Harvard Pilgrim Health Care | TUFTS Health Plan

Point32Health companies

Payment Policy:

Laboratory: Testing for the Diagnosis of Inflammatory Bowel 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

Inflammatory bowel disease (IBD) is a class of inflammatory bowel disorders comprised of two major disorders: ulcerative colitis and Crohn's disease each with distinct pathologic and clinical characteristics.

Ulcerative colitis (UC) is a chronic inflammatory condition characterized by relapsing and remitting episodes of inflammation limited to the mucosal layer of the colon beginning at the rectum and may extend in a proximal and continuous fashion to involve other parts of the colon/

Crohn's disease (CD) is characterized by patchy transmural inflammation (skip lesions) of the gastrointestinal tract resulting in sinus tracts, and ultimately microperforations and fistulae. It may also lead to fibrosis, strictures and to obstructive clinical presentations that are not typically seen in ulcerative colitis.

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. Fecal lactoferrin testing **MEETS COVERAGE CRITERIA** for any of the following situations:
    a. For the differential diagnosis between non-inflammatory gastrointestinal disease (e.g., IBS) and inflammatory gastrointestinal disease (e.g., IBD).
    b. To monitor individuals with IBD (e.g., assess for response to therapy or relapse).

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. For all other situations not described above, fecal lactoferrin testing **DOES NOT MEET COVERAGE CRITERIA**.
3. For the workup and monitoring of individuals with inflammatory bowel disease (IBD), the use of serologic markers (e.g., anti-neutrophil cytoplasmic antibody [ANCA]; perinuclear ANCA; anti-Saccharomyces cerevisiae antibody; antibody to Escherichia coli outer membrane porin C; anti-CBir1 flagellin antibody; antibody to Pseudomonas fluorescens-associated sequence I2; antichitobioside, antilaminaribioside, or antimannobioside antibodies; pyruvate kinase M2) **DOES NOT MEET COVERAGE CRITERIA**.
4. The use of multianalyte serum biomarker panels (with or without algorithmic analysis) that are designed to distinguish between IBD and non-IBD or that are designed to diagnose or monitor IBD (e.g., ibs-smart™, PredictSURE IBD™ Test, Prometheus® testing) **DOES NOT MEET COVERAGE CRITERIA.**

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
81401	Molecular pathology procedure, Level 2 (e.g., 2-10 SNPs, 1 methylated variant, or 1 somatic variant [typically using nonsequencing target variant analysis], or detection of a dynamic mutation disorder/triplet repeat)
81479	Unlisted molecular pathology procedure
82397	Chemiluminescent assay
83516	Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; qualitative or semiquantitative, multiple step method
83520	Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; quantitative, not otherwise specified
83630	Lactoferrin, fecal; qualitative (Effective for DOS beginning June 1, 2026)
86021	Antibody identification; leukocyte antibodies
86036	Antineutrophil cytoplasmic antibody (ANCA); screen, each antibody
86037	Antineutrophil cytoplasmic antibody (ANCA); titer, each antibody
86255	Fluorescent noninfectious agent antibody; screen, each antibody
86671	Antibody; fungus, not elsewhere specified
88346	Immunofluorescence, per specimen; initial single antibody stain procedure
88350	Immunofluorescence, per specimen; each additional single antibody stain procedure (List separately in addition to code for primary procedure)
0164U	Gastroenterology (irritable bowel syndrome [IBS]), immunoassay for anti-CdtB and anti-vinculin antibodies, utilizing plasma, algorithm for elevated or not elevated qualitative results Proprietary test: ibs-smart™ Lab/Manufacturer: Gemelli Biotech
0176U	Cytolethal distending toxin B (CdtB) and vinculin IgG antibodies by immunoassay (i.e., ELISA) Proprietary test: IBSchek® Lab/Manufacturer: Commonwealth Diagnostics International, Inc
0203U	Autoimmune (inflammatory bowel disease), mRNA, gene expression profiling by quantitative RT-PCR, 17 genes (15 target and 2 reference genes), whole blood, reported as a continuous risk score and classification of inflammatory bowel disease aggressiveness Proprietary test: PredictSURE IBD™ Test Lab/Manufacturer: KSL Diagnostics
0598U	Gastroenterology (irritable bowel syndrome), IgG antibodies to 18 food items by microarray-based immunoassay, whole blood or serum, report as elevated (positive) or normal (negative) antibody levels. (Effective for DOS beginning June 1, 2026) Proprietary test: inFoods® IBS Test Lab/Manufacturer: Ethos Laboratories, Biomerica

Evidence-based Scientific References

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Publication History

06/01/2026: Annual policy review; administrative edits; added 83630 and 0598U to coding grid, effective for DOS beginning

June 1, 2026

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.