



## 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.

### Laboratory Testing for the Diagnosis of Inflammatory Bowel Disease

**Policy Number: CPCPLAB035**

**Version 1.0**

**Enterprise Clinical Payment and Coding Policy Committee Approval Date: July 5, 2023**

**Plan Effective Date: November 1, 2023**

#### 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 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. Ppyruvate kinase M2 (PKM2)
2. For the diagnosis or monitoring of individuals with IBD, the use of diagnostic algorithm-based testing, including testing that combines serologic, genetic, and inflammation markers (such as Prometheus® testing), **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
82397, 83516, 83520, 86021, 86036, 86037, 86255, 86671, 88346, 88350, 0164U, 0176U

## References:

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>

AGA. (2015). *Ulcerative Colitis CLINICAL CARE PATHWAY*. American Gastroenterological Association.

<https://s3.amazonaws.com/agaassets/pdf/guidelines/UlcerativeColitis/index.html>

Ahmed, Z., Lysek, M., Zhang, N., & Malik, T. A. (2020). Association Between Serological Markers and Crohn's Disease Activity. *J Clin Med Res*, 12(1), 6-12. <https://doi.org/10.14740/jocmr4016>

Akasaka, E., Nakano, H., Korekawa, A., Fukui, T., Kaneko, T., Koga, H., Hashimoto, T., & Sawamura, D. (2015). Anti-laminin gamma1 pemphigoid associated with ulcerative colitis and psoriasis vulgaris showing autoantibodies to laminin gamma1, type XVII collagen and laminin-332. *Eur J Dermatol*, 25(2), 198-199. <https://doi.org/10.1684/ejd.2014.2499>

Almoussa, A. A., Morris, M., Fowler, S., Jones, J., & Alcorn, J. (2018). Elevation of serum pyruvate kinase M2 (PKM2) in IBD and its relationship to IBD indices. *Clin Biochem*, 53, 19-24.

<https://doi.org/https://doi.org/10.1016/j.clinbiochem.2017.12.007>

Ben-Shachar, S., Finezilber, Y., Elad, H., Rabinowitz, K., Goren, I., Isakov, O., Yanai, H., & Dotan, I. (2019). Genotype-Serotype Interactions Shed Light on Genetic Components of Inflammatory Bowel Diseases. *Inflamm Bowel Dis*, 25(2), 336-344. <https://doi.org/10.1093/ibd/izy231>

Benor, S., Russell, G. H., Silver, M., Israel, E. J., Yuan, Q., & Winter, H. S. (2010). Shortcomings of the inflammatory bowel disease Serology 7 panel. *Pediatrics*, 125(6), 1230-1236. <https://doi.org/10.1542/peds.2009-1936>

Bernstein, C. N., Eliakim, A., Fedail, S., Fried, M., Gearry, R., Goh, K. L., Hamid, S., Khan, A. G., Khalif, I., Ng, S. C., Ouyang, Q., Rey, J. F., Sood, A., Steinwurz, F., Watermeyer, G., & LeMair, A. (2016). World Gastroenterology Organisation Global Guidelines Inflammatory Bowel Disease: Update August 2015. *J Clin Gastroenterol*, 50(10), 803-818. <https://doi.org/10.1097/mcg.0000000000000660>

Biasci, D., Lee, J. C., Noor, N. M., Pombal, D. R., Hou, M., Lewis, N., Ahmad, T., Hart, A., Parkes, M., McKinney, E. F., Lyons, P. A., & Smith, K. G. C. (2019). A blood-based prognostic biomarker in IBD. *Gut*, 68(8), 1386. <https://doi.org/10.1136/gutjnl-2019-318343>

Blumberg, R. S., Saubermann, L. J., & Strober, W. (1999). Animal models of mucosal inflammation and their relation to human inflammatory bowel disease. *Curr Opin Immunol*, 11(6), 648-656. <https://www.sciencedirect.com/science/article/pii/S0952791599000321>

Bousvaros, A., Antonioli, D. A., Colletti, R. B., Dubinsky, M. C., Glickman, J. N., Gold, B. D., Griffiths, A. M., Jevon, G. P., Higuchi, L. M., Hyams, J. S., Kirschner, B. S., Kugathasan, S., Baldassano, R. N., & Russo, P. A. (2007). 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. *J Pediatr Gastroenterol Nutr*, 44(5), 653-674. <https://doi.org/10.1097/MPG.0b013e31805563f3>

