



BlueCross BlueShield
of Alabama

Name of Blue Advantage Policy:

Fecal Analysis in the Diagnosis of Intestinal Dysbiosis

Policy #: 407

Latest Review Date: December 2020

Category: Laboratory/Pathology

Policy Grade: C

BACKGROUND:

Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
 - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
 - *Furnished in a setting appropriate to the patient's medical needs and condition;*
 - *Ordered and furnished by qualified personnel;*
 - *One that meets, but does not exceed, the patient's medical need; and*
 - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Effective for dates of service on or after April 20, 2010:

Blue Advantage will treat **fecal analysis** of the following components as a **non-covered** benefit and as **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*, *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-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

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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.

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 the below table.

Table. 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) b-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 ^a

Fecal calprotectin as a stand-alone test is addressed separately in Medical Policy #472- Fecal Calprotectin Testing.

A related topic, fecal microbiota transplantation (FMT), the infusion of intestinal microorganisms to restore normal intestinal flora is addressed in Medical Policy #584- Fecal Microbiota Transplantation. FMT has been rigorously studied for the treatment of patients with recurrent Clostridium difficile infection (CDI).

KEY POINTS:

The most recent literature review was updated through November 9, 2020.

Summary of Evidence

For individuals who have gastrointestinal conditions such as suspected intestinal dysbiosis, irritable bowel syndrome (IBS), malabsorption, or small intestinal bacterial overgrowth who receive testing with fecal analysis, the evidence 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. 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 compared health outcomes in patients managed with and without fecal analysis tests. No studies were identified that directly informed on 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.

Practice Guidelines and Position Statements

No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations

Not applicable.

KEY WORDS:

Comprehensive Digestive Stool Analysis 2.0, Fecal Analysis, Intestinal Dysbiosis, Genova Diagnostics, Stool Analysis, comprehensive stool analysis

APPROVED BY GOVERNING BODIES:

Clinical laboratories may develop and validate tests in-house and market them as a laboratory service; laboratory-developed tests must meet the general regulatory standards of the Clinical Laboratory Improvement Amendments. Laboratories that offer laboratory-developed tests must be licensed by the Clinical Laboratory Improvement Amendments for high-complexity testing. To date, the U.S. Food and Drug Administration has chosen not to require any regulatory review of comprehensive testing for fecal dysbiosis.

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes:

The following CPT codes may be used to identify individual components of fecal analysis of intestinal dysbiosis:

82239	Bile acids, total
82542	Column chromatography, includes mass spectrometry, if performed (e.g., HPLC, LC, LC/MS, LC/MS-MS, GC, GC/MS-MS, GC/MS, HPLC/MS, non-drug analyte(s) not elsewhere specified, qualitative or quantitative, each specimen
82656	Elastase, pancreatic (EL1), fecal, qualitative or semi-quantitative
82710	Fat or lipids, feces; quantitative (used to test for fecal triglycerides)
82715	Fat differential, feces, quantitative (used to test for fecal cholesterol)
82725	Fatty acids, nonesterified (used to test for long chain fatty acids)
83520	Immunoassay, for analyte other than infectious agent antibody or infectious agent antigen; quantitative, not otherwise specified (used for eosinophil protein X)
83630	Lactoferrin, fecal; qualitative
83986	pH, body fluid, except blood (used to measure fecal pH)
83993	Calprotectin, fecal
84311	Spectrophotometry, analyte, not elsewhere specified (used twice, once each to test for stool B-glucuronidase and chymotrypsin)
87102	Culture, fungi, isolation, with presumptive identification of isolates: other source (used for fecal culture for fungi)
87328	Infectious agent antigen detection by immunoassay technique, qualitative or semiquantitative, multiple-step method; cryptosporidium
87329	Infectious agent antigen detection by immunoassay technique, qualitative or semiquantitative, multiple-step method; giardia
87336	Infectious agent antigen detection by immunoassay technique, qualitative or semiquantitative, multiple-step method; Entamoeba histolytica dispar group
89160	Meat fibers, feces

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POLICY HISTORY:

Adopted for Blue Advantage, February 2010

Available for comment February 4-April 19, 2010

Medical Policy Panel, February 2010

Medical Policy Group, