus statement: elastography assessment of liver fibrosis</td>
<td><strong>Key points:</strong>&lt;br&gt;- Statement considered transient elastography, MRE, and both point estimate and 2-dimensional ARFI.&lt;br&gt;- TE and ARFI techniques appear at least equivalent.&lt;br&gt;- MRE has superior performance but limited by the cost and accessibility.&lt;br&gt;- Recommend using two cutoff values: one to select patients at low-risk for clinically significant fibrosis (METAIR stages F0 and F1) who would not require additional follow-up and another cutoff value to select patients at high-risk for advanced fibrosis or cirrhosis (some F3 and F4) who require different management and prioritization for therapy.&lt;br&gt;  - F2 group between these cutoff values requires additional data to determine follow-up.&lt;br&gt;- Clinical indications for liver elastography: detect and stage liver fibrosis; monitor fibrosis progression; assess known cirrhosis to establish clinically significant PH; evaluate unexplained PH; and assess treatment response.</td>
</tr>
<tr>
<td>Njei (2016) Use of transient elastography in patients with HIV-HCV coinfection</td>
<td><strong>Key points:</strong>&lt;br&gt;- Systematic review and meta-analysis of six cohort studies (756 total patients).&lt;br&gt;- Assessing moderate (≥ F2) fibrosis: diagnostic accuracy 88% (95% CI 0.85 to 0.90); Se 97% (95% CI 0.82 to 0.91); Sp 64% (95% CI 0.45 to 0.79).&lt;br&gt;- Assessing cirrhosis: diagnostic accuracy 94% (95% CI 0.91 to 0.95); Se 90% (95% CI 0.74 to 0.97); Sp 87% (95% CI 0.80 to 0.92).&lt;br&gt;- CD4 cell count did not impact diagnostic accuracy of elastography.</td>
</tr>
<tr>
<td>Singh (2016) MRE for staging liver fibrosis in NAFLD</td>
<td><strong>Key points:</strong>&lt;br&gt;- Systematic review and individual patient data meta-analysis of nine studies (six independent cohorts with 232 total patients; mean age, 51 +/- 13 years; 37.5% males; BMI 33.5 +/- 6.7 kg/m²; interval between MRE and biopsy &lt; one year, 98.3%).&lt;br&gt;- Overall quality: low. Mostly retrospective, potential spectrum bias and referral bias.&lt;br&gt;- Fibrosis stage distribution (stage 0/1/2/3/4): 33.6%, 32.3%, 10.8%, 12.9%, and 10.4%, respectively.&lt;br&gt;- Mean AUROC (95% CI) for diagnosis of any, significant, or advanced fibrosis and cirrhosis was 0.86 (0.82 to 0.90), 0.87 (0.82 to 0.93), 0.90 (0.84 to 0.94) and 0.91 (0.76 to 0.95), respectively.&lt;br&gt;- Results are independent of BMI and degree of inflammation.</td>
</tr>
<tr>
<td>Houot (2016)</td>
<td><strong>Key points:</strong></td>
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<tr>
<td>Citation</td>
<td>Comments, Methods, Recommendations</td>
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</table>
| Biopsy versus FibroScan® or blood tests (FibroTest, FIB-4, or aspartate aminotransferase to platelet ratio index [APRI]) | • Systematic review and Bayesian analyses of 71 studies comprising 185 direct comparisons of test performance based on AUROC curves: 99 studies (12,725 patients with advanced fibrosis) and 86 studies (10,929 patients with cirrhosis); 77 groups according to etiology (HCV, HBV, or mixed).  
• Overall study quality: good (6%), fair (74%), and poor (20%).  
• In chronic HCV and HBV infection, APRI had lower test performances than FIB-4, FibroScan®, and FibroTest.  
• Lower test performance with FibroScan® than FibroTest for identifying advanced fibrosis in all etiologies, but no significant difference for identifying cirrhosis across all groups.                                                                                                                                                                                                                                                                                                                                                          |
| Li (2016)                    | **Key points:**                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Transient elastography in chronic HBV infection                           | • Meta-analysis of 27 studies (4,386 total patients) based on fibrosis stage.  
• F ≥ 2: Se 81%; Sp 82%; summary ROC curve 0.88 (95% CI 0.85 to 0.91).  
• F ≥ 3: Se = 82%; Sp = 87%; ROC = 0.91 (95% CI 0.88 to 0.93).  
• F = 4: Se = 86%; Sp = 88%; ROC = 0.93 (95% CI 0.91 to 0.95).  
• Patient age contributed to heterogeneity.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Crossan (2015)               | **Key points:**                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Non-invasive liver tests (NILTs)                                        | • Meta-analysis and cost effectiveness analysis from the UK perspective.  
• A majority of tests had only one study from which diagnostic accuracy was derived and lack validated cut-offs for diagnosis of specific fibrosis stages; therefore, there is a high risk of bias.  
• Further evidence of treatment effectiveness needed for alcoholic liver disease and NAFLD.  
• Treating everyone without NILTs is cost effective for patients with HCV who are hepatitis B e-antigen negative if the higher cost-effectiveness threshold (£30,000) is appropriate. If hepatitis B e-antigen positive, two NILTs applied sequentially were cost-effective at the threshold (£20,000) but highly uncertain.                                                                                                                                                                                                                                                                                                                                 |
| Hayes (2014, updated 2015)   | **Key points:**                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Transient elastography in chronic HCV                                   | • Systematic review of 15 prospective cross-sectional, two cohort studies, and two meta-analyses. All studies had > 200 patients.  
• Overall quality: Moderate. Limited by lack of standardization of test cutoffs used to determine degrees of fibrosis.  
• All studies provided some measure of the accuracy of transient elastography for detecting fibrosis ≥ one stage of fibrosis compared with liver biopsy, primarily based on AUROC and, to a lesser extent, simple accuracy measures.  
• Preferential patient selection for those with BMI < 30 kg/m²                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Liu (2015)                   | **Key points:**                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| ARFI in NAFLD                | • Systematic review and meta-analysis of seven studies (723 total patients with fibrosis stage F2–F4).  
• Modest test performance: Se 80%, Sp 85%, AUROC curve 0.898 (standard error [SE] 0.031; Q* index 0.830 [SE: 0.033]).  
• Head to head comparison of ARFI and other elastographic imaging is needed.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Singh (2015)                 | **Key points:**                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| MRE for staging liver        | • Systematic review and meta-analysis of 12 retrospective studies (697 total patients) with
### Comments, Methods, Recommendations