Condino, A. A., Hoffenberg, E. J., Accurso, F., Penvari, C., Anthony, M., Gralla, J., & O'Connor, J. A. (2005). Frequency of ASCA seropositivity in children with cystic fibrosis. *J Pediatr Gastroenterol Nutr*, 41(1), 23-26. <http://dx.doi.org/>

Coukos, J. A., Howard, L. A., Weinberg, J. M., Becker, J. M., Stucchi, A. F., & Farraye, F. A. (2012). ASCA IgG and CBir antibodies are associated with the development of Crohn's disease and fistulae following ileal pouch-anal anastomosis. *Dig Dis Sci*, 57(6), 1544-1553. <https://doi.org/10.1007/s10620-012-2050-6>

Czub, E., Nowak, J. K., Szaflarska-Poplawska, A., Grzybowska-Chlebowczyk, U., Landowski, P., Moczko, J., Adamczak, D., Mankowski, P., Banasiewicz, T., Plawski, A., & Walkowiak, J. (2014). Comparison of fecal pyruvate kinase isoform M2 and calprotectin in assessment of pediatric inflammatory bowel disease severity and activity. *Acta Biochim Pol*, 61(1), 99-102.

D'Haens, G. R., Geboes, K., Peeters, M., Baert, F., Penninckx, F., & Rutgeerts, P. (1998). Early lesions of recurrent Crohn's disease caused by infusion of intestinal contents in excluded ileum. *Gastroenterology*, 114(2), 262-267. <http://dx.doi.org/>

De Simone, B., Davies, J., Chouillard, E., Di Saverio, S., Hoentjen, F., Tarasconi, A., Sartelli, M., Biffi, W. L., Ansaloni, L., Coccolini, F., Chiarugi, M., De'Angelis, N., Moore, E. E., Kluger, Y., Abu-Zidan, F., Sakakushev, B., Coimbra, R., Celentano, V., Wani, I., . . . Catena, F. (2021). WSES-AAST guidelines: management of

inflammatory bowel disease in the emergency setting. *World Journal of Emergency Surgery*, 16(1), 23. <https://doi.org/10.1186/s13017-021-00362-3>

Donato, L. J., Lueke, A., Kenyon, S. M., Meeusen, J. W., & Camilleri, M. (2018). Description of analytical method and clinical utility of measuring serum 7-alpha-hydroxy-4-cholesten-3-one (7aC4) by mass spectrometry. *Clin Biochem*, 52, 106-111. <https://doi.org/10.1016/j.clinbiochem.2017.10.008>

Dotan, I., Fishman, S., Dgani, Y., Schwartz, M., Karban, A., Lerner, A., Weishauss, O., Spector, L., Shtevi, A., Altstock, R. T., Dotan, N., & Halpern, Z. (2006). Antibodies against laminaribioside and chitobioside are novel serologic markers in Crohn's disease. *Gastroenterology*, 131(2), 366-378. <https://doi.org/10.1053/j.gastro.2006.04.030>

Duarte-Silva, M., Afonso, P. C., de Souza, P. R., Peghini, B. C., Rodrigues-Júnior, V., & de Barros Cardoso, C. R. (2019). Reappraisal of antibodies against *Saccharomyces cerevisiae* (ASCA) as persistent biomarkers in quiescent Crohn's disease. *Autoimmunity*, 52(1), 37-47. <https://doi.org/10.1080/08916934.2019.1588889>

Eltabbakh, M. (2021). Diagnostic Utility of Beta 2 Microglobulin in Patients with Irritable Bowel Syndrome and Ulcerative Colitis. *Egyptian Journal of Medical Microbiology* 30. <https://doi.org/https://doi.org/10.51429/EJMM30213>

Feuerstein, J. D., Ho, E. Y., Shmidt, E., Singh, H., Falck-Ytter, Y., Sultan, S., Terdiman, J. P., Sultan, S., Cohen, B. L., Chachu, K., Day, L., Davitkov, P., Lebowitz, B., Levin, T. R., Patel, A., Peery, A. F., Shah, R., Singh, H., Singh, S., . . . Weiss, J. M. (2021). AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. *Gastroenterology*, 160(7), 2496-2508. <https://doi.org/10.1053/j.gastro.2021.04.022>

Gao, X., & Zhang, Y. (2021). Serological markers facilitate the diagnosis of Crohn's disease. *Postgraduate Medicine*, 133(3), 286-290. <https://doi.org/10.1080/00325481.2021.1873649>

