The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Preauthorization is not required but is recommended if, despite this Protocol position, you feel this service is medically necessary. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

Description

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 (IBS) and malabsorption. Laboratory analysis of fecal samples is proposed as a method of identifying individuals with intestinal dysbiosis.

Background

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 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 a diet high in fat and animal flesh and low in insoluble fiber, i.e., typical of a Western-style diet. It is thought that, compared with normal patterns of intestinal flora, this diet produces an increased concentration of *Bacteroides* sp. and a decreased concentration of bifidobacteria in stools. The increased concentration of *Bacteroides* sp. is thought to be associated with increased urease, ultimately leading to a rising fecal pH. *Bacteroides* 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 principally characterized 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 bifidobacteria, 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 (1) 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*, and *Vibrio.*
- Identification and quantitation of fecal yeast (including *Candida albicans, Candida tropicalis, Rhodotorula*, and *Geotrichum*)

**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 IBD, including to identify patients for endoscopy, is not within the scope of this Protocol.

**Regulatory Status**

Genova Diagnostics is an accredited medical laboratory, certified by six 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.

**Related Protocol**

Diagnosis and Management of Idiopathic Environmental Intolerance (i.e., Multiple Chemical Sensitivities)
Policy (Formerly Corporate Medical Guideline)

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:

- 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, B. cereus, Campylobacter, Citrobacter, Klebsiella, Proteus, Pseudomonas, Salmonella, Shigella, S. aureus, and Vibrio
- Identification and quantitation of fecal yeast (including Candida albicans, Candida tropicalis, Rhodotorula, and Geotrichum)
- N-butyrate
- 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)
- Fecal secretory IgA.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.


