EFFECTIVE DATE: 04|01|2020
POLICY LAST UPDATED: 02|03|2021

OVERVIEW
Fecal calprotectin is a calcium and zinc-binding protein that is a potential marker of intestinal inflammation. Fecal calprotectin testing is proposed as a noninvasive test to diagnose inflammatory bowel disease (IBD). Other potential uses are to evaluate response to treatment for patients with IBD and as a marker of relapse.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Medicare Advantage Plans
Fecal calprotectin testing is considered medically necessary for the evaluation of patients when the differential diagnosis is inflammatory bowel disease or noninflammatory bowel disease (including irritable bowel syndrome) for whom endoscopy with biopsy is being considered.

Fecal calprotectin testing is considered not covered in the management of inflammatory bowel disease, including the management of active inflammatory bowel disease and surveillance for relapse of disease in remission as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products
Fecal calprotectin testing is considered medically necessary for the evaluation of patients when the differential diagnosis is inflammatory bowel disease or noninflammatory bowel disease (including irritable bowel syndrome) for whom endoscopy with biopsy is being considered.

Fecal calprotectin testing is considered not medically necessary in the management of inflammatory bowel disease, including the management of active inflammatory bowel disease and surveillance for relapse of disease in remission as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE
Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable laboratory not medically necessary/not covered benefits/coverage.

BACKGROUND
Calprotectin is a calcium- and zinc-binding protein that is a potential marker of intestinal inflammation. Fecal calprotectin testing is proposed as a noninvasive means to diagnose inflammatory bowel disease (IBD). Other potential uses are to evaluate treatment response for patients with IBD and as a marker of relapse.

For individuals who have a suspicion of IBD when endoscopy with biopsy is being considered who receive fecal calprotectin testing to select patients who can forgo endoscopy, the evidence includes prospective and retrospective diagnostic accuracy studies and systematic reviews. Rrelevant outcomes are test validity, symptoms, change in disease status, quality of life, hospitalizations, and medication use. Twenty-eight studies in a systematic review evaluated the diagnostic accuracy of fecal calprotectin in patients suspected of having IBD for whom noninflammatory bowel disease, such as irritable bowel syndrome, remains a consideration. Studies varied in the fecal calprotectin protein level cutoff used to indicate the presence of disease but most used a cutoff of 50 µg/g, which is the recommended lower bound. Studies have indicated that, at this threshold, the test has a sensitivity of 93% to 99% for IBD and a negative predictive value of 73% to 100% for intestinal inflammation. Out of 100 cases of suspected IBD, approximately 49 invasive tests would be avoided with 1 case missed. Therefore, fecal calprotectin can be used to inform a decision of whether to proceed with endoscopy. Clinical input supported that the use of fecal calprotectin testing for individuals with suspected IBD provides a clinically meaningful improvement in net health outcome by providing clinically valid and clinically useful information to guide the clinical decision-making. Specifically, fecal calprotectin testing can inform the decision by using a positive fecal calprotectin result to refer for endoscopy with biopsy or to use a negative fecal calprotectin results to exclude inflammatory bowel disease and avoid endoscopy with biopsy with acceptably low tradeoffs in missed diagnoses of IBD in those who have false negative FCP results. Input further highlighted that the use of fecal calprotectin is particularly important in pediatric populations, where children may not be able to fully participate as medical historians and may have non-specific and/or atypical symptoms. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have active IBD who receive fecal calprotectin testing to monitor disease activity, the evidence includes prospective and retrospective diagnostic studies, systematic reviews, and a randomized controlled trial (RCT). Relevant outcomes are test validity, symptoms, change in disease status, quality of life, hospitalizations, and medication use. RCTs are needed to determine whether guiding treatment based on fecal calprotectin levels can improve disease management. A 2017 RCT included fecal calprotectin as one of several indicators of inflammation to test the effect of tight control of IBD on health outcomes. The independent contribution of fecal calprotectin could not be determined from this study design. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have IBD in remission who receive fecal calprotectin testing to predict relapse, the evidence includes prospective and retrospective diagnostic studies, systematic reviews, and an RCT. Relevant outcomes are test validity, symptoms, change in disease status, quality of life, hospitalizations, and medication use. One RCT found no significant difference in the rate of relapse in patients whose medication was modified based on fecal calprotectin or standard clinical indicators, however, this RCT had design and conduct limitations that affected the interpretation of its results. Further study in high-quality RCTs is needed to determine whether adding fecal calprotectin to standard clinical practice improves the management of IBD patients in remission. The evidence is insufficient to determine the effects of the technology on health outcomes.

CODING

Medicare Advantage Plans and Commercial Products

The following HCPCS codes are considered medically necessary when filed with the ICD-10 diagnosis codes listed below.

83993 Calprotectin, fecal

ICD-10 Diagnosis Codes that may support medical necessity:

K50.00-K50.919
K51.00-K51.019
K51.50-K51.919
K52.3
R19.8

RELATED POLICIES
Not applicable

PUBLISHED
Provider Update, April 2021
Provider Update, April 2020
Provider Update, June 2019
Provider Update, February 2019
Provider Update, June 2017

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