Gasche, C., Scholmerich, J., Brynskov, J., D'Haens, G., Hanauer, S. B., Irvine, E. J., Jewell, D. P., Rachmilewitz, D., Sachar, D. B., Sandborn, W. J., & Sutherland, L. R. (2000). A simple classification of Crohn's disease: report of the Working Party for the World Congresses of Gastroenterology, Vienna 1998. *Inflamm Bowel Dis*, 6(1), 8-15. <http://dx.doi.org/>

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>

Granito, A., Zauli, D., Muratori, P., Muratori, L., Grassi, A., Bortolotti, R., Petrolini, N., Veronesi, L., Gionchetti, P., Bianchi, F. B., & Volta, U. (2005). Anti-*Saccharomyces cerevisiae* and perinuclear anti-neutrophil cytoplasmic antibodies in coeliac disease before and after gluten-free diet. *Aliment Pharmacol Ther*, 21(7), 881-887. <https://doi.org/10.1111/j.1365-2036.2005.02417.x>

Higuchi, L. M., Bousvaros, Athos. (2020). *Clinical presentation and diagnosis of inflammatory bowel disease in children*. <https://www.uptodate.com/contents/clinical-presentation-and-diagnosis-of-inflammatory-bowel-disease-in-children>

Joossens, S., Reinisch, W., Vermeire, S., Sendid, B., Poulain, D., Peeters, M., Geboes, K., Bossuyt, X., Vandewalle, P., Oberhuber, G., Vogelsang, H., Rutgeerts, P., & Colombel, J. F. (2002). The value of serologic markers in indeterminate colitis: a prospective follow-up study. *Gastroenterology*, *122*(5), 1242-1247. <http://dx.doi.org/>

Jostins, L., Ripke, S., Weersma, R. K., Duerr, R. H., McGovern, D. P., Hui, K. Y., Lee, J. C., Schumm, L. P., Sharma, Y., Anderson, C. A., Essers, J., Mitrovic, M., Ning, K., Cleynen, I., Theatre, E., Spain, S. L., Raychaudhuri, S., Goyette, P., Wei, Z., . . . Cho, J. H. (2012). Host-microbe interactions have shaped the genetic architecture of inflammatory bowel disease. *Nature*, *491*(7422), 119-124. <https://doi.org/10.1038/nature11582>

Kaul, A., Hutfless, S., Liu, L., Bayless, T. M., Marohn, M. R., & Li, X. (2012). Serum anti-glycan antibody biomarkers for inflammatory bowel disease diagnosis and progression: a systematic review and meta-analysis. *Inflamm Bowel Dis*, *18*(10), 1872-1884. <https://doi.org/10.1002/ibd.22862>

Kelsen, J. R., Sullivan, K. E., Rabizadeh, S., Singh, N., Snapper, S., Elkadri, A., & Grossman, A. B. (2019). NASPGHAN Position Paper on The Evaluation and Management for Patients with Very Early-Onset Inflammatory Bowel Disease (VEO-IBD). *J Pediatr Gastroenterol Nutr*. <https://doi.org/10.1097/mpg.0000000000002567>

Kovacs, G., Sipeki, N., Suga, B., Tornai, T., Fechner, K., Norman, G. L., Shums, Z., Antal-Szalmas, P., & Papp, M. (2018). Significance of serological markers in the disease course of ulcerative colitis in a prospective clinical cohort of patients. *PLoS One*, *13*(3), e0194166. <https://doi.org/10.1371/journal.pone.0194166>

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. *Official journal of the American College of Gastroenterology | ACG*, *116*(1), 17-44. <https://doi.org/10.14309/ajg.0000000000001036>

Lamb, C. A., Kennedy, N. A., Raine, T., Hendy, P. A., Smith, P. J., Limdi, J. K., Hayee, B. H., Lomer, M. C. E., Parkes, G. C., Selinger, C., Barrett, K. J., Davies, R. J., Bennett, C., Gittens, S., Dunlop, M. G., Faiz, O., Fraser, A., Garrick, V., Johnston, P. D., . . . Hawthorne, A. B. (2019). British Society of Gastroenterology consensus guidelines on the management of inflammatory bowel disease in adults. *Gut*, *68*(Suppl 3), s1. <https://doi.org/10.1136/gutjnl-2019-318484>

Landers, C. J., Cohavy, O., Misra, R., Yang, H., Lin, Y. C., Braun, J., & Targan, S. R. (2002). Selected loss of tolerance evidenced by Crohn's disease-associated immune responses to auto- and microbial antigens. *Gastroenterology*, *123*(3), 689-699. <https://www.sciencedirect.com/science/article/abs/pii/S0016508502001592>

