05-82000-33

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Reviewed: 02/22/24

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Subject: Fecal Analysis in the Diagnosis of Intestinal Dysbiosis

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

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

Summary and Analysis of Evidence: For patients with gastrointestinal conditions such as suspected intestinal dysbiosis, IBS, 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 available retrospective cohort studies on fecal analysis have suggested that some components of the 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 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 that the technology results in an improvement in the net health outcome.

POSITION STATEMENT:

Fecal analysis of the following components is considered **experimental or investigational** as a diagnostic test for 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 Escherichia 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, Candida tropicalis, Rhodoptorula, 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 immunoglobulin A (IgA).

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

BILLING/CODING INFORMATION:

There are no specific CPT or HCPCS codes to report fecal analysis of intestinal dysbiosis.

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline reviewed date

DEFINITIONS:

No guideline specific definitions apply.

RELATED GUIDELINES:

Fecal Microbiota Transplantation, 02-40000-24

OTHER:

Other names used to report fecal analysis of intestinal dysbiosis:

Note: The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

- Comprehensive Digestive Stool Analysis
- Comprehensive Digestive Sool Analysis/Parasitology™
- Complete Digestive Stool Analysis 2.0™
- Fecal Analysis, Intestinal Dysbiosis
- Genova Diagnostics, Comprehensive Digestive Stool Analysis
- Great Smokies Diagnostic Laboratory, Comprehensive Digestive Stool Analysis
- Intestinal Dysbiosis.

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 02/22/24.

GUIDELINE UPDATE INFORMATION:

12/15/03	New Medical Coverage Guideline.
12/15/04	Reviewed; no change in investigational status.
01/01/06	Annual review; no change in investigational status.
11/15/06	Annual review; no change in investigational status.

07/15/07	Annual review, investigational status maintained, guideline reformatted, references updated.
11/15/08	Annual review: position statement maintained, references updated.
09/15/09	Annual review: position statement maintained, description section and references updated.
05/11/14	Revision: Program Exceptions section updated.
03/15/17	Revision; Investigational position statement maintained; description section and references updated.
03/15/19	Review; Position statement maintained; references updated.
03/15/21	Review; Position statement maintained and references updated.
04/15/22	Review: Position statement maintained; references updated.
01/01/24	Position statements maintained.
03/15/24	Review: Position statement maintained; description and references updated.