



If a conflict arises between a Clinical Payment and Coding Policy and any plan document under which a member is entitled to Covered Services, the plan document will govern. If a conflict arises between a CPCP and any provider contract pursuant to which a provider participates in and/or provides Covered Services to eligible member(s) and/or plans, the provider contract will govern. "Plan documents" include, but are not limited to, Certificates of Health Care Benefits, benefit booklets, Summary Plan Descriptions, and other coverage documents. Blue Cross and Blue Shield of Texas may use reasonable discretion interpreting and applying this policy to services being delivered in a particular case. BCBSTX has full and final discretionary authority for their interpretation and application to the extent provided under any applicable plan documents.

Providers are responsible for submission of accurate documentation of services performed. Providers are expected to submit claims for services rendered using valid code combinations from Health Insurance Portability and Accountability Act approved code sets. Claims should be coded appropriately according to industry standard coding guidelines including, but not limited to: Uniform Billing Editor, American Medical Association, Current Procedural Terminology, CPT® Assistant, Healthcare Common Procedure Coding System, ICD-10 CM and PCS, National Drug Codes, Diagnosis Related Group guidelines, Centers for Medicare and Medicaid Services National Correct Coding Initiative Policy Manual, CCI table edits and other CMS guidelines.

Claims are subject to the code edit protocols for services/procedures billed. Claim submissions are subject to claim review including but not limited to, any terms of benefit coverage, provider contract language, medical policies, clinical payment and coding policies as well as coding software logic. Upon request, the provider is urged to submit any additional documentation.

Laboratory Testing for the Diagnosis of Inflammatory Bowel Disease

Policy Number: CPCPLAB035

Version 1.0

Approval Date: Sept. 26, 2025

Plan Effective Date: Jan. 3, 2026

Description

The plan has implemented certain lab management reimbursement criteria. Not all requirements apply to each product. Providers are urged to review Plan documents for eligible coverage for services rendered.

Reimbursement Information:

1. Fecal calprotectin **or** fecal lactoferrin testing (see Note 1) **may be reimbursable** 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).
2. For all other situations not described above, fecal calprotectin and fecal lactoferrin testing **is not reimbursable**.
3. For the workup and monitoring of individuals with inflammatory bowel disease (IBD) the use of serologic markers including, but not limited to, the following **is not reimbursable**:
 - a. Anti-neutrophil cytoplasmic antibody (ANCA),
 - b. Anti-*Saccharomyces cerevisiae* antibody (ASCA),
 - c. Perinuclear anti-neutrophilic cytoplasmic antibody (pANCA),
 - d. Antibody to *Escherichia coli* outer membrane porin C (anti-OmpC),
 - e. Antibody to *Pseudomonas fluorescens*-associated sequence I2 (anti-I2),
 - f. Anti-CBir1 flagellin antibody (anti-cBir1),
 - g. Antichitobioside antibodies (ACCA IgA),
 - h. Antilaminaribioside antibodies (ALCA IgG),
 - i. Antimannobioside antibodies (AMCA IgG),
 - j. Pyruvate kinase M2 (PKM2)
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™, IBSchek®, Prometheus® testing), **is not reimbursable**.

Note 1: Fecal calprotectin is the preferred biomarker. If fecal calprotectin and fecal lactoferrin are ordered at the same time, only fecal calprotectin will be approved.

Procedure Codes

The following is not an all-encompassing code list. The inclusion of a code does not guarantee it is a covered service or eligible for reimbursement.

Codes
82397, 83516, 83520, 83630, 83993, 86021, 86036, 86037, 86255, 86671, 88346, 88350, 0164U, 0176U, 0598U

References:

