

Corporate Medical Policy

Fecal Analysis in the Diagnosis of Intestinal Dysbiosis

File Name:	Fecal_analysis_for_intestinal_dysbiosis
Origination:	5/2001
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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.

The concept of dysbiosis rests on the assumption that patterns of intestinal flora, specifically overgrowth of some microorganisms found commonly in intestinal flora, have an impact on human health.

Symptoms and conditions attributed to dysbiosis include chronic intestinal disorders including irritable bowel syndrome (IBS), 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. Leo Galland, MD, a researcher who has focused his studies on dysbiosis, has proposed four patterns of dysbiosis:

- Putrefaction

Putrefaction dysbiosis results from diet high in fat and animal flesh and low in insoluble fiber, i.e., typical of Western-style diet. It is thought that, compared to normal patterns of intestinal flora, this diet produces an increased concentration of *Bacteriodes* sp., and a decreased concentration of bifidiobacteria in stools. The increased concentration of *Bacteriodes* sp. is thought to be associated with increased urease, ultimately leading to a rising fecal pH. *Bacteriodes* sp. is also thought to be associated with increased beta-glucuronidase, which functions to deconjugate bile acids, which are thought to be toxic to the colonic epithelium, causing diarrhea. Increased levels of beta-glucuronidase may also have an impact on estrogen metabolism.

- Fermentation

A fermentation pattern of dysbiosis has been attributed to bacterial overgrowth. In mild cases, fermentation may be characterized principally by carbohydrate intolerance, manifested by abdominal distention, flatulence, diarrhea, constipation, and feelings of malaise.

- Deficiency

Antibiotic therapy or decrease in dietary fiber may result in relative deficiencies of normal fecal flora, including bifidiobacteria, lactobacillus, and *Escherichia coli*.

- Sensitization

A sensitization pattern of dysbiosis has been characterized as an abnormal immune response to the endotoxins and antigens associated with normal intestinal flora.

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:

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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 *Geotrichem*)

Metabolic Markers

- N-butyrate (considered key energy source for colonic epithelial cells)
- Beta-glucuronidase
- pH
- 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 policy entitled Fecal Calprotectin Test.

Regulatory Status

Genova Diagnostics is an accredited medical laboratory, certified by 6 separate health agencies, including the Centers for Medicare & Medicaid Services, which oversees clinical labs in the United States under the federal Clinical Laboratory Improvement Amendment (CLIA).

*****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. BCBSNC does not provide coverage for investigational services and 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.

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When fecal analysis for intestinal dysbiosis is covered

Not applicable.

When fecal analysis for 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;
- 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.

Note: Intestinal dysbiosis may also be considered a manifestation of idiopathic environmental intolerance (i.e. clinical ecology).

Policy Guidelines

Laboratory analysis of fecal samples is proposed as a method of identifying individuals with intestinal dysbiosis (defined as a state of disordered microbial ecology). There is insufficient evidence that fecal analysis to identify intestinal dysbiosis improves the net health outcome in patients with gastrointestinal tract symptoms. Moreover, there is insufficient evidence that fecal analysis aids in the diagnosis or management of patients with irritable bowel syndrome, malabsorption, or small intestine bacterial overgrowth.

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

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The following CPT codes may be used to identify individual components of fecal analysis of intestinal dysbiosis: 82239, 82492, 82656, 82710, 82715, 82725, 83520, 83530, 83986, 83993, 84311, 87102, 887328, 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).

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.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual, 11/20/2001; 2.04.26.
Specialty Matched Consultant Advisory Panel, 6/2002
BCBSA Medical Policy Reference Manual [Electronic Version]. 2.04.26, 7/17/2003.
Specialty Matched Consultant Advisory Panel - 5/2004
BCBSA Medical Policy Reference Manual [Electronic Version]. 2.04.26, 8/17/2005.
Specialty Matched Consultant Advisory Panel - 4/2006
BCBSA Medical Policy Reference Manual [Electronic Version]. 2.04.26, 4/17/07.
Specialty Matched Consultant Advisory Panel - 4/2008
BCBSA Medical Policy Reference Manual [Electronic Version]. 2.04.26, 2/11/2010
BCBSA Medical Policy Reference Manual [Electronic Version]. 2.04.26, 2/9/2012
Specialty Matched Consultant Advisory Panel - 4/18/12

Policy Implementation/Update Information

5/2002	Original policy issued.
6/2002	Specialty Matched Consultant Advisory Panel. No changes. Approve.
4/04	Benefits Application and Billing/Coding sections updated for consistency.
6/10/04	Specialty Matched Consultant Advisory Panel review. No change to criteria. References added. Notification given 6/10/2004. Effective date 8/12/2004.
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 "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)

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- 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)

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.