<table>
<thead>
<tr>
<th>Citation</th>
<th>Comments, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>fibrosis</td>
<td>fibrosis stage 0 (19.5%), stage 1 (19.4%), stage 2 (15.5%), stage 3 (15.9%), and stage 4 (29.7%).</td>
</tr>
<tr>
<td></td>
<td>• Mean AUROC (95% CI) by stage:</td>
</tr>
<tr>
<td></td>
<td>• Any (≥ stage 1), 0.84 (0.76 to 0.92).</td>
</tr>
<tr>
<td></td>
<td>• Significant (≥ stage 2), 0.88 (0.84 to 0.91).</td>
</tr>
<tr>
<td></td>
<td>• Advanced fibrosis (≥ stage 3), 0.93 (0.90 to 0.95).</td>
</tr>
<tr>
<td></td>
<td>• Cirrhosis, 0.92 (0.90 to 0.94).</td>
</tr>
<tr>
<td></td>
<td>• Overall failure rate 4.3%. Results are independent of BMI and etiology.</td>
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<td>• Prospective studies needed to better understand the diagnostic performance of MRE.</td>
</tr>
</tbody>
</table>

#### Department of Veterans Affairs (2014)

**Key points:**

- Both elastography and ARFI are FDA-approved, ultrasound-based techniques for estimating the extent of liver fibrosis.  
- FibroScan® value of > 12.5 kilopascals has been associated with histologic cirrhosis.  
- ARFI value of > 1.75 meters/second has been associated with histologic cirrhosis.

#### Moroşan (2014)

**Liver biopsy versus FibroScan®**

**Key points:**

- Retrospective study of 185 patients serologically diagnosed with chronic hepatitis. (183 patients with HCV, two patients with HBV and HCV).  
- Strongest correlation between tests was in F0 – F1 and F4 stages.  
- FibroScan® is able to distinguish patients with minimal or no fibrosis from patients with extensive fibrosis.  
- Liver biopsy still remains valuable for offering reliable measure of liver changes, as it is regarded more of a selective than routine technique.

### References

**Professional organizations:**


**Peer reviewed references:**


**CMS National Coverage Determinations (NCDs):**

No NCDs identified as of the writing of this policy.

**Local Coverage Determinations (LCDs):**

Add-on code 0346T listed as a non-covered service in the following LCDs:


**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>91200</td>
<td>Liver elastography, mechanically induced shear wave (eg, vibration, without imaging with interpretation and report</td>
<td></td>
</tr>
<tr>
<td>0346T</td>
<td>Add-on code; ultrasound elastography</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>B17.10</td>
<td>Acute hepatitis C without hepatic coma</td>
<td></td>
</tr>
<tr>
<td>B17.11</td>
<td>Acute hepatitis C with hepatic coma</td>
<td></td>
</tr>
<tr>
<td>B18.2</td>
<td>Chronic viral hepatitis C</td>
<td></td>
</tr>
<tr>
<td>B19.20</td>
<td>Unspecified viral hepatitis C without hepatic coma</td>
<td></td>
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<tr>
<td>K74.0</td>
<td>Hepatic fibrosis</td>
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<tr>
<td>HCPCS Level II Code</td>
<td>Description</td>
<td>Comment</td>
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<td>N/A</td>
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