Fecal Analysis in the Diagnosis of Intestinal Dysbiosis

This Protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.

The following Protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. 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.

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individuals:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| With suspected intestinal dysbiosis, irritable bowel syndrome, malabsorption or small intestinal overgrowth of bacteria | Interventions of interest are:  
| Fecal analysis | Comparators of interest are:  
| Standard approach to diagnosing specific conditions | Relevant outcomes include:  
| Test accuracy  
| Test validity  
| Symptoms  
| Functional outcomes |

Description

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.

Summary of Evidence

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. 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. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy

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
- 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)
- Fecal secretory IgA.

**Background**

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\(^1\) 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.

A related topic, fecal microbiota transplantation (FMT), the infusion of intestinal microorganisms to restore normal intestinal flora is addressed in the Fecal Microbiota Transplantation Protocol. FMT has been rigorously studied for the treatment of patients with recurrent Clostridium difficile infection (CDI). Use of the procedure to treat any other condition remains controversial and 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 Act (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 Protocols

Diagnosis and Management of Idiopathic Environmental Intolerance and Intracellular Micronutrient Analysis
Fecal Microbiota Transplantation

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.