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Medicare Advantage Policy Manual

Policy ID: M-LAB47

## **Multianalyte Assays with Algorithmic Analysis for the Evaluation and Monitoring of Patients with Chronic Liver Disease**

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Medicare Link(s) Revised: N/A

### **IMPORTANT REMINDER**

*The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member, including care that may be both medically reasonable and necessary.*

*The Medicare Advantage medical policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and Centers of Medicare and Medicaid Services (CMS) policies and manuals, along with general CMS rules and regulations. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of a specific CMS coverage determination for a requested service, item or procedure, the health plan may apply CMS regulations, as well as their Medical Policy Manual or other applicable utilization management vendor criteria developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.*

*Some services or items may appear to be medically indicated for an individual, but may be a direct exclusion of Medicare or the member's benefit plan. Medicare and member EOCs exclude from coverage, among other things, services or procedures considered to be investigational (experimental) or cosmetic, as well as services or items considered not medically reasonable and necessary under Title XVIII of the Social Security Act, §1862(a)(1)(A). In some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services. Members, their appointed representative, or a treating provider can request coverage of a service or item by submitting a pre-service organization determination prior to services being rendered.*

## **DESCRIPTION**

Multianalyte serum assays with algorithmic analysis are being evaluated as a substitute for biopsy in the screening, evaluation, and monitoring of patients with chronic liver disease. These tests are proposed to detect fibrosis, steatosis (fatty liver), or steatohepatitis (fatty liver with inflammation) in patients with hepatitis C, alcoholic liver disease, and non-alcoholic fatty liver disease. There has been interest in analyzing multiple markers using mathematical algorithms to generate a score that categorizes patients according to the biopsy score. It is proposed that these algorithms can be used as an alternative to liver biopsy in patients with liver disease. This type of test is known as a multianalyte assay with algorithmic analyses, or MAAA.

## MEDICARE ADVANTAGE POLICY CRITERIA

**Note:** Commercially available tests include, but may not be limited to, the following:

- HCV FibroSure™ (aka, FibroTest™), ASH FibroSURE™ (ASH Test), and NASH FibroSURE™ (NASH Test) (manufactured by BioPredictive S.A.S., but may be performed by other laboratories)
- Elasto-FibroTest® (this test combines the FibroTest with liver stiffness measurement, or LSM)
- FibroSpect II (Prometheus Laboratories)
- LiverFASt (Fibronostics)
- Enhanced Liver Fibrosis™ (ELF™) Test (Siemens Healthcare Diagnostics Inc./Siemens Healthcare Laboratory LLC)

These tests are laboratory developed tests (LDTs) and none have been cleared or approved by the U.S. Food and Drug Administration (FDA).

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<b>CMS Coverage Manuals*</b>	None
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<b>National Coverage Determinations (NCDs)*</b>	None
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<b>Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles (LCAs)*</b>	None
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<b>Medical Policy Manual</b>	<i>Medicare coverage guidance is not available for multianalyte liver disease tests. Therefore, the health plan's medical policy is applicable.</i>
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Multianalyte Assays with Algorithmic Analysis for the Evaluation and Monitoring of Patients with Chronic Liver Disease, Laboratory, [Policy No. 47](#) (see "NOTE" below)

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**NOTE:** If a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered as not reasonable and necessary to treat illness or injury. ([Medicare IOM Pub. No. 100-04, Ch. 23, §30 A](#)). According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an **objective, evidence-based process, based on authoritative evidence**. ([Medicare IOM Pub. No. 100-16, Ch. 4, §90.5](#)). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan's evidence-assessment process (see Cross References).

## POLICY GUIDELINES

### MEDICARE AND MEDICAL NECESSITY

To be eligible for Medicare coverage, Medicare requires diagnostic laboratory tests be ordered by the physician who is treating the beneficiary for a specific medical problem and who will use the test results in the management of that specific medical problem.<sup>[1,2]</sup> The clinical usefulness of MAAs for people with chronic liver disease is based on whether the test results will inform management changes that lead to improved outcomes, as compared with management of symptoms, clinical assessment, and standard laboratory evaluation. There is not enough research to know if MAAs improve health outcomes for people with chronic liver disease. Therefore, the use of multianalyte assays to evaluate or monitor people with chronic liver disease is considered not medically necessary under SSA §1862(a)(1)(A).

## CROSS REFERENCES

[Investigational \(Experimental\) Services, New and Emerging Medical Technologies and Procedures, and Other Non-Covered Services](#), Medicine, Policy No. M-149

## REFERENCES

1. [42 CFR §410.32\(a\)](#)
2. Medicare Benefit Policy Manual, Ch. 15 – Covered Medical and Other Health Services, [§80.1 - Clinical Laboratory Services](#)

## CODING

Codes	Number	Description
CPT	0002M	ASH FibroSURE™, BioPredictive S.A.S., Liver disease, 10 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	NASH FibroSURE™, BioPredictive, S.A.S., Liver disease, 10 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 non-alcoholic steatohepatitis (NASH)
	0014M	Liver disease, analysis of 3 biomarkers (hyaluronic acid [HA], procollagen III amino terminal peptide [PIIINP], tissue inhibitor of metalloproteinase 1 [TIMP-1]), using immunoassays, utilizing serum, prognostic algorithm reported as a risk score and risk of liver fibrosis and liver-related clinical events within 5 years
	0166U	Liver disease, 10 biochemical assays (α2macroglobulin, haptoglobin, apolipoprotein A1, bilirubin, GGT, ALT, AST, triglycerides, cholesterol, fasting glucose) and biometric and demographic data, utilizing serum, algorithm reported as scores for fibrosis, necroinflammatory activity, and steatosis with a summary interpretation
	81517	Liver disease, analysis of 3 biomarkers (hyaluronic acid [HA], procollagen III amino terminal peptide [PIIINP], tissue inhibitor of metalloproteinase 1

	[TIMP-1]), using immunoassays, utilizing serum, prognostic algorithm reported as a risk score and risk of liver fibrosis and liver-related clinical events within 5 years
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
81599	Multianalyte assay with algorithmic analysis
83520	Immunoassay, analyte, quantitative; not otherwise specified] tissue inhibitor of metalloproteinase (TIMP-1)
83883	Alpha-2 macroglobulin– Nephelometry, each analyte not elsewhere specified
84999	Unlisted chemistry procedure
<b>HCPCS</b>	None

**\*IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.