1. Peppercorn M, Cheifetz AS. Definition, epidemiology, and risk factors in inflammatory bowel disease. Updated May 13, 2025.
<https://www.uptodate.com/contents/definitions-epidemiology-and-risk-factors-for-inflammatory-bowel-disease>
2. Silverberg MS, Satsangi J, Ahmad T, et al. Toward an integrated clinical, molecular and serological classification of inflammatory bowel disease: report of a Working Party of the 2005 Montreal World Congress of Gastroenterology. *Canadian journal of gastroenterology = Journal canadien de gastroenterologie*. 2005;19 Suppl A:5a-36a.
3. Peppercorn M, Kane SV. Clinical manifestations, diagnosis, and prognosis of ulcerative colitis in adults. Updated May 17, 2025.
<https://www.uptodate.com/contents/clinical-manifestations-diagnosis-and-prognosis-of-ulcerative-colitis-in-adults>
4. Peppercorn M, Kane SV. Clinical manifestations, diagnosis and prognosis of Crohn disease in adults Updated July 2, 2025.
<https://www.uptodate.com/contents/clinical-manifestations-diagnosis-and-prognosis-of-crohn-disease-in-adults>
5. Gasche C, Scholmerich J, Brynskov J, et al. A simple classification of Crohn's disease: report of the Working Party for the World Congresses of Gastroenterology, Vienna 1998. *Inflammatory bowel diseases*. 2000;6(1):8-15.
6. Boirivant M, Cossu A. Inflammatory bowel disease. *Oral Dis*. 2012;18(1):1-15. doi:10.1111/j.1601-0825.2011.01811.x
7. Burri E, Beglinger C. The use of fecal calprotectin as a biomarker in gastrointestinal disease. *Expert review of gastroenterology & hepatology*. 2014;8(2):197-210. doi:10.1586/17474124.2014.869476
8. Almario CV, Ballal ML, Chey WD, Nordstrom C, Khanna D, Spiegel BMR. Burden of Gastrointestinal Symptoms in the United States: Results of a Nationally Representative Survey of Over 71,000 Americans. *Am J Gastroenterol*. 2018;113(11):1701-1710. doi:10.1038/s41395-018-0256-8
9. Gibson P. Approach to persistent gastrointestinal symptoms in adults with inflammatory bowel disease in remission. Updated May 20, 2025.
<https://www.uptodate.com/contents/approach-to-persistent-gastrointestinal-symptoms-in-adults-with-inflammatory-bowel-disease-in-remission>
10. Halpin SJ, Ford AC. Prevalence of symptoms meeting criteria for irritable bowel syndrome in inflammatory bowel disease: systematic review and meta-analysis. *Am J Gastroenterol*. 2012;107(10):1474-82. doi:10.1038/ajg.2012.260
11. Walsham NE, Sherwood RA. Fecal calprotectin in inflammatory bowel disease. *Clin Exp Gastroenterol*. 2016;9:21-9. doi:10.2147/ceg.s51902
12. Strober W, Fuss IJ, Blumberg RS. The immunology of mucosal models of inflammation. *Annual review of immunology*. 2002;20:495-549. doi:10.1146/annurev.immunol.20.100301.064816
13. Blumberg RS, Saubermann LJ, Strober W. Animal models of mucosal inflammation and their relation to human inflammatory bowel disease. *Current opinion in immunology*. 1999;11(6):648-56.

