



**BlueCross BlueShield
of Oklahoma**

If a conflict arises between a Clinical Payment and Coding Policy (“CPCP”) 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. BCBSOK may use reasonable discretion interpreting and applying this policy to services being delivered in a particular case. BCBSOK 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 (“HIPAA”) approved code sets. Claims should be coded appropriately according to industry standard coding guidelines including, but not limited to: Uniform Billing (“UB”) Editor, American Medical Association (“AMA”), Current Procedural Terminology (“CPT®”), CPT® Assistant, Healthcare Common Procedure Coding System (“HCPCS”), ICD-10 CM and PCS, National Drug Codes (“NDC”), Diagnosis Related Group (“DRG”) guidelines, Centers for Medicare and Medicaid Services (“CMS”) National Correct Coding Initiative (“NCCI”) 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.

Fecal Calprotectin Testing in Adults

Policy Number: CPCPLAB026

Version 1.0

Enterprise Clinical Payment and Coding Policy Committee Approval Date:

Plan Effective Date: Feb. 1, 2024

Description

BCBSOK 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. For individuals 18 years of age or older, fecal calprotectin testing for the differential diagnosis between non-inflammatory gastrointestinal disease (e.g., IBS) and inflammatory gastrointestinal disease (e.g., IBD) **may be reimbursable**.
2. For individuals 18 years of age or older, fecal calprotectin testing either to assess for response to therapy or for relapse or to monitor gastrointestinal conditions such as inflammatory bowel disease (IBD) **may be reimbursable**.
3. For individuals 18 years of age or older, fecal calprotectin testing for all other situations not discussed above **is not reimbursable**.

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
83993

References:

Abej, E., El-Matary, W., Singh, H., & Bernstein, C. N. (2016). The Utility of Fecal Calprotectin in the Real-World Clinical Care of Patients with Inflammatory Bowel Disease. *Can J Gastroenterol Hepatol*, 2016, 2483261. <https://doi.org/10.1155/2016/2483261>

Almario, C. V., Ballal, M. L., Chey, W. D., Nordstrom, C., Khanna, D., & Spiegel, B. M. R. (2018). Burden of Gastrointestinal Symptoms in the United States: Results of a Nationally Representative Survey of Over 71,000 Americans. *Am J Gastroenterol*, 113(11), 1701-1710. <https://doi.org/10.1038/s41395-018-0256-8>

Boirivant, M., & Cossu, A. (2012). Inflammatory bowel disease. *Oral Dis*, 18(1), 1-15. <https://doi.org/10.1111/j.1601-0825.2011.01811.x>

Burri, E., & Beglinger, C. (2014). The use of fecal calprotectin as a biomarker in gastrointestinal disease. *Expert Rev Gastroenterol Hepatol*, 8(2), 197-210. <https://doi.org/10.1586/17474124.2014.869476>

Campbell, J. P., Zierold, C., Rode, A. M., Blocki, F. A., & Vaughn, B. P. (2021). Clinical Performance of a Novel LIAISON Fecal Calprotectin Assay for Differentiation of Inflammatory Bowel Disease From Irritable Bowel Syndrome. *J Clin Gastroenterol*, 55(3), 239-243. <https://doi.org/10.1097/mcg.0000000000001359>

Colombel, J. F., Shin, A., & Gibson, P. R. (2019). AGA Clinical Practice Update on Functional Gastrointestinal Symptoms in Patients With Inflammatory Bowel Disease: Expert Review. *Clin Gastroenterol Hepatol*, 17(3), 380-390.e381. <https://doi.org/10.1016/j.cgh.2018.08.001>

Fagerhol, M. K., Dale, I., & Andersson, T. (1980). A radioimmunoassay for a granulocyte protein as a marker in studies on the turnover of such cells. *Bull Eur Physiopathol Respir*, 16 Suppl, 273-282.

FDA. (2006). 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
https://www.accessdata.fda.gov/cdrh_docs/reviews/K050007.pdf

FDA. (2016). 510(k) https://www.accessdata.fda.gov/cdrh_docs/pdf16/K160447.pdf

FDA. (2018a). 510(k) https://www.accessdata.fda.gov/cdrh_docs/pdf18/K182698.pdf

FDA. (2018b). LIAISON Calprotectin. https://www.accessdata.fda.gov/cdrh_docs/pdf18/K182698.pdf

FDA. (2019). *Buhlmann FCAL Turbo And CALEX Cap*.
<https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm?db=pmn&id=K191718>

Gibson, P. (2022). *Irritable bowel syndrome in patients with inflammatory bowel disease - UpToDate*.
<https://www.uptodate.com/contents/irritable-bowel-syndrome-in-patients-with-inflammatory-bowel-disease>

Gomollón, F., Dignass, A., Annese, V., Tilg, H., Van Assche, G., Lindsay, J. O., Peyrin-Biroulet, L., Cullen, G. J., Daperno, M., Kucharzik, T., Rieder, F., Almer, S., Armuzzi, A., Harbord, M., Langhorst, J., Sans, M., Chowers, Y., Fiorino, G., Juillerat, P., . . . on behalf of, E. (2016). 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*, 11(1), 3-25. <https://doi.org/10.1093/ecco-jcc/jjw168>

Halpin, S. J., & Ford, A. C. (2012). Prevalence of symptoms meeting criteria for irritable bowel syndrome in inflammatory bowel disease: systematic review and meta-analysis. *Am J Gastroenterol*, 107(10), 1474-1482. <https://doi.org/10.1038/ajg.2012.260>

Higuchi, L. M., & Bousvaros, A. (2022). Clinical presentation and diagnosis of inflammatory bowel disease in children - UpToDate. In M. Heyman (Ed.), *UpToDate*.
<https://www.uptodate.com/contents/clinical-presentation-and-diagnosis-of-inflammatory-bowel-disease-in-children>

Hsu, K., Champaiboon, C., Guenther, B. D., Sorenson, B. S., Khammanivong, A., Ross, K. F., Geczy, C. L., & Herzberg, M. C. (2009). ANTI-INFECTIVE PROTECTIVE PROPERTIES OF S100 CALGRANULINS. *Antiinflamm Antiallergy Agents Med Chem*, 8(4), 290-305. <http://dx.doi.org/>

Johnson, L. M., Spannagl, M., Wojtalewicz, N., & Durner, J. (2022). Comparison of fecal calprotectin and pancreatic elastase assays based on proficiency testing results. *Clin Biochem*, 107, 19-23.
<https://doi.org/10.1016/j.clinbiochem.2022.05.002>

Khaki-Khatibi, F., Qujeq, D., Kashifard, M., Moein, S., Maniati, M., & Vaghari-Tabari, M. (2020). Calprotectin in inflammatory bowel disease. *Clin Chim Acta*, 510, 556-565.
<https://doi.org/10.1016/j.cca.2020.08.025>

Lacy, B. E., Pimentel, M., Brenner, D. M., Chey, W. D., Keefer, L. A., Long, M. D., & Moshiree, B. (2021). ACG Clinical Guideline: Management of Irritable Bowel Syndrome. *Am J Gastroenterol*, 116(1), 17-44.
<https://doi.org/10.14309/ajg.0000000000001036>

Lichtenstein, G. R., Loftus, E. V., Isaacs, K. L., Regueiro, M. D., Gerson, L. B., & Sands, B. E. (2018). ACG Clinical Guideline: Management of Crohn's Disease in Adults. *Am J Gastroenterol*, 113(4), 481-517.
<https://doi.org/10.1038/ajg.2018.27>

Maaser, C., Sturm, A., Vavricka, S. R., Kucharzik, T., Fiorino, G., Annese, V., Calabrese, E., Baumgart, D. C., Bettenworth, D., Borralho Nunes, P., Burisch, J., Castiglione, F., Eliakim, R., Ellul, P., González-Lama, Y., Gordon, H., Halligan, S., Katsanos, K., Kopylov, U., . . . Stoker, J. (2019). ECCO-ESGAR Guideline for Diagnostic Assessment in IBD Part 1: Initial diagnosis, monitoring of known IBD, detection of complications. *J Crohns Colitis*, 13(2), 144-164. <https://doi.org/10.1093/ecco-jcc/jjy113>

Magro, F., Gionchetti, P., Eliakim, R., Ardizzone, S., Armuzzi, A., Barreiro-de Acosta, M., Burisch, J., Gecse, K. B., Hart, A. L., Hindryckx, P., Langner, C., Limdi, J. K., Pellino, G., Zagórowicz, E., Raine, T., Harbord, M., Rieder, F., for the European, C. s., & Colitis, O. (2017). 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*, 11(6), 649-670. <https://doi.org/10.1093/ecco-jcc/jjx008>

Mao, R., Xiao, Y. L., Gao, X., Chen, B. L., He, Y., Yang, L., Hu, P. J., & Chen, M. H. (2012). Fecal calprotectin in predicting relapse of inflammatory bowel diseases: a meta-analysis of prospective studies. *Inflamm Bowel Dis*, 18(10), 1894-1899. <https://doi.org/10.1002/ibd.22861>

Molander, P., af Bjorkesten, C. G., Mustonen, H., Haapamaki, J., Vauhkonen, M., Kolho, K. L., Farkkila, M., & Sipponen, T. (2012). Fecal calprotectin concentration predicts outcome in inflammatory bowel disease after induction therapy with TNFalpha blocking agents. *Inflamm Bowel Dis*, 18(11), 2011-2017. <https://doi.org/10.1002/ibd.22863>