Lewis, J. D. (2011). The Utility of Biomarkers in the Diagnosis and Therapy of Inflammatory Bowel Disease. *Gastroenterology*, *140*(6), 1817-1826 e1812. <https://doi.org/10.1053/j.gastro.2010.11.058>

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>

Liu, J. Z., & Anderson, C. A. (2014). Genetic studies of Crohn's disease: Past, present and future. In *Best Pract Res Clin Gastroenterol* (Vol. 28, pp. 373-386). <https://doi.org/10.1016/j.bpg.2014.04.009>

Liu, J. Z., van Sommeren, S., Huang, H., Ng, S. C., Alberts, R., Takahashi, A., Ripke, S., Lee, J. C., Jostins, L., Shah, T., Abedian, S., Cheon, J. H., Cho, J., Dayani, N. E., Franke, L., Fuyuno, Y., Hart, A., Juyal, R. C., Juyal, G., . . . Weersma, R. K. (2015). Association analyses identify 38 susceptibility loci for inflammatory bowel disease and highlight shared genetic risk across populations. *Nat Genet*, *47*(9), 979-986. <https://doi.org/10.1038/ng.3359>

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. (2018). ECCO-ESGAR Guideline for Diagnostic Assessment in IBD Part 1: Initial diagnosis, monitoring of known IBD, detection of complications. *Journal of Crohn's and Colitis*, *13*(2), 144-164K. <https://doi.org/10.1093/ecco-icc/jjy113>

Magro, F., Doherty, G., Peyrin-Biroulet, L., Svrcek, M., Borralho, P., Walsh, A., Carneiro, F., Rosini, F., de Hertogh, G., Biedermann, L., Pouillon, L., Scharl, M., Tripathi, M., Danese, S., Villanacci, V., & Feakins, R. (2020). ECCO Position Paper: Harmonisation of the approach to Ulcerative Colitis Histopathology. *J Crohns Colitis*. <https://doi.org/10.1093/ecco-icc/jjaa110>

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-icc/jjx008>

McGovern, D., Kugathasan, S., & Cho, J. H. (2015). Genetics of Inflammatory Bowel Diseases. *Gastroenterology*, *149*(5), 1163-1176 e1162. <https://doi.org/10.1053/j.gastro.2015.08.001>

Menees, S. B., Powell, C., Kurlander, J., Goel, A., & Chey, W. D. (2015). 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*, *110*(3), 444-454. <https://doi.org/10.1038/ajg.2015.6>

Mitsuyama, K., Niwa, M., Masuda, J., Yamasaki, H., Kuwaki, K., Takedatsu, H., Kobayashi, T., Kinjo, F., Kishimoto, K., Matsui, T., Hirai, F., Makiyama, K., Ohba, K., Abe, H., Tsubouchi, H., Fujita, H., Maekawa, R., Yoshida, H., & Sata, M. (2014). Possible diagnostic role of antibodies to Crohn's disease peptide (ACP): results of a multicenter study in a Japanese cohort. *J Gastroenterol*, *49*(4), 683-691. <https://doi.org/10.1007/s00535-013-0916-9>

Mitsuyama, K., Niwa, M., Takedatsu, H., Yamasaki, H., Kuwaki, K., Yoshioka, S., Yamauchi, R., Fukunaga, S., & Torimura, T. (2016). Antibody markers in the diagnosis of inflammatory bowel disease. *World J Gastroenterol*, *22*(3), 1304-1310. <https://doi.org/10.3748/wjg.v22.i3.1304>

Nakov, R., Snegarova, V., Dimitrova-Yurukova, D., & Velikova, T. (2022). Biomarkers in Irritable Bowel Syndrome: Biological Rationale and Diagnostic Value. *Digestive Diseases*, *40*(1), 23-32. <https://doi.org/10.1159/000516027>

NICE. (2019a). Crohn's disease overview. <https://pathways.nice.org.uk/pathways/crohns-disease#content=view-index>

NICE. (2019b). Ulcerative colitis overview. <https://pathways.nice.org.uk/pathways/ulcerative-colitis#content=view-node%3Anodes-diagnostic-and-prognostic-tests>

