Fecal Calprotectin Testing
Corporate Medical Policy

Description/Summary

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 treatment response for patients with IBD and as a marker of relapse.

For individuals who have suspected IBD who receive fecal calprotectin testing, the evidence includes prospective and retrospective diagnostic accuracy studies and systematic reviews. Relevant outcomes are test accuracy and validity, symptoms, change in disease status, quality of life, hospitalizations, and medication use. There is a large body of evidence evaluating the diagnostic accuracy of fecal calprotectin in patients considered to have IBD, and for whom irritable bowel syndrome is a consideration. In general, these studies have indicated that the commercially available test has very high sensitivity for IBD. Studies have varied in the cutoff of fecal calprotectin used to indicate the presence of disease, but most have used a cutoff of 50 μg/g. However, there is relatively little data on the use of calprotectin in the general population and potential for spectrum effect; given the possibility of more widespread use in practice, additional clinical validity data in the target population would be indicated. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have diagnosed IBD who receive fecal calprotectin testing for disease activity assessment or relapse prediction, the evidence includes prospective and retrospective diagnostic studies, meta-analyses, and a randomized controlled trial. Relevant outcomes are test accuracy and validity, symptoms, change in disease status, quality of life, hospitalizations, and medication use. The diagnostic accuracy for fecal calprotectin for these indications is uncertain, as are the patient management changes associated with specific calprotectin levels. The evidence is insufficient to determine the effects of the technology on health outcomes.
Policy

Coding Information
Click the links below for attachments, coding tables & instructions.
Attachment I - Procedural Coding Table & Instructions

When a service may be considered medically necessary

Fecal calprotectin testing may be considered medically necessary for adult members who meet ALL of the following criteria:

- diagnosed with inflammatory bowel disease (Crohn’s disease or Ulcerative colitis) AND
- has a flare of symptoms such as diarrhea, to differentiate exacerbation of inflammatory bowel disease from other etiologies.

Fecal calprotectin testing may be considered medically necessary for pediatric members for ANY of the following indications:

- as an adjunctive non-invasive test for confirming a diagnosis of inflammatory bowel disease and in determining if an endoscopy may be needed OR
- to obtain a baseline value at the time of diagnosis of inflammatory bowel disease (Crohn’s disease or Ulcerative colitis) OR
- if a pediatric patient is diagnosed with inflammatory bowel disease AND has a flare of symptoms such as diarrhea, to differentiate exacerbation of inflammatory bowel disease from other etiologies.

When a service may be considered investigational

Fecal calprotectin testing is considered investigative in all other situations.

SUMMARY OF EVIDENCE

For individuals who have suspected IBD who receive fecal calprotectin testing, the evidence includes prospective and retrospective diagnostic accuracy studies and systematic reviews. Relevant outcomes are test accuracy and validity, symptoms, change in disease status, quality of life, hospitalizations, and medication use. There is a large body of evidence evaluating the diagnostic accuracy of fecal calprotectin in patients considered to have IBD, and for whom irritable bowel syndrome is a consideration. In general, these studies have indicated that the commercially available test has very high sensitivity for IBD. Studies have varied in the cutoff of fecal calprotectin used to indicate the presence of disease, but most have used a cutoff of 50 μg/g. However, there is relatively little data on the use of calprotectin in the general population and potential for spectrum effect; given the possibility of more widespread use in practice, additional clinical validity data in the target population would be indicated. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have diagnosed IBD who receive fecal calprotectin testing for disease activity assessment or relapse prediction, the evidence includes prospective and retrospective diagnostic studies, meta-analyses, and a randomized controlled trial. Relevant outcomes are
test accuracy and validity, symptoms, change in disease status, quality of life, hospitalizations, and medication use. The diagnostic accuracy for fecal calprotectin for these indications is uncertain, as are the patient management changes associated with specific calprotectin levels. The evidence is insufficient to determine the effects of the technology on health outcomes.

For pediatric individuals, several studies have found that calprotectin is significantly more likely to be raised than any commonly employed blood tests at IBD diagnosis. When used in combination with these bloods tests an abnormality was demonstrated in 1 or both tests in all patients at diagnosis in this study. Fecal calprotectin measurement may be an advance when used contemporaneously and in addition to a routine pane of blood tests in the diagnosis of pediatric IBD.

Reference Resources


Document Precedence

Blue Cross and Blue Shield of Vermont (BCBSVT) Medical Policies are developed to provide clinical guidance and are based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. The applicable group/individual contract and member certificate language, or employer’s benefit plan if an ASO group, determines benefits that are in effect at the time of service. Since medical practices and knowledge are constantly evolving, BCBSVT reserves the right to review and revise its medical policies periodically. To the extent that there may be any conflict between medical policy and contract/employer benefit plan language, the member’s contract/employer benefit plan language takes precedence.

Audit Information

BCBSVT reserves the right to conduct audits on any provider and/or facility to ensure compliance with the guidelines stated in the medical policy. If an audit identifies instances of non-compliance with this medical policy, BCBSVT reserves the right to recoup all non-compliant payments.
Administrative and Contractual Guidance

Benefit Determination Guidance

Prior approval is required and benefits are subject to all terms, limitations and conditions of the subscriber contract.

Incomplete authorization requests may result in a delay of decision pending submission of missing information. To be considered complete, see policy guidelines above.

NEHP/ABNE members may have different benefits for services listed in this policy. To confirm benefits, please contact the customer service department at the member’s health plan.

Federal Employee Program (FEP): Members may have different benefits that apply. For further information please contact FEP customer service or refer to the FEP Service Benefit Plan Brochure. It is important to verify the member’s benefits prior to providing the service to determine if benefits are available or if there is a specific exclusion in the member’s benefit.

Coverage varies according to the member’s group or individual contract. Not all groups are required to follow the Vermont legislative mandates. Member Contract language takes precedence over medical policy when there is a conflict.

If the member receives benefits through an Administrative Services Only (ASO) group, benefits may vary or not apply. To verify benefit information, please refer to the member’s employer benefit plan documents or contact the customer service department. Language in the employer benefit plan documents takes precedence over medical policy when there is a conflict.

Policy Implementation/Update information

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<thead>
<tr>
<th>Date</th>
<th>Information</th>
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Eligible providers

Qualified healthcare professionals practicing within the scope of their license(s).

Approved by BCBSVT Medical Directors

Joshua Plavin, MD, MPH, MBA
Chief Medical Officer

Kate McIntosh, MD, FAAP
Senior Medical Direct
## Attachment I

Procedural Coding Table & instructions

<table>
<thead>
<tr>
<th>Code Type</th>
<th>Number</th>
<th>Brief Description</th>
<th>Policy Instructions</th>
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<tbody>
<tr>
<td>CPT®</td>
<td>83993</td>
<td>Calprotectin, fecal</td>
<td>Prior Approval Required</td>
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The following code will be considered when applicable criteria have been met.