


**Prior Authorization Review Panel**

**CHC-MCO Policy Submission**

A separate copy of this form must accompany each policy submitted for review.  
Policies submitted without this form will not be considered for review.

<b>Plan: PA Health &amp; Wellness</b>	<b>Submission Date: 1/1/2020</b>
<b>Policy Number: PA.CP.MP. 135</b>	<b>Effective Date: 1/2018</b> <b>Revision Date: 1/2019</b>
<b>Policy Name: Fecal Calprotectin Assay</b>	<b>HC Approval Date:</b>
<p><b>Type of Submission – Check all that apply:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> <b>New Policy</b></li> <li><input type="checkbox"/> <b>Revised Policy*</b></li> <li><input checked="" type="checkbox"/> <b>Retiring Policy</b> – <i>This option indicates the retirement of an active policy. If there is no indicated replacement, then “NONE” will be listed as the New/Replacement Policy.</i></li> <li><input type="checkbox"/> <b>Annual Review – No Revisions</b></li> <li><input type="checkbox"/> <b>Statewide PDL</b> - <i>Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.</i></li> </ul>	
<p><b>*All revisions to the policy <u>must</u> be highlighted using track changes throughout the document.</b></p> <p><b>Please provide any changes or clarifying information for the policy below:</b></p> <p><b>This policy is being retired</b></p>	
<p><b>Name of Authorized Individual (Please type or print):</b></p> <p>Carla Huitt, MD MPH</p>	<p><b>Signature of Authorized Individual:</b></p> 

## Clinical Policy: Fecal Calprotectin Assay

Reference Number: PA/CP.MP.135

Last Review Date: 09/18

Effective Date: 09/18

Retirement Effective Date: 1/1/20

[Coding Implications](#)  
[Revision Log](#)

### 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 PA Health & Wellness (PHW)<sup>®</sup> 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. <sup>2, 5, 7, 8</sup>

*American College of Gastroenterology*

There is no mention on this site of fecal calprotectin assay for IBD. <sup>10</sup>

*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. <sup>12</sup>

*Crohn's and Colitis Foundation of America*

There is no mention of the fecal calprotectin assay for IBD on the site. <sup>4</sup>

*North American Society of Pediatric Gastroenterology, Hepatology, and Nutrition*

There is no mention on this site of fecal calprotectin assay for IBD. <sup>11</sup>

*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. <sup>9</sup>

*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. <sup>3</sup>

**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 Developed	09/18	10/18
Policy Retired	01/20	

### 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 Crohn's 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 Crohn 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.