14. D'Haens GR, Geboes K, Peeters M, Baert F, Penninckx F, Rutgeerts P. Early lesions of recurrent Crohn's disease caused by infusion of intestinal contents in excluded ileum. *Gastroenterology*. 1998;114(2):262-7.
15. Akasaka E, Nakano H, Korekawa A, et al. Anti-laminin gamma1 pemphigoid associated with ulcerative colitis and psoriasis vulgaris showing autoantibodies to laminin gamma1, type XVII collagen and laminin-332. *European journal of dermatology : EJD*. 2015;25(2):198-9. doi:10.1684/ejd.2014.2499
16. Landers CJ, Cohavy O, Misra R, et al. Selected loss of tolerance evidenced by Crohn's disease-associated immune responses to auto- and microbial antigens. *Gastroenterology*. 2002;123(3):689-99. doi:10.1053/gast.2002.35379
17. Peeters M, Joossens S, Vermeire S, Vlietinck R, Bossuyt X, Rutgeerts P. Diagnostic value of anti-Saccharomyces cerevisiae and antineutrophil cytoplasmic autoantibodies in inflammatory bowel disease. *Am J Gastroenterol*. 2001;96(3):730-4. doi:10.1111/j.1572-0241.2001.03613.x
18. Higuchi LM, Bousvaros, Athos. Clinical presentation and diagnosis of inflammatory bowel disease in children. Updated September 10, 2024. <https://www.uptodate.com/contents/clinical-presentation-and-diagnosis-of-inflammatory-bowel-disease-in-children>
19. Mitsuyama K, Niwa M, Takedatsu H, et al. Antibody markers in the diagnosis of inflammatory bowel disease. *World J Gastroenterol*. 2016;22(3):1304-10. doi:10.3748/wjg.v22.i3.1304
20. Sandborn WJ, Loftus EV, Colombel JF, et al. Utility of perinuclear anti-neutrophil cytoplasmic antibodies (pANCA), anti-saccharomyces cerevisiae (ASCA), and anti-pancreatic antibodies (APA) as serologic markers in a population based cohort of patients with Crohn's disease (CD) and ulcerative colitis (UC). *Gastroenterology*. 2000;118(4)doi:10.1016/S0016-5085(00)82501-9
21. Ruemmele FM, Targan SR, Levy G, Dubinsky M, Braun J, Seidman EG. Diagnostic accuracy of serological assays in pediatric inflammatory bowel disease. *Gastroenterology*. 1998;115(4):822-9. doi:10.1016/s0016-5085(98)70252-5
22. Reese GE, Constantinides VA, Simillis C, et al. Diagnostic precision of anti-Saccharomyces cerevisiae antibodies and perinuclear antineutrophil cytoplasmic antibodies in inflammatory bowel disease. *Am J Gastroenterol*. 2006;101(10):2410-22. doi:10.1111/j.1572-0241.2006.00840.x
23. Joossens S, Reinisch W, Vermeire S, et al. The value of serologic markers in indeterminate colitis: a prospective follow-up study. *Gastroenterology*. 2002;122(5):1242-7. doi:10.1053/gast.2002.32980
24. Granito A, Zauli D, Muratori P, et al. Anti-Saccharomyces cerevisiae and perinuclear anti-neutrophil cytoplasmic antibodies in coeliac disease before and after gluten-free diet. *Alimentary pharmacology & therapeutics*. 2005;21(7):881-7. doi:10.1111/j.1365-2036.2005.02417.x
25. Condino AA, Hoffenberg Ej, Accurso F, et al. Frequency of ASCA seropositivity in children with cystic fibrosis. *Journal of pediatric gastroenterology and nutrition*. 2005;41(1):23-6. doi:10.1097/01.mpg.0000166801.61708.60
26. Targan SR, Landers CJ, Yang H, et al. Antibodies to CBir1 flagellin define a unique response that is associated independently with complicated Crohn's disease. *Gastroenterology*. 2005;128(7):2020-8. doi:10.1053/j.gastro.2005.03.046

27. Dotan I, Fishman S, Dgani Y, et al. Antibodies against laminaribioside and chitobioside are novel serologic markers in Crohn's disease. *Gastroenterology*. 2006;131(2):366-78. doi:10.1053/j.gastro.2006.04.030
28. Wang ZZ, Shi K, Peng J. Serologic testing of a panel of five antibodies in inflammatory bowel diseases: Diagnostic value and correlation with disease phenotype. *Biomed Rep*. 2017;401-10. vol. 4.
29. Vijayvargiya P, Busciglio I, Burton D, Donato L, Lueke A, Camilleri M. Bile Acid Deficiency in a Subgroup of Patients With Irritable Bowel Syndrome With Constipation Based on Biomarkers in Serum and Fecal Samples. *Clinical gastroenterology and hepatology : the official clinical practice journal of the American Gastroenterological Association*. 2018;16(4):522-527. doi:10.1016/j.cgh.2017.06.039
30. Donato LJ, Lueke A, Kenyon SM, Meeusen JW, Camilleri M. Description of analytical method and clinical utility of measuring serum 7-alpha-hydroxy-4-cholest-3-one (7aC4) by mass spectrometry. *Clinical biochemistry*. 2018;52:106-111. doi:10.1016/j.clinbiochem.2017.10.008
31. Walters JRF, Pattni SS. Managing bile acid diarrhoea. *Therap Adv Gastroenterol*. 2010;3(6):349-57. doi:10.1177/1756283x10377126
32. Almousa AA, Morris M, Fowler S, Jones J, Alcorn J. Elevation of serum pyruvate kinase M2 (PKM2) in IBD and its relationship to IBD indices. *Clinical biochemistry*. 2018;53:19-24.
33. Jostins L, Ripke S, Weersma RK, et al. Host-microbe interactions have shaped the genetic architecture of inflammatory bowel disease. *Nature*. 2012;491(7422):119-24. doi:10.1038/nature11582
34. Liu JZ, van Sommeren S, Huang H, et al. Association analyses identify 38 susceptibility loci for inflammatory bowel disease and highlight shared genetic risk across populations. *Nat Genet*. 2015;47(9):979-86. doi:10.1038/ng.3359
35. Snapper S, Abraham C. Immune and microbial mechanisms in the pathogenesis of inflammatory bowel disease - UpToDate. Updated February 14, 2025. <https://www.uptodate.com/contents/immune-and-microbial-mechanisms-in-the-pathogenesis-of-inflammatory-bowel-disease>
36. Liu JZ, Anderson CA. Genetic studies of Crohn's disease: Past, present and future. *Best Pract Res Clin Gastroenterol*. 2014;373-86. vol. 3.
37. Shirts B, von Roon AC, Tebo AE. The entire predictive value of the prometheus IBD sgi diagnostic product may be due to the three least expensive and most available components. *Am J Gastroenterol*. 2012;1760-1. vol. 11.
38. Lichtenstein GR, Loftus EV, Isaacs KL, Regueiro MD, Gerson LB, Sands BE. ACG Clinical Guideline: Management of Crohn's Disease in Adults. *Am J Gastroenterol*. 2018;113(4):481-517. doi:10.1038/ajg.2018.27
39. McGovern D, Kugathasan S, Cho JH. Genetics of Inflammatory Bowel Diseases. *Gastroenterology*. 2015;149(5):1163-1176 e2. doi:10.1053/j.gastro.2015.08.001
40. Lewis JD. The Utility of Biomarkers in the Diagnosis and Therapy of Inflammatory Bowel Disease. *Gastroenterology*. 2011;140(6):1817-1826 e2. doi:10.1053/j.gastro.2010.11.058
41. Menees SB, Powell C, Kurlander J, Goel A, Chey WD. A meta-analysis of the utility of C-reactive protein, erythrocyte sedimentation rate, fecal calprotectin, and fecal lactoferrin to exclude inflammatory bowel disease in adults with IBS. *Am J Gastroenterol*. 2015;110(3):444-54. doi:10.1038/ajg.2015.6

