Harvard Pilgrim Health Care | TUFTS Health Plan

Point32Health companies

Payment Policy:

Laboratory: Serum Testing for Hepatic Fibrosis in the Evaluation and Monitoring of Chronic Liver Disease

Effective date: Nov. 1, 2025

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products
☐ Tufts Health Plan Commercial products

Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan
☐ Tufts Health One Care – A dual-eligible product

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO) (a dual-eligible product)
☐ Tufts Medicare Preferred HMO/PPO (Medicare Advantage products)

Policy

Chronic liver disease (CLD) refers to a wide range of liver pathologies that include inflammation (chronic hepatitis), liver cirrhosis, and hepatocellular carcinoma.

Hepatic fibrosis is associated with a cycle of extracellular matrix deposition and degradation. Biomarkers of extracellular matrix turnover are used to directly assess fibrosis and, theoretically, to monitor progression or regression. These markers include several glycoproteins, members of the collagen family, collagenases and their inhibitors, and several cytokines involved in the fibrogenic process. The markers may be utilized individually, as well as in panel combinations.

Indications and/or Limitations of Coverage

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

1. The following biomarker panels to assess liver injury **DO NOT MEET COVERAGE CRITERIA**:
   a. ASH FibroSURE®
   b. LIVERFASt™
   c. NASH FibroSURE®
   d. NASHnext™
   e. OWLiver®

The following does not meet coverage criteria due to a lack of available published scientific literature confirming that the test(s) is/are required and beneficial for the diagnosis and treatment of an individual's illness.

2. The use of the following serum biomarkers in the diagnosis, prognosis, or monitoring of chronic liver disease **DOES NOT MEET COVERAGE CRITERIA**:
   a. Signal-induced proliferation-associated 1 like 1 (SIPA1L1)
   b. microRNA (miRNA or miR) analysis, including but not limited to, the following:
      i. microRNA-21 (miRNA-21 or miR-21)
      ii. miRNA-29a (miR-29a)
      iii. miRNA-122 (miR-122)
      iv. miRNA-221 (miR-221)
      v. miRNA-222 (miR-222)
   c. Chitinase 3-like 1 (CHI3L1)
   d. Hyaluronic acid

e. Type III procollagen (PCIII)
f. Type IV collagen
g. Laminin
h. Plasma caspase-generated cytokeratin-18
i. Micro-fibrillar associated glycoprotein 4 (MFAP4)

Applicable CPT/HCPCS Procedure Codes

Procedure codes appearing in policy documents are included only as a general reference tool for each policy. They may not be all-inclusive.

Coding

Code	Description
81599	Unlisted multianalyte assay with algorithmic analysis
84999	Unlisted chemistry procedure
0002M	Liver disease, ten 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) Proprietary test: ASH FibroSURE™ Laboratory/Manufacturer: BioPredictive S.A.S
0003M	Liver disease, ten 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 nonalcoholic steatohepatitis (NASH) Proprietary test: NASH FibroSURE™ Laboratory/Manufacturer: BioPredictive S.A.S
0166U	Liver disease, 10 biochemical assays (α2-macroglobulin, 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 Proprietary test: LiverFASt™ Lab/Manufacturer: Fibronostics
0344U	Hepatology (nonalcoholic fatty liver disease [NAFLD]), semiquantitative evaluation of 28 lipid markers by liquid chromatography with tandem mass spectrometry (LC-MS/MS), serum, reported as at-risk for nonalcoholic steatohepatitis (NASH) or not NASH Proprietary test: OWLiver® Lab/Manufacturer: CIMA Sciences, LLC
0468U	Hepatology (nonalcoholic steatohepatitis [NASH]), miR-34a5p, alpha 2-macroglobulin, YKL40, HbA1c, serum and whole blood, algorithm reported as a single score for NASH activity and fibrosis Proprietary test: NASHnextTM (NIS4TM) Lab/Manufacturer: Labcorp

Evidence-based Scientific References

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Publication History

04/01/2026: Annual policy review; removed 88341 and 88342 from coding grid; administrative edits
09/01/2025: Policy created to support coverage guidelines, effective for dates of service beginning Nov. 1, 2025

Background and Disclaimer Information

This policy applies to the products of Harvard Pilgrim Health Care and Tufts Health Plan and their affiliates, as identified in the check boxes on the first page for services performed by contracted providers.

Payment is based on member benefits and eligibility on the date of service, medical necessity review, where applicable, and the provider's network participation agreement with the Plan. As every claim is unique, this policy is neither a guarantee of payment, nor a final indication of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization, and utilization management requirements (when applicable), adherence to Plan policies and procedures, and claims editing logic. An authorization is not a guarantee of payment.

Point32Health reserves the right to amend a payment policy at its discretion. CPT and HCPCS codes are updated as applicable; please adhere to the most recent CPT and HCPCS coding guidelines.

We reserve the right to conduct audits on any provider and/or facility to ensure accuracy and compliance with the guidelines stated in this payment policy. If such an audit determines that a provider/facility did not comply with this payment policy, Harvard Pilgrim Health Care and Tufts Health Plan will expect the provider/facility to refund all payments related to noncompliance.