

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

**Published:** 08/01/2019

**Next Review:** 05/2020

**Last Review:** 06/2019

**Medicare Link(s) Revised:** 08/01/2019

### **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.*

*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 the Centers of Medicare and Medicaid Services (CMS) policies, when available. 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 CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCG™ criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.*

*Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and 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.*

## **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)

<b>CMS Coverage Manuals*</b>	None
<b>National Coverage Determinations (NCDs)*</b>	None
<b>Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles (LCAs)*</b>	<p>See References<sup>[1,2]</sup></p> <p>Noridian works closely with the Medicare Molecular Diagnostics (MoIDX) Program contractor to assure beneficiary access to tests that meet the technical and clinical validity standards and that have a clear role in the treatment of the patient's specific disease. The MoIDX Program requires labs to submit a technology assessment (TA) to provide evidence of analytical and clinical validity (AV/CV), and clinical utility (CU). <i>(Noridian LCA A54554)</i> Reimbursement is only allowed for "approved tests... for dates of service consistent with the effective date of the coverage determination" after MoIDX review. <i>(Noridian LCD L36256)</i> If a test does not have a coverage determination available, coverage is not allowed because evidence of clinical validity or utility has not been established via the TA review process. These tests are not considered medically reasonable and necessary under SSA §1862(a)(1)(A) until a MoIDX review is complete and coverage is indicated by MoIDX or Noridian.</p> <p>For <b><i>FibroSURE™ tests (LabCorp, or other laboratories in Noridian J-E or J-F service area) (Proprietary MAAA codes 0001M-0003M and CPT 81596):</i></b></p> <ul style="list-style-type: none"> <li>✓ <a href="#">Excluded Test List – as of 08/01/2016</a> <i>(For laboratories in the health plan's service area)</i></li> <li>✓ <a href="#">Excluded Test List – as of 08/01/2016</a> <i>(For testing performed in California)</i></li> <li>✓ <i>Noncoverage of FibroSURE™ tests remains in place whether reported with 0001M or 81596 until either MoIDX or Noridian indicate coverage is available.</i></li> </ul>

## Medical Policy Manual

Medicare coverage guidance is not available for multianalyte tests other than the FibroSURE tests. Therefore, for these tests, the health plan's medical policy is applicable.

For **any other applicable tests (e.g., Elasto-FibroTest®, FibroSpect II)**:

- ✓ Multianalyte Assays with Algorithmic Analysis for the Evaluation and Monitoring of Patients with Chronic Liver Disease, Laboratory, [Policy No. 47](#) (see "NOTE" below)

**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).

## CROSS REFERENCES

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

## REFERENCES

1. Noridian Medicare Part B Jurisdiction F (J-F) Website for [MoIDX Excluded Tests](#)
2. Noridian Medicare Part B J-F Website for [Molecular Diagnostic Services \(MoIDX\)](#)

## CODING

Codes	Number	Description
CPT	0001M	HCV FibroSURE™, LabCorp, Infectious disease, HCV, 6 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 01/01/2019)
	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)
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.