Clinical Policy: Fecal Calprotectin Assay

Reference Number: CP.MP.135 Coding Implications
Last Review Date: 11/17 Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Calprotectin is a calcium binding protein that is excreted in stool in patients with inflammatory bowel disease (IBD) and other gastrointestinal conditions. Fecal calprotectin (FC), used as a noninvasive marker of intestinal inflammation, has been proposed to aid in the diagnosis and as a predictor of relapse in IBD including Crohn's disease (CD) and ulcerative colitis (UC), rather than relying solely on clinical symptoms. The policy provides a statement of medical necessity for FC assay testing.

Policy/Criteria
It is the policy of health plans affiliated with Centene Corporation® that the FC assay is **investigational** for both the diagnosis and screening of IBD. Although there are many ongoing studies on FC assays, there is conflicting and inconsistent evidence regarding the optimal calprotectin cutoff level.

Background
Noninvasive diagnose of IBD is difficult because the clinical manifestations of intestinal disorders and colon cancer are relatively non-specific. One of the primary biological functions of calprotectin seems to be inhibition of bacterial growth. It is released by immune system cells that trigger and maintain the inflammation involved in IBD. FC is a biochemical measurement of the protein calprotectin in the stool that is usually measured with an enzyme-linked immunosorbent assay (ELISA). Elevated FC indicates the migration of neutrophils to the intestinal mucosa, which occurs during intestinal inflammation, including inflammation caused by IBD.

Per the existing research, FC assay testing seems to be safe; however, the studies do not provide enough information to support its clinical use. The use of this testing for detection of IBD activity or prediction of relapse requires clearly defined cutoffs for determining which patients have active disease and which patients are predicted to undergo relapse. These cutoffs do not have to be exactly the same since they are used for detection in different patient populations. The issue is that the studies provided cutoffs that were scattered over wide ranges, from 120 to 340 mg/g, and have overestimated the apparent sensitivity and specificity of this test by using its interpretation for several small subpopulations of patients. These studies do not provide reliable evidence of the accuracy of FC versus other available tests due to lack of comparative analysis and failure to agree upon cutoffs for interpreting the FC testing results. Additional peer-reviewed, randomized controlled or comparative studies are needed to define uniform cutoffs for FC testing, as well as to evaluate and compare with other tests that have been used for the management of IBD. [2, 5, 7, 8]

American College of Gastroenterology

There is no mention on this site of fecal calprotectin assay for IBD. [10]

American Gastroenterological Association
The AGA mentions FC in their laboratory criteria to assess inflammatory status for the identification, assessment and initial medical treatment in CD. [12]

Crohn's and Colitis Foundation of America
There is no mention of the fecal calprotectin assay for IBD on the site. [4]

North American Society of Pediatric Gastroenterology, Hepatology, and Nutrition
There is no mention on this site of fecal calprotectin assay for IBD. [11]

National Institute for Health and Care Excellence
Faecal calprotectin testing is recommended by NICE as an option to help doctors distinguish between IBD, such as CD and UC, and non-inflammatory bowel diseases, such as irritable bowel syndrome. Specific criteria must be met. [9]

World Gastroenterology Organization
Calprotectin, a simple, reliable, and readily available test for measuring IBD activity, may be better for UC than CD; the rapid fecal calprotectin tests could be very helpful in developing countries. [3]

Coding Implications
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CPT® Codes	Description
83993	Calprotectin, fecal

HCPCS Codes	Description
N/A	

Related ICD-10-CM Diagnosis Codes

ICD-10-CM Code	Description
K50.90	Crohn's disease, unspecified without complications
K50.911-K50.919	Crohn's disease with complications
K51.00	Ulcerative (chronic) pancolitis without complications

ICD-10-CM Code	Description
K51.011-K51.019	Ulcerative (chronic) pancolitis with complications
K51.20	Ulcerative (chronic) proctitis without complications
K51.211-K51.219	Ulcerative (chronic) proctitis with complications
K51.50	Left sided colitis without complications
K51.511-K51.519	Left sided colitis with complications
K51.80	Other ulcerative colitis without complications
K51.811-K51.819	Other ulcerative colitis with complications
K52.0-K52.2	Other and unspecified noninfective gastroenteritis and colitis
Z13.811	Encounter for screening for lower gastrointestinal disorder

Reviews, Revisions, and Approvals	Date	Approval Date
Policy Adopted from Health Net NMP#205 Fecal Calprotectin Assay	11/16	11/16
References reviewed and updated.	10/17	11/17

References

1. American Gastroenterological Association (AGA). AGA Institute Guidelines for the Identification, Assessment and Initial Medical Treatment in Crohn's Disease
2. Bachiller HMT, Andres Barrio, Salazar F, et al. The utility of faecal calprotectin to predict post-operative recurrence in Crohńs disease. Scand J Gastroenterol. 2016;51(6):720-6. doi: 10.3109/00365521.2015.1130164. Epub 2016 Jan 12.
3. Bernstein C, Eliakim A, Fedail S, et al. Inflammatory Bowel Disease. World Gastroenterology Organisation Global Guidelines. 2012.
4. Crohn's and Colitis Foundation of America. Diagnosing and Managing IBD. 2016.
5. Hayes. Medical Technology Directory. Fecal Calprotectin Assay for Management of Crohn's Disease. October 15, 2013. Updated September 6, 2016.
6. Hayes. Medical Technology Directory. Fecal Calprotectin Assay for Monitoring Disease Activity in Chrohn Disease. July 7, 2017.
7. Hayes Medical Technology Directory. Fecal Calprotectin Assay for Monitoring Postoperative Recurrence of Chron Disease. June 30, 2017.
8. Higuchi LM, Bousvaros A. Clinical Presentation of Irritable Bowel Disease in Infants, Children and Adolescents. UpToDate. Accessed November 3, 2017.
9. Hukkinen M, Pakarinen MP, Merras-Salmio L, et al. Fecal calprotectin in the prediction of postoperative recurrence of Crohn's disease in children and adolescents. J Pediatr Surg. 2016 Sep;51(9):1467-72. doi: 10.1016/j.jpedsurg.2016.01.017. Epub 2016 Feb 4.
10. Nancey S, Boschetti G, Moussata D, et al. Neopterin is a novel reliable fecal marker as accurate as calprotectin for predicting endoscopic disease activity in patients with inflammatory bowel diseases. *Inflamm Bowel Dis.* 2013;19(5):1043-1052.
11. National Institute for Health and Care Excellence (NICE). Faecal calprotectin diagnostic tests for inflammatory diseases of the bowel. October 2013. Available at: http://guidance.nice.org.uk/DG11.

12. Practice Parameters Committee of the American College of Gastroenterology. Management of Crohn's Disease in Adults. January 6, 2009. Available at: http://gi.org/guideline/management-of-crohn%E2%80%99s-disease-in-adults
13. Rufo PA, Denson LA, Sylvester FA, et al. Health Supervision in the Management of Children and Adolescents with IBD: North American Society of Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN) Recommendations. 2012.
14. Sandborn WJ. Crohn's Disease Evaluation and Treatment: Clinical Decision Tool. Gastroenterology. 2014;147:702-705.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.
Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.