Fecal Analysis in the Diagnosis of Intestinal Dysbiosis

**Description of Procedure or Service**

Intestinal dysbiosis may be defined as a state of disordered microbial ecology that is believed to cause disease, including conditions such as irritable bowel syndrome and malabsorption. Laboratory analysis of fecal samples is proposed as a method of identifying individuals with intestinal dysbiosis and other gastrointestinal disorders.

The gastrointestinal tract is colonized by a large number and variety of microorganisms including bacteria, fungi, and archaea. The concept of intestinal dysbiosis rests on the assumption that abnormal patterns of intestinal flora, such as overgrowth of some commonly found microorganisms, have an impact on human health. Symptoms and conditions attributed to intestinal dysbiosis include chronic disorders such as irritable bowel syndrome, inflammatory or autoimmune disorders, food allergy, atopic eczema, unexplained fatigue, arthritis, and ankylosing spondylitis, malnutrition, or neuropsychiatric symptoms including autism, and breast and colon cancer.

Laboratory analysis of both stool and urine has been investigated as markers of dysbiosis. Reference laboratories specializing in the evaluation of dysbiosis may offer comprehensive testing of various aspects of digestion, absorption, microbiology, and metabolic markers. For example, Genova Diagnostics offers a “Comprehensive Digestive Stool Analysis 2.0” that evaluates a stool sample for the following components:

**Digestion**
- Triglycerides
- Chymotrypsin
- Iso-butyrate, iso-valerate, and n-valerate
- Meat and vegetable fibers

**Absorption**
- Long chain fatty acids
- Cholesterol
- Total fecal fat
- Total short chain fatty acids

**Microbiology**
- Levels of Lactobacilli, bifidobacteria, and *E. coli* and other “potential pathogens,” including *Aeromonas, Bacillus cereus, Campylobacter, Citrobacter, Klebsiella, Proteus, Pseudomonas, Salmonella, Shigella, Staphylococcus aureus, Vibrio*.
- Identification and quantitation of fecal yeast (including *Candida albicans, C. tropicalis, Rhodotorula*, and *Geotrichum*).

**Metabolic Markers**
- N-butyrate (considered key energy source for colonic epithelial cells)
- Beta-glucuronidase
- pH
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- Short chain fatty acid distribution (adequate amount and proportions of the different short chain fatty acids reflect the basic status of intestinal metabolism)

**Immunology**

- Fecal secretory IgA (as a measure of luminal immunologic function)
- Calprotectin

The comprehensive stool analysis package has an optional parasitology component.

The use of fecal calprotectin as a stand-alone test in the evaluation of patients with inflammatory bowel disease (IBD), including to identify patients for endoscopy, is not within the scope of this policy. Fecal calprotectin testing is addressed in the Medical Policy entitled Fecal Calprotectin Test.

A related topic, fecal microbiota transplantation (FMT), the infusion of intestinal microorganisms to restore normal intestinal flora is addressed in the Medical Policy entitled Fecal Microbiota Transplantation. FMT has been rigorously studied for the treatment of patients with recurrent *Clostridium difficile* infection (CDI). No specific stool testing, other than the identification of CDI, is currently recommended.

**Regulatory Status**

Clinical laboratories may develop and validate tests in-house and market them as a laboratory service; laboratory-developed tests (LDTs) must meet the general regulatory standards of the Clinical Laboratory Improvement Amendments (CLIA). The Genova Diagnostics test is available under the auspices of CLIA. To date, the U.S. Food and Drug Administration has chosen not to require any regulatory review of this test.

**Related Policies**

- Fecal Calprotectin
- Fecal Microbiota Transplantation

***Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

**Policy**

Fecal Analysis in the Diagnosis of Intestinal Dysbiosis is considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.

**Benefits Application**

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

**When Fecal Analysis in the Diagnosis of Intestinal Dysbiosis is covered**

Not applicable.