Molander, P., Farkkila, M., Ristimaki, A., Salminen, K., Kempainen, H., Blomster, T., Koskela, R., Jussila, A., Rautiainen, H., Nissinen, M., Haapamaki, J., Arkkila, P., Nieminen, U., Kuisma, J., Punkkinen, J., Kolho, K. L., Mustonen, H., & Sipponen, T. (2015). Does fecal calprotectin predict short-term relapse after stopping TNFalpha-blocking agents in inflammatory bowel disease patients in deep remission? *J Crohns Colitis*, 9(1), 33-40. <https://doi.org/10.1016/j.crohns.2014.06.012>

Mumolo, M. G., Bertani, L., Ceccarelli, L., Laino, G., Di Fluri, G., Albano, E., Tapete, G., & Costa, F. (2018). From bench to bedside: Fecal calprotectin in inflammatory bowel diseases clinical setting. *World J Gastroenterol*, 24(33), 3681-3694. <https://doi.org/10.3748/wjg.v24.i33.3681>

NICE. (2017). Faecal calprotectin diagnostic tests for inflammatory diseases of the bowel DG11. *NICE Diagnostics guidance*. <https://www.nice.org.uk/guidance/DG11>

Rosenfeld, G., Greenup, A. J., Round, A., Takach, O., Halparin, L., Saadeddin, A., Ho, J. K., Lee, T., Enns, R., & Bressler, B. (2016). FOCUS: Future of fecal calprotectin utility study in inflammatory bowel disease. *World J Gastroenterol*, 22(36), 8211-8218. <https://doi.org/10.3748/wjg.v22.i36.8211>

Rubin, D. T., Ananthakrishnan, A. N., Siegel, C. A., Sauer, B. G., & Long, M. D. (2019). ACG Clinical Guideline: Ulcerative Colitis in Adults. *Am J Gastroenterol*, 114(3), 384-413. <https://doi.org/10.14309/ajg.000000000000152>

Singh, S., Ananthakrishnan, A. N., Nguyen, N. H., Cohen, B. L., Velayos, F. S., Weiss, J. M., Sultan, S., Siddique, S. M., Adler, J., & Chachu, K. A. (2023). AGA Clinical Practice Guideline on the Role of Biomarkers for the Management of Ulcerative Colitis. *Gastroenterology*, 164(3), 344-372. <https://doi.org/10.1053/j.gastro.2022.12.007>

Tham, Y. S., Yung, D. E., Fay, S., Yamamoto, T., Ben-Horin, S., Eliakim, R., Koulaouzidis, A., & Kopylov, U. (2018). Fecal calprotectin for detection of postoperative endoscopic recurrence in Crohn's disease: systematic review and meta-analysis. *Therap Adv Gastroenterol*, *11*, 1756284818785571. <https://doi.org/10.1177/1756284818785571>

Tibble, J. A., Sigthorsson, G., Foster, R., Forgacs, I., & Bjarnason, I. (2002). Use of surrogate markers of inflammation and Rome criteria to distinguish organic from nonorganic intestinal disease. *Gastroenterology*, *123*(2), 450-460.

van Rheenen, P. F., Van de Vijver, E., & Fidler, V. (2010). Faecal calprotectin for screening of patients with suspected inflammatory bowel disease: diagnostic meta-analysis. *Bmj*, *341*, c3369. <https://doi.org/10.1136/bmj.c3369>

von Roon, A. C., Karamountzos, L., Purkayastha, S., Reese, G. E., Darzi, A. W., Teare, J. P., Paraskeva, P., & Tekkis, P. P. (2007). Diagnostic precision of fecal calprotectin for inflammatory bowel disease and colorectal malignancy. *Am J Gastroenterol*, *102*(4), 803-813. <https://doi.org/10.1111/j.1572-0241.2007.01126.x>

Walsham, N. E., & Sherwood, R. A. (2016). Fecal calprotectin in inflammatory bowel disease. *Clin Exp Gastroenterol*, *9*, 21-29. <https://doi.org/10.2147/ceg.s51902>

Waugh, N., Cummins, E., Royle, P., Kandala, N. B., Shyangdan, D., Arasaradnam, R., Clar, C., & Johnston, R. (2013). Faecal calprotectin testing for differentiating amongst inflammatory and non-inflammatory bowel diseases: systematic review and economic evaluation. *Health Technol Assess*, *17*(55), xv-xix, 1-211. <https://doi.org/10.3310/hta17550>

Yang, Z., Clark, N., & Park, K. T. (2014). Effectiveness and cost-effectiveness of measuring fecal calprotectin in diagnosis of inflammatory bowel disease in adults and children. *Clin Gastroenterol Hepatol*, *12*(2), 253-262.e252. <https://doi.org/10.1016/j.cgh.2013.06.028>

Policy Update History:

Effective Date	Summary of Change
02/01/2024	Document updated with literature review. Reimbursement Information revised for clarity to specifically indicate this testing is relevant to adult individuals 18 years of age and older only. References revised.
11/01/2023	Document updated with literature review. Reimbursement information revised for clarity. References updated.
11/1/2022	New policy

