Noninvasive 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 include multianalyte serum assays with algorithmic analysis and specialized radiologic methods including magnetic resonance elastography, transient elastography, and acoustic radiation for impulse imaging and real-time transient elastography.

Multianalyte assays with algorithmic analyses are proposed as an alternative to simple serum tests (e.g., ALT, AST, platelet count and prothrombin index). They use a combination of serum biochemical markers of liver function and age, sex, height and weight. The algorithmic analysis provides a score that purportedly correlates with the degree of liver damage in individuals with a variety of liver diseases. These lab tests include, but are not limited to:

- **HCV FibroSURE®** (FibroTest® in Europe) - 6 biomarkers (a2-macroglobulin, haptoglobin, bilirubin, γ-glutamyl transpeptidase (GGT), ALT, and apolipoprotein A1) yielding a prognostic algorithm scores for fibrosis and necroinflammatory activity
- **ASH FibroSURE®** - 10 biomarkers (a2-macroglobulin, haptoglobin, apolipoprotein A1, bilirubin, GGT, ALT, AST, total cholesterol, triglycerides, and fasting glucose) yielding a prognostic algorithm score for fibrosis, steatosis, and alcoholic steatohepatitis
- **NASH FibroSURE®** - 10 biomarkers (a2-macroglobulin, haptoglobin, apolipoprotein A1, bilirubin, GGT, ALT, AST, total cholesterol, triglycerides, and fasting glucose) yielding a prognostic algorithm score for fibrosis, steatosis, and nonalcoholic steatohepatitis
- **FibroSpect II®** - 3 biomarkers (hyaluronic acid, TIMP-1, and a2-macroglobulin) that directly measure fibrogenesis of the liver with algorithmic analysis

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®) – This technique transmits an elastic shear wave that propagates within the liver. The speed of the shear wave (the harder the tissue, the faster the shear propagates) is measured and quantified to determine the stage of fibrosis.
- **Acoustic radiation force impulses (ARFI)** (e.g., Acuson S2000™) – permits evaluation of liver stiffness in a smaller region.
- **Real-time tissue elastography** (e.g., HI VISION PreirusTM) ultrasound able to display real-time elastography images.
- **Magnetic resonance elastography** – Combines MRI imaging with sound waves to create a visual map (elastogram) showing the stiffness of body tissues.

Note: This policy does not address 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.**

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

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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:

- Magnetic resonance elastography
- Acoustic radiation force impulse imaging (e.g., Acuson S2000™)
- Real-time tissue elastography (e.g., HI VISION Preirus™)

Multianalyte assays with algorithmic analyses (e.g., FibroSURE™, FibroSpect™) for the evaluation and/or monitoring of individuals with chronic liver disease are considered investigational.

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, the express terms of the health plan will govern.

ADDITIONAL INFORMATION

The evidence to support the use of noninvasive radiologic methods other than transient elastography for liver fibrosis measurement is limited due to varying cutoffs not prespecified or validated. The evidence is insufficient to determine the effects of the technology on health outcomes.

SOURCES


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**EFFECTIVE DATE**

12/1/2017

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