42. Mumolo MG, Bertani L, Ceccarelli L, et al. From bench to bedside: Fecal calprotectin in inflammatory bowel diseases clinical setting. *World J Gastroenterol.* 2018;24(33):3681-3694. doi:10.3748/wjg.v24.i33.3681
43. Maaser C, Sturm A, Vavricka SR, et al. ECCO-ESGAR Guideline for Diagnostic Assessment in IBD Part 1: Initial diagnosis, monitoring of known IBD, detection of complications. *J Crohns Colitis.* 2019;13(2):144-164. doi:10.1093/ecco-jcc/jjy113
44. Khaki-Khatibi F, Qujeq D, Kashifard M, Moein S, Maniati M, Vaghari-Tabari M. Calprotectin in inflammatory bowel disease. *Clin Chim Acta.* 2020;510:556-565. doi:10.1016/j.cca.2020.08.025
45. Tibble JA, Sigthorsson G, Foster R, Forgacs I, Bjarnason I. Use of surrogate markers of inflammation and Rome criteria to distinguish organic from nonorganic intestinal disease. *Gastroenterology.* 2002;123(2):450-60. doi:10.1053/gast.2002.34755
46. Plevy S, Silverberg MS, Lockton S, et al. Combined serological, genetic, and inflammatory markers differentiate non-IBD, Crohn's disease, and ulcerative colitis patients. *Inflammatory bowel diseases.* 2013;19(6):1139-48. doi:10.1097/MIB.0b013e318280b19e
47. Kaul A, Hutfless S, Liu L, Bayless TM, Marohn MR, Li X. Serum anti-glycan antibody biomarkers for inflammatory bowel disease diagnosis and progression: a systematic review and meta-analysis. *Inflammatory bowel diseases.* 2012;18(10):1872-84. doi:10.1002/ibd.22862
48. Coukos JA, Howard LA, Weinberg JM, Becker JM, Stucchi AF, Farraye FA. ASCA IgG and CBir antibodies are associated with the development of Crohn's disease and fistulae following ileal pouch-anal anastomosis. *Digestive diseases and sciences.* 2012;57(6):1544-53. doi:10.1007/s10620-012-2050-6
49. Sura SP, Ahmed A, Cheifetz AS, Moss AC. Characteristics of inflammatory bowel disease serology in patients with indeterminate colitis. *Journal of clinical gastroenterology.* 2014;48(4):351-5. doi:10.1097/mcg.0000000000000083
50. Benor S, Russell GH, Silver M, Israel EJ, Yuan Q, Winter HS. Shortcomings of the inflammatory bowel disease Serology 7 panel. *Pediatrics.* 2010;125(6):1230-6. doi:10.1542/peds.2009-1936
51. Prometheus. IBDsgi Diagnostic. <https://www.prometheuslabs.com/disease-tests/ibd-sgi-diagnostic/>
52. Prometheus. Monitr Crohn's. <https://www.prometheuslabs.com/monitr-crohns-disease/about-monitr/>
53. Prometheus. Prometheus Laboratories Announces the Launch of PredictrPKTM IFX, A Revolutionary Test Enabling Precision-Guided Dosing for Inflammatory Bowel Disease. <https://www.prometheuslabs.com/prometheus-laboratories-announces-the-launch-of-predictrpktm-ifx/>
54. Higuchi LM, Bousvaros A. Clinical presentation and diagnosis of inflammatory bowel disease in children - UpToDate. Updated September 10, 2024. <https://www.uptodate.com/contents/clinical-presentation-and-diagnosis-of-inflammatory-bowel-disease-in-children>
55. von Roon AC, Karamountzos L, Purkayastha S, et al. Diagnostic precision of fecal calprotectin for inflammatory bowel disease and colorectal malignancy. *Am J Gastroenterol.* 2007;102(4):803-13. doi:10.1111/j.1572-0241.2007.01126.x

56. van Rheenen PF, Van de Vijver E, Fidler V. Faecal calprotectin for screening of patients with suspected inflammatory bowel disease: diagnostic meta-analysis. *BMJ (Clinical research ed)*. 2010;341:c3369. doi:10.1136/bmj.c3369
57. Waugh N, Cummins E, Royle P, et al. Faecal calprotectin testing for differentiating amongst inflammatory and non-inflammatory bowel diseases: systematic review and economic evaluation. *Health technology assessment (Winchester, England)*. 2013;17(55):xv-xix, 1-211. doi:10.3310/hta17550
58. Molander P, af Bjorkesten CG, Mustonen H, et al. Fecal calprotectin concentration predicts outcome in inflammatory bowel disease after induction therapy with TNFalpha blocking agents. *Inflammatory bowel diseases*. 2012;18(11):2011-7. doi:10.1002/ibd.22863
59. Mitsuyama K, Niwa M, Masuda J, et al. Possible diagnostic role of antibodies to Crohn's disease peptide (ACP): results of a multicenter study in a Japanese cohort. *Journal of gastroenterology*. 2014;49(4):683-91. doi:10.1007/s00535-013-0916-9
60. Schoepfer AM, Trummler M, Seeholzer P, Seibold-Schmid B, Seibold F. Discriminating IBD from IBS: comparison of the test performance of fecal markers, blood leukocytes, CRP, and IBD antibodies. *Inflammatory bowel diseases*. 2008;14(1):32-9. doi:10.1002/ibd.20275
61. Molander P, Farkkila M, Ristimaki A, et al. Does fecal calprotectin predict short-term relapse after stopping TNFalpha-blocking agents in inflammatory bowel disease patients in deep remission? *J Crohns Colitis*. 2015;9(1):33-40. doi:10.1016/j.crohns.2014.06.012
62. Biasci D, Lee JC, Noor NM, et al. A blood-based prognostic biomarker in IBD. *Gut*. 2019;68(8):1386. doi:10.1136/gutjnl-2019-318343
63. Czub E, Nowak JK, Szaflarska-Poplawska A, et al. Comparison of fecal pyruvate kinase isoform M2 and calprotectin in assessment of pediatric inflammatory bowel disease severity and activity. *Acta biochimica Polonica*. 2014;61(1):99-102.
64. Kovacs G, Sipeki N, Suga B, et al. Significance of serological markers in the disease course of ulcerative colitis in a prospective clinical cohort of patients. *PLoS One*. 2018;13(3):e0194166. doi:10.1371/journal.pone.0194166
65. Tham YS, Yung DE, Fay S, et al. Fecal calprotectin for detection of postoperative endoscopic recurrence in Crohn's disease: systematic review and meta-analysis. *Therap Adv Gastroenterol*. 2018;11:1756284818785571. doi:10.1177/1756284818785571
66. Ben-Shachar S, Finezilber Y, Elad H, et al. Genotype-Serotype Interactions Shed Light on Genetic Components of Inflammatory Bowel Diseases. *Inflammatory bowel diseases*. 2019;25(2):336-344. doi:10.1093/ibd/izy231
67. Ahmed Z, Lysek M, Zhang N, Malik TA. Association Between Serological Markers and Crohn's Disease Activity. *J Clin Med Res*. 2020;12(1):6-12. doi:10.14740/jocmr4016
68. Duarte-Silva M, Afonso PC, de Souza PR, Peghini BC, Rodrigues-Júnior V, de Barros Cardoso CR. Reappraisal of antibodies against *Saccharomyces cerevisiae* (ASCA) as persistent biomarkers in quiescent Crohn's disease. *Autoimmunity*. 2019;52(1):37-47. doi:10.1080/08916934.2019.1588889
69. Campbell JP, Zierold C, Rode AM, Blocki FA, Vaughn BP. Clinical Performance of a Novel LIAISON Fecal Calprotectin Assay for Differentiation of Inflammatory

