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Noninvasive Imaging Techniques for Evaluation and Monitoring of Chronic Liver Diseases

DESCRIPTION

Noninvasive techniques to diagnose and monitor liver fibrosis are being investigated as alternatives to liver biopsy in individuals with chronic liver disease. Options for noninvasive monitoring consist of multianalyte serum assays with algorithmic analysis and specialized radiologic methods including magnetic resonance elastography, transient elastography, acoustic radiation for impulse imaging and real-time transient elastography.

Noninvasive imaging is proposed as an alternative to liver biopsy to diagnose and evaluate the degree of fibrosis by mapping the elastic properties of soft tissue. Imaging techniques currently being investigated include:

- **Transient Elastography** (FibroScan®) – Also known as vibration-controlled transient elastography (VCTE), this technique uses a mechanical vibrator to generate low-frequency (50Hz), mild-amplitude shear waves that propagate through the liver. Shear-wave velocity, which increases the tissue stiffness, is measured and quantified to estimate the degree of liver fibrosis. Other transient elastography techniques include:
    - Hepatus®, which combines visualized transient elastography (ViTE) with a conventional ultrasound to quantify liver stiffness (kPa) and steatosis using LiSA (an ultrasound attenuation metric) and provides real-time two-dimensional image guidance.
    - Liverscan C, a portable, wireless, palm-sized transient elastography ultrasound system that measures shear-wave speed (liver stiffness), an ultrasound attenuation parameter known as MAP (mobile attenuation parameter), and provides real-time B-mode image guidance.
- **Acoustic radiation force impulses (ARFI)** (e.g., Acuson S2000™ Virtual Touch, Acuson S3000™ Virtual Touch, Acuson Sequoia, Acuson Maple, Canon Aplio series Shear Wave Elastography, GE LOGIQ pSWE / SWE, Philips ElastQ Imaging, Philips ElastPQ, EPIQ 7, Samsung S-Shearwave™, Siemens Virtual Touch™, Siemens Virtual Touch™ IQ, SuperSonic® Imagine Aixplorer® and Aixplorer® Ultimate Ultrasound Systems, SuperSonic® MACH®/MACH 20/MACH 30/MACH 40, SuperSonic® HepaVu™) – ARFI imaging uses an ultrasound probe to produce an acoustic “push” pulse, which generates shear waves that propagate in tissue to assess liver stiffness. Permits evaluation within a localized region. There are two main categories:
    - Qualitative ARFI - The tissue is pushed by a focused ultrasound pulse and the localized displacement is imaged. This provides a visual contrast between soft (brighter) and stiff (darker) tissues. There is no numerical stiffness value.
    - Quantitative ARFI – Measures the speed of shear waves generated by the ARFI push pulse. Since shear waves travel faster in stiffer tissue, velocity can be converted to stiffness.
        - Point shear wave elastography (pSWE) - generates a shear wave and measures its speed at one location.
        - Two-dimensional shear wave elastography (2D-SWE) - pushes tissue repeatedly to generate shear waves across a region, creating a full elastography map.
- **Real-time tissue elastography** (e.g., HI VISION Preirus™) - Ultrasound able to display real-time elastography images.
- **Magnetic resonance elastography (MRE)** (e.g., Resoundant, QED SureWave™ Elastography, Canon MR Elastoplasty) - Combines MRI imaging with sound waves to create a visual map (elastogram) showing the stiffness of body tissues.
- **Multiparametric magnetic resonance imaging (MMRI)** (e.g. LiverMultiScan) – Combines an assessment of hepatic fat content that can be used to determine steatosis grading with T1 and T2 mapping to evaluate

liver tissue characteristics. T1 relaxation times reflect increases in extracellular fluid associated with the fibrosis and inflammation, while T2 relaxation times are used to asses hepatic iron content.

Note: This policy does not address multianalyte serum assays, standard imaging with ultrasound, or MRI.

POLICY

- Transient elastography imaging (i.e., FibroScan®) when used to evaluate and/or monitor individuals with chronic liver disease is considered ***medically necessary***.

- Magnetic resonance elastography is considered ***medically necessary*** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**

- Transient elastography imaging (i.e., FibroScan®) when used to evaluate and/or monitor individuals with focal liver disease is considered ***investigational.***

- All other noninvasive imaging that maps the elastic properties of soft tissue to evaluate and/or monitor individuals with chronic liver disease are considered ***investigational***. These technologies include, but are not limited to, the following:
  - Acoustic radiation force impulse imaging (e.g., Acuson S2000™, et al)
  - Real-time tissue elastography (e.g., HI VISION Preirus™)
  - Multiparametric MRI (e.g., LiverMultiScan)

MEDICAL APPROPRIATENESS

- Magnetic resonance elastography is considered **medically appropriate** if **ALL** of the following are met:
  - Chronic liver disease, as indicated by **ANY ONE** of the following:
    - Metabolic dysfunction-associated steatotic liver disease (formerly nonalcoholic fatty liver disease), and hepatic fibrosis or cirrhosis is known or suspected
    - Chronic liver disease excluding metabolic dysfunction-associated steatotic liver disease (formerly nonalcoholic fatty liver disease) (e.g., chronic hepatitis C virus infection, chronic hepatitis B virus infection) and need to assess for advanced fibrosis or cirrhosis with **ANY ONE** of the following:
      - BMI of 30 or greater
      - Vibration-controlled transient elastography is unavailable, contraindicated, or results are indeterminate

IMPORTANT REMINDERS

- Any specific products referenced in this policy are just examples and are intended for illustrative purposes only. It is not intended to be a recommendation of one product over another and is not intended to represent a complete listing of all products available. These examples are contained in the parenthetical e.g. statement.

- We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits, or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

ADDITIONAL INFORMATION

The evidence base is limited for noninvasive radiologic methods of liver fibrosis measurement beyond transient elastography and magnetic resonance elastography. Furthermore, evidence is insufficient to support alternative transient elastography techniques, such as ViTE (e.g., Hepatus®) or MAP (e.g., Liverscan C]) at this time. The clinical impact of these technologies on health outcomes has not been established.

Expert consensus guidelines have recommended standardized thresholds for classification of fibrosis based on magnetic resonance elastography-based stiffness measurements. Individuals with severe hepatic iron overload (e.g., due to hemochromatosis) may require the use of alternative image acquisition techniques to overcome lower signal intensity of the shear wave displacement.

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EFFECTIVE DATE 7/31/2026

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