**When Fecal Analysis in the Diagnosis of Intestinal Dysbiosis is not covered**

Fecal analysis of the following components is considered investigational as a diagnostic test for the evaluation of intestinal dysbiosis, irritable bowel syndrome, malabsorption, or small intestinal overgrowth of bacteria:

1) Triglycerides;
2) Chymotrypsin;
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3) Iso-butyrate, iso-valerate and n-valerate;
4) Meat and vegetable fibers;
5) Long chain fatty acids;
6) Cholesterol;
7) Total short chain fatty acids;
8) Levels of Lactobacilli, bifidobacteria and E. coli and other "potential pathogens," including Aeromonas, Bacillus cereus, Campylobacter, Citrobacter, Klebsiella, Proteus, Pseudomonas, Salmonella, Shigella, S. aureus, Vibrio;
9) Identification and quantitation of fecal yeast (including C. albicans, C. tropicalis, Rhodotorula and Geotrichum);
10) N-butyrate;
11) Beta-glucuronidase;
12) pH;
13) Short chain fatty acid distribution (adequate amount and proportions of the different short chain fatty acids reflect the basic status of intestinal metabolism);
14) Fecal secretory IgA.

Policy Guidelines

The evidence for fecal analysis in patients who have suspected intestinal dysbiosis, irritable bowel syndrome, malabsorption, or small intestinal overgrowth of bacteria includes several cohort and case control studies comparing fecal microbiota in patients with a known disease and healthy controls. Relevant outcomes are test accuracy and validity, symptoms, and functional outcomes. The available retrospective cohort studies on fecal analysis have suggested that some components of fecal microbiome and inflammatory markers may differ across patients with IBS subtypes. No studies were identified on the diagnostic accuracy of fecal analysis versus another diagnostic approach or compared health outcomes in patients managed with and without fecal analysis tests. No studies were identified that directly informed on the use of fecal analysis in the evaluation of intestinal dysbiosis, malabsorption, or small intestinal bacterial overgrowth. The evidence is insufficient to determine the effects of the technology on health outcomes.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

**Applicable service codes: no specific code**

_The following CPT codes may be used to identify individual components of fecal analysis of intestinal dysbiosis: 82239, 82656, 82710, 82715, 82725, 83520, 83630, 83986, 83993, 84311, 87102, 87328, 87329, 87336, 89160_

_Fecal analysis may also include other standard components such as stool culture, stool parasitology and fecal occult blood (87045-87046, 87075, 87177, 87209, 82272-82274)._  

_For a qualitative column chromatography procedure, use the appropriate specific analyte code, if available, or 82542._

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.
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Scientific Background and Reference Sources

- Specialty Matched Consultant Advisory Panel review 5/2015
- Medical Director review 5/2016.
- Medical Director review 12/2016
- Specialty Matched Consultant Advisory Panel review 5/2017
- Medical Director review 5/2017

Policy Implementation/Update Information

- 4/04 Benefits Application and Billing/Coding sections updated for consistency.
- 5/22/06 Specialty Matched Consultant Advisory Panel review 4/20/2006. Added additional information to "When Not Covered" section; Listed specific names of pathogens to #8 and "Results can be reported individually or by combining the results of the gut microbiology, pH, and short chain fatty acids to form a
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"dysbiosis risk index." Note: Intestinal dysbiosis may also be considered a manifestation of idiopathic environmental intolerance (i.e. clinical ecology).” Rationale added to “Policy Guidelines” section. References added.

6/16/08 Specialty Matched Consultant Advisory Panel review 4/30/08. No changes to policy statement. Updated rationale in "Policy Guidelines" section. References added. (btw)

6/22/10 Policy Number(s) removed (amw)

11/23/10 Description section extensively revised. No change in policy statement. Specialty Matched Consultant Advisory Panel review 10/28/10, policy accepted as written. (adn)

5/10/11 Deleted the following statement from the Not Covered section: Results can be reported individually or by combining the results of the gut microbiology, pH, and short chain fatty acids to form a “dysbiosis risk index.” Updated the Policy Guidelines section. The following CPT codes were added to the Billing/Coding section: 82239, 82492, 82656, 83520, 83530, 83993, 87328, 87329, 87336, 87075, 87209. The following CPT codes were deleted from the Billing/Coding section: 82491, 86403. Specialty Matched Consultant Advisory Panel review 4/27/11. (adn)

5/1/12 Summary statement added to Policy Guidelines. No change to policy intent. Specialty Matched Consultant Advisory Panel review 4/18/12. (sk)


4/15/14 Reference added. No change to Guideline statement. (sk)


3/31/15 References updated. Policy Statement unchanged. (td)


12/30/15 Billing/Coding section updated to delete code: 82492. (td)

4/1/16 Description section updated. Policy Guidelines section revised. References updated. (td)


1/27/17 Minor revisions to the Description section and Policy Guidelines. References updated. Medical Director review 12/2016. (jd)

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.