- Bowel Disease From Irritable Bowel Syndrome. *Journal of clinical gastroenterology*. 2021;55(3):239-243. doi:10.1097/mcg.0000000000001359
70. Nakov R, Snegarova V, Dimitrova-Yurukova D, Velikova T. Biomarkers in Irritable Bowel Syndrome: Biological Rationale and Diagnostic Value. *Digestive Diseases*. 2022;40(1):23-32. doi:10.1159/000516027
71. Johnson LM, Spannagl M, Wojtalewicz N, Durner J. Comparison of fecal calprotectin and pancreatic elastase assays based on proficiency testing results. *Clinical biochemistry*. 2022;107:19-23. doi:10.1016/j.clinbiochem.2022.05.002
72. Vestergaard MV, Allin KH, Poulsen GJ, Lee JC, Jess T. Characterizing the pre-clinical phase of inflammatory bowel disease. *Cell Rep Med*. 2023;4(11):101263. doi:10.1016/j.xcrm.2023.101263
73. Mourad F, Zreik AE, Halwani A, Saab J, Rizk C, Hashash JG. S1235 Utilization and Usefulness of Fecal Calprotectin for Suspected Inflammatory Bowel Disease in Clinical Practice: Real-World Data. *Official journal of the American College of Gastroenterology | ACG*. 2024;119(10S):S879. doi:10.14309/01.agj.0001034308.58875.23
74. AGA. Ulcerative Colitis Clinical Care Pathway. American Gastroenterological Association. <https://s3.amazonaws.com/agaassets/pdf/guidelines/UlcerativeColitis/index.html>
75. AGA. Identification, Assessment and Initial Medical Treatment in Crohn's Disease Clinical Decision Support Tool. American Gastroenterological Association. <https://s3.amazonaws.com/agaassets/pdf/guidelines/IBDCarePathway.pdf>
76. Feuerstein JD, Ho EY, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. *Gastroenterology*. 2021;160(7):2496-2508. doi:10.1053/j.gastro.2021.04.022
77. Smalley W, Falck-Ytter C, Carrasco-Labra A, Wani S, Lytvyn L, Falck-Ytter Y. AGA Clinical Practice Guidelines on the Laboratory Evaluation of Functional Diarrhea and Diarrhea-Predominant Irritable Bowel Syndrome in Adults (IBS-D). *Gastroenterology*. 2019;157(3):851-854. doi:10.1053/j.gastro.2019.07.004
78. Ananthakrishnan AN, Nguyen GC, Bernstein CN. AGA Clinical Practice Update on Management of Inflammatory Bowel Disease in Elderly Patients: Expert Review. *Gastroenterology*. 2021;160(1):445-451. doi:10.1053/j.gastro.2020.08.060
79. Singh S, Ananthakrishnan AN, Nguyen NH, et al. AGA Clinical Practice Guideline on the Role of Biomarkers for the Management of Ulcerative Colitis. *Gastroenterology*. 2023;164(3):344-372. doi:10.1053/j.gastro.2022.12.007
80. Colombel JF, Shin A, Gibson PR. AGA Clinical Practice Update on Functional Gastrointestinal Symptoms in Patients With Inflammatory Bowel Disease: Expert Review. *Clinical gastroenterology and hepatology : the official clinical practice journal of the American Gastroenterological Association*. 2019;17(3):380-390.e1. doi:10.1016/j.cgh.2018.08.001
81. Lichtenstein GR, Loftus EV, Afzali A, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. *Official journal of the American College of Gastroenterology | ACG*. 2025;120(6):1225-1264. doi:10.14309/ajg.0000000000003465
82. Rubin DT, Ananthakrishnan AN, Siegel CA, Barnes EL, Long MD. ACG Clinical Guideline Update: Ulcerative Colitis in Adults. *Official journal of the American*

