MASSACHUSETTS

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Medical Policy

Fecal Analysis in the Diagnosis of Intestinal Dysbiosis

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Policy Number: 556

BCBSA Reference Number: 2.04.26
NCD/LCD: NA

Related Policies

- Diagnosis and Management of Idiopathic Environmental Intolerance (i.e., Clinical Ecology), #264
- Fecal Calprotectin, #329
- Fecal Microbiota Transplantation, #682

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue℠ and Medicare PPO Blue℠ Members

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

- Triglycerides
- Chymotrypsin
- Iso-butyrate, iso-valerate, and n-valerate
- Meat and vegetable fibers
- Long-chain fatty acids
- Cholesterol
- Total short-chain fatty acids
- 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*
- Identification and quantitation of fecal yeast (including *C. albicans, C. tropicalis, Rhodotorula, and Geotrichum)*
- N-butyrate
- Beta-glucoronidase
- pH
- Short--chain fatty acid distribution (adequate amount and proportions of the different short-chain fatty acids reflect the basic status of intestinal metabolism)

- Fecal secretory IgA.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	This is **not** a covered service.
Commercial PPO and Indemnity	This is **not** a covered service.
Medicare HMO Blue℠	This is **not** a covered service.
Medicare PPO Blue℠	This is **not** a covered service.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes

There is no specific CPT code for this service.

ICD-9 Diagnosis Codes

Investigational for all diagnoses

Description

Intestinal Dysbiosis

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 in addition to gastrointestinal disorders include chronic disorders (eg, irritable bowel syndrome, inflammatory or autoimmune disorders, food allergy, atopic eczema, unexplained fatigue, arthritis, ankylosing spondylitis), malnutrition, or neuropsychiatric symptoms or neurodevelopmental conditions (eg, autism), and breast and colon cancer.

The gastrointestinal tract symptoms attributed to intestinal dysbiosis (ie, bloating, flatulence, diarrhea, constipation) overlap in part with either irritable bowel syndrome or small intestinal bacterial overgrowth syndrome. The diagnosis of irritable bowel syndrome is typically made clinically, based on a set of criteria referred to as the Rome criteria. The small intestine normally contains a limited number of bacteria, at least as compared with the large intestine. Small intestine bacterial overgrowth may occur due to altered motility (including blind loops), decreased acidity, exposure to antibiotics, or surgical resection of the small bowel. Symptoms include malabsorption, diarrhea, fatigue, and lethargy. The laboratory criterion standard for diagnosis consists of the culture of a jejunal fluid sample, but this requires invasive testing. Hydrogen breath tests, commonly used to evaluate lactose intolerance, have been adapted for use in diagnosing small intestinal bacterial overgrowth.

Fecal Markers of Dysbiosis

Laboratory analysis of both stool and urine has been investigated as markers of dysbiosis. Commercial laboratories may offer testing for comprehensive panels or individual components of various aspects of digestion, absorption, microbiology, and metabolic markers. Representative components of fecal dysbiosis testing are summarized in Table 1.

Table 1. Components of the Fecal Dysbiosis Marker Analysis

Markers	Analytes
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 *Escherichia coli* and other "potential pathogens," *including Aeromonas, Bacillus cereus, Campylobacter, Citrobacter, Klebsiella, Proteus, Pseudomonas, Salmonella, Shigella, Staphylococcus aureus,* and *Vibrio*
	• Identification and quantitation of fecal yeast (including *Candida albicans*, *Candida tropicalis*, *Rhodotorula*, and *Geotrichum*) (optional viral and/or parasitology components)
Metabolic	• *N*-butyrate (considered key energy source for colonic epithelial cells)
	• β-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 immunoglobulin A (as a measure of luminal immunologic function)

	• Calprotectin

Fecal calprotectin as a stand-alone test is addressed in policy #329

A related topic, fecal microbiota transplantation, the infusion of intestinal microorganisms to restore normal intestinal flora, is addressed in policy #682. Fecal microbiota transplantation has been rigorously studied for the treatment of patients with recurrent *Clostridium difficile* infection.

Summary

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

For individuals who have gastrointestinal conditions such as suspected intestinal dysbiosis, irritable bowel syndrome, malabsorption, or small intestinal bacterial overgrowth who receive fecal analysis testing, the evidence includes several cohort and case-control studies comparing fecal microbiota in patients who had a known disease with healthy controls. The relevant outcomes are test validity, symptoms, and functional outcomes. The available retrospective cohort studies on fecal analysis have suggested that some components of the fecal microbiome and inflammatory markers may differ across patients with irritable bowel syndrome subtypes. No studies were identified on the diagnostic accuracy of fecal analysis vs another diagnostic approach or that compared health outcomes in patients managed with and without fecal analysis tests. No studies were identified that directly informed 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.

Policy History

Date	Action
2/2019	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
1/2017	New references added from BCBSA National medical policy.
3/2015	New references added from BCBSA National medical policy.
5/2014	New references from BCBSA National medical policy.
4/2013	New references from BCBSA National medical policy.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
10/2011	Reviewed - Medical Policy Group - GI, Nutrition and Organ Transplantation. No changes to policy statements.
5/2011	New policy effective 5/2011 describing ongoing non-coverage.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References

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2. Genova Diagnostics. Comprehensive Digestive Stool Analysis (CDSA)™. 2018; https://www.gdx.net/product/comprehensive-digestive-stool-analysis-cdsa. Accessed November 26, 2018.

3. Goepp J, Fowler E, McBride T, et al. Frequency of abnormal fecal biomarkers in irritable bowel syndrome. *Glob Adv Health Med.* May 2014;3(3):9-15. PMID 24891989
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5. Sobhani I, Tap J, Roudot-Thoraval F, et al. Microbial dysbiosis in colorectal cancer (CRC) patients. *PLoS One.* Jan 27 2011;6(1):e16393. PMID 21297998
6. Joossens M, Huys G, Cnockaert M, et al. Dysbiosis of the faecal microbiota in patients with Crohn's disease and their unaffected relatives. *Gut.* May 2011;60(5):631-637. PMID 21209126
7. Langhorst J, Elsenbruch S, Koelzer J, et al. Noninvasive markers in the assessment of intestinal inflammation in inflammatory bowel diseases: performance of fecal lactoferrin, calprotectin, and PMN-elastase, CRP, and clinical indices. *Am J Gastroenterol.* Jan 2008;103(1):162-169. PMID 17916108