Peeters, M., Joossens, S., Vermeire, S., Vlietinck, R., Bossuyt, X., & Rutgeerts, P. (2001). Diagnostic value of anti-Saccharomyces cerevisiae and antineutrophil cytoplasmic autoantibodies in inflammatory bowel disease. *Am J Gastroenterol*, 96(3), 730-734. <https://doi.org/10.1111/j.1572-0241.2001.03613.x>

Peppercorn, M., & Cheifetz, A. S. (2021, 08/10/2021). *Definition, epidemiology, and risk factors in inflammatory bowel disease - UpToDate*. <https://www.uptodate.com/contents/definitions-epidemiology-and-risk-factors-for-inflammatory-bowel-disease>

Peppercorn, M., & Kane, S. (2022a, 03/23/2022). *Clinical manifestations, diagnosis and prognosis of Crohn disease in adults* <https://www.uptodate.com/contents/clinical-manifestations-diagnosis-and-prognosis-of-crohn-disease-in-adults>

Peppercorn, M., & Kane, S. (2022b, 03/21/2022). *Clinical manifestations, diagnosis, and prognosis of ulcerative colitis in adults*. <https://www.uptodate.com/contents/clinical-manifestations-diagnosis-and-prognosis-of-ulcerative-colitis-in-adults>

Plevy, S., Silverberg, M. S., Lockton, S., Stockfisch, T., Croner, L., Stachelski, J., Brown, M., Triggs, C., Chuang, E., Princen, F., & Singh, S. (2013). Combined serological, genetic, and inflammatory markers differentiate non-IBD, Crohn's disease, and ulcerative colitis patients. *Inflamm Bowel Dis*, 19(6), 1139-1148. <https://doi.org/10.1097/MIB.0b013e318280b19e>

Prometheus. (2022a). *IBDsgi Diagnostic*. <https://www.prometheuslabs.com/disease-tests/ibd-sgi-diagnostic/>

Prometheus. (2022b). *Monitr Crohn's*. <https://www.prometheuslabs.com/monitr-crohns-disease/about-monitr/>

Prometheus. (2022c). *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/>

Reese, G. E., Constantinides, V. A., Simillis, C., Darzi, A. W., Orchard, T. R., Fazio, V. W., & Tekkis, P. P. (2006). Diagnostic precision of anti-Saccharomyces cerevisiae antibodies and perinuclear antineutrophil cytoplasmic antibodies in inflammatory bowel disease. *Am J Gastroenterol*, 101(10), 2410-2422. <https://doi.org/10.1111/j.1572-0241.2006.00840.x>

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>

Ruemmele, F. M., Targan, S. R., Levy, G., Dubinsky, M., Braun, J., & Seidman, E. G. (1998). Diagnostic accuracy of serological assays in pediatric inflammatory bowel disease. *Gastroenterology*, *115*(4), 822-829. <http://dx.doi.org/>

Sandborn, W. J., Loftus, E. V., Colombel, J. F., Fleming, K., Seibold, F., Homburger, H. A., Sendid, B., Chapman, R. W., Tremaine, W. J., Kaul, D. K., Harmsen, W. S., & Targan, S. R. (2000). 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*, *118*(4). [https://doi.org/10.1016/S0016-5085\(00\)82501-9](https://doi.org/10.1016/S0016-5085(00)82501-9)

Schoepfer, A. M., Trummel, M., Seeholzer, P., Seibold-Schmid, B., & Seibold, F. (2008). Discriminating IBD from IBS: comparison of the test performance of fecal markers, blood leukocytes, CRP, and IBD antibodies. *Inflamm Bowel Dis*, *14*(1), 32-39. <https://doi.org/10.1002/ibd.20275>

Shirts, B., von Roon, A. C., & Tebo, A. E. (2012). The entire predictive value of the prometheus IBD sgi diagnostic product may be due to the three least expensive and most available components. In *Am J Gastroenterol* (Vol. 107, pp. 1760-1761). <https://doi.org/10.1038/ajg.2012.238>

Silverberg, M. S., Satsangi, J., Ahmad, T., Arnott, I. D., Bernstein, C. N., Brant, S. R., Caprilli, R., Colombel, J. F., Gasche, C., Geboes, K., Jewell, D. P., Karban, A., Loftus, E. V., Jr., Pena, A. S., Riddell, R. H., Sachar, D. B., Schreiber, S., Steinhart, A. H., Targan, S. R., . . . Warren, B. F. (2005). 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. *Can J Gastroenterol*, *19 Suppl A*, 5a-36a. <http://dx.doi.org/>