- College of Gastroenterology | ACG.* 2025;120(6):1187-1224.
doi:10.14309/ajg.0000000000003463
83. Rubin DT, Ananthakrishnan AN, Siegel CA, Sauer BG, Long MD. ACG Clinical Guideline: Ulcerative Colitis in Adults. *Am J Gastroenterol.* 2019;114(3):384-413.
doi:10.14309/ajg.000000000000152
84. Lacy BE, Pimentel M, Brenner DM, et al. ACG Clinical Guideline: Management of Irritable Bowel Syndrome. *Official journal of the American College of Gastroenterology | ACG.* 2021;116(1):17-44. doi:10.14309/ajg.0000000000001036
85. Gomollón F, Dignass A, Annese V, et al. 3rd European Evidence-based Consensus on the Diagnosis and Management of Crohn's Disease 2016: Part 1: Diagnosis and Medical Management. *Journal of Crohn's and Colitis.* 2016;11(1):3-25.
doi:10.1093/ecco-jcc/jjw168
86. Magro F, Gionchetti P, Eliakim R, et al. Third European Evidence-based Consensus on Diagnosis and Management of Ulcerative Colitis. Part 1: Definitions, Diagnosis, Extra-intestinal Manifestations, Pregnancy, Cancer Surveillance, Surgery, and Ileo-anal Pouch Disorders. *Journal of Crohn's and Colitis.* 2017;11(6):649-670. doi:10.1093/ecco-jcc/jjx008
87. Magro F, Doherty G, Peyrin-Biroulet L, et al. ECCO Position Paper: Harmonisation of the approach to Ulcerative Colitis Histopathology. *J Crohns Colitis.* 2020;doi:10.1093/ecco-jcc/jja110
88. Torres J, Bonovas S, Doherty G, et al. ECCO Guidelines on Therapeutics in Crohn's Disease: Medical Treatment. *Journal of Crohn's and Colitis.* 2019;14(1):4-22. doi:10.1093/ecco-jcc/jjz180
89. Gordon H, Minozzi S, Kopylov U, et al. ECCO Guidelines on Therapeutics in Crohn's Disease: Medical Treatment. *Journal of Crohn's and Colitis.* 2024;18(10):1531-1555. doi:10.1093/ecco-jcc/jjae091
90. Kucharzik T, Ellul P, Greuter T, et al. ECCO Guidelines on the Prevention, Diagnosis, and Management of Infections in Inflammatory Bowel Disease. *J Crohns Colitis.* 2021;15(6):879-913. doi:10.1093/ecco-jcc/jjab052
91. Turner D, Ruemmele FM, Orlanski-Meyer E, et al. Management of Paediatric Ulcerative Colitis, Part 1: Ambulatory Care—An Evidence-based Guideline From European Crohn's and Colitis Organization and European Society of Paediatric Gastroenterology, Hepatology and Nutrition. *Journal of pediatric gastroenterology and nutrition.* 2018;67(2)doi:10.1097/MPG.0000000000002035
92. Bernstein CN, Eliakim A, Fedail S, et al. World Gastroenterology Organisation Global Guidelines Inflammatory Bowel Disease: Update August 2015. *Journal of clinical gastroenterology.* 2016;50(10):803-818.
doi:10.1097/mcg.0000000000000660
93. Bousvaros A, Antonioli DA, Colletti RB, et al. Differentiating ulcerative colitis from Crohn disease in children and young adults: report of a working group of the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition and the Crohn's and Colitis Foundation of America. *Journal of pediatric gastroenterology and nutrition.* 2007;44(5):653-74.
doi:10.1097/MPG.0b013e31805563f3
94. Kelsen JR, Sullivan KE, Rabizadeh S, et al. NASPGHAN Position Paper on The Evaluation and Management for Patients with Very Early-Onset Inflammatory Bowel Disease (VEO-IBD). *Journal of pediatric gastroenterology and nutrition.* 2019;doi:10.1097/mpg.0000000000002567