Snapper, S., & Abraham, C. (2020). Immune and microbial mechanisms in the pathogenesis of inflammatory bowel disease - UpToDate. In K. Robson (Ed.), *UpToDate*. UpToDate, Inc. <https://www.uptodate.com/contents/immune-and-microbial-mechanisms-in-the-pathogenesis-of-inflammatory-bowel-disease>

Strober, W., Fuss, I. J., & Blumberg, R. S. (2002). The immunology of mucosal models of inflammation. *Annu Rev Immunol*, *20*, 495-549. <https://doi.org/10.1146/annurev.immunol.20.100301.064816>

Sura, S. P., Ahmed, A., Cheifetz, A. S., & Moss, A. C. (2014). Characteristics of inflammatory bowel disease serology in patients with indeterminate colitis. *J Clin Gastroenterol*, *48*(4), 351-355. <https://doi.org/10.1097/mcg.000000000000083>

Targan, S. R., Landers, C. J., Yang, H., Lodes, M. J., Cong, Y., Papadakis, K. A., Vasilias, E., Elson, C. O., & Hershberg, R. M. (2005). Antibodies to CBir1 flagellin define a unique response that is associated independently with complicated Crohn's disease. *Gastroenterology*, *128*(7), 2020-2028. [https://www.gastrojournal.org/article/S0016-5085\(05\)00569-X/fulltext](https://www.gastrojournal.org/article/S0016-5085(05)00569-X/fulltext)

Torres, J., Bonovas, S., Doherty, G., Kucharzik, T., Gisbert, J. P., Raine, T., Adamina, M., Armuzzi, A., Bachmann, O., Bager, P., Biancone, L., Bokemeyer, B., Bossuyt, P., Burisch, J., Collins, P., El-Hussuna, A., Ellul, P., Frei-Lanter, C., Furfaro, F., . . . Organisation, C. (2019). ECCO Guidelines on Therapeutics in Crohn's Disease: Medical Treatment. *Journal of Crohn's and Colitis*, *14*(1), 4-22. <https://doi.org/10.1093/ecco-jcc/jjz180>



Turner, D., Ruemmele, F. M., Orlanski-Meyer, E., Griffiths, A. M., de Carpi, J. M., Bronsky, J., Veres, G., Aloï, M., Strisciuglio, C., Braegger, C. P., Assa, A., Romano, C., Hussey, S., Stanton, M., Pakarinen, M., de Ridder, L., Katsanos, K., Croft, N., Navas-López, V., . . . Russell, R. K. (2018). 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. *J Pediatr Gastroenterol Nutr*, 67(2).  
[https://journals.lww.com/jpgn/Fulltext/2018/08000/Management\\_of\\_Paediatric\\_Ulcerative\\_Colitis,\\_Part.24.aspx](https://journals.lww.com/jpgn/Fulltext/2018/08000/Management_of_Paediatric_Ulcerative_Colitis,_Part.24.aspx)

Vasant, D. H., Paine, P. A., Black, C. J., Houghton, L. A., Everitt, H. A., Corsetti, M., Agrawal, A., Aziz, I., Farmer, A. D., Eugenicos, M. P., Moss-Morris, R., Yiannakou, Y., & Ford, A. C. (2021). British Society of Gastroenterology guidelines on the management of irritable bowel syndrome. *Gut*, 70(7), 1214-1240.  
<https://doi.org/10.1136/gutjnl-2021-324598>

Vijayvargiya, P., Busciglio, I., Burton, D., Donato, L., Lueke, A., & Camilleri, M. (2018). Bile Acid Deficiency in a Subgroup of Patients With Irritable Bowel Syndrome With Constipation Based on Biomarkers in Serum and Fecal Samples. *Clin Gastroenterol Hepatol*, 16(4), 522-527.  
<https://doi.org/10.1016/j.cgh.2017.06.039>

Walters, J. R. F., & Patti, S. S. (2010). Managing bile acid diarrhoea. *Therap Adv Gastroenterol*, 3(6), 349-357. <https://doi.org/10.1177/1756283x10377126>

Wang, Z. Z., Shi, K., & Peng, J. (2017). Serologic testing of a panel of five antibodies in inflammatory bowel diseases: Diagnostic value and correlation with disease phenotype. In *Biomed Rep* (Vol. 6, pp. 401-410). <https://doi.org/10.3892/br.2017.860>

### Policy Update History:

7/5/2023	Document updated with literature review. Reimbursement information revised for clarity. References revised.
11/1/2022	New policy