95. NICE. Faecal calprotectin diagnostic tests for inflammatory diseases of the bowel DG11. NICE. Updated October 2, 2013. <https://www.nice.org.uk/guidance/DG11>
96. NICE. Ulcerative colitis: management. Updated May 3, 2019.
<https://www.nice.org.uk/guidance/ng130>
97. NICE. Crohn's disease: management. Updated May 3, 2019.
<https://www.nice.org.uk/guidance/ng129>
98. Lamb CA, Kennedy NA, Raine T, et al. British Society of Gastroenterology consensus guidelines on the management of inflammatory bowel disease in adults. *Gut*. 2019;68(Suppl 3):s1. doi:10.1136/gutjnl-2019-318484
99. Vasant DH, Paine PA, Black CJ, et al. British Society of Gastroenterology guidelines on the management of irritable bowel syndrome. *Gut*. 2021;70(7):1214-1240. doi:10.1136/gutjnl-2021-324598
100. De Simone B, Davies J, Chouillard E, et al. WSES-AAST guidelines: management of inflammatory bowel disease in the emergency setting. *World Journal of Emergency Surgery*. 2021;16(1):23. doi:10.1186/s13017-021-00362-3
101. FDA. 510(k) Substantial Equivalence Determination.
https://www.accessdata.fda.gov/cdrh_docs/reviews/K050007.pdf
102. FDA. 510(k) https://www.accessdata.fda.gov/cdrh_docs/pdf18/K182698.pdf
103. FDA. 510(k) https://www.accessdata.fda.gov/cdrh_docs/pdf16/K160447.pdf
104. FDA. LIAISON Calprotectin.
https://www.accessdata.fda.gov/cdrh_docs/pdf18/K182698.pdf
105. FDA. Buhlmann FCAL Turbo And CALEX Cap.
<https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm?db=pmn&id=K191718>

Policy Update History:

Approval Date	Effective Date; Summary of Changes
09/26/2025	01/03/2026; Document updated with literature review. The following changes were made to Reimbursement Information: Combined CPCPLAB026 Fecal Calprotectin Testing in Adults into this policy, resulting in new #1 and #2: 1. "Fecal calprotectin or fecal lactoferrin testing (see Note 1) may be reimbursable 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)." 2. "For all other situations not described above, fecal calprotectin and fecal lactoferrin testing is not reimbursable." Former #2, now #4 revised: "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™, IBSchek®, Prometheus® testing) is not reimbursable." Added Note 1: "Fecal calprotectin is the preferred biomarker. If fecal calprotectin and fecal lactoferrin are ordered at the same time, only fecal calprotectin will be approved." Added codes 83630, 93993. References revised.
08/01/2025	10/01/2025; Added code 0598U effective 10/1/2025.
02/05/2025	05/15/2025; Document updated with literature review. Reimbursement Information revised to include ibs-smart™ as example in #2. References revised.
09/13/2024	01/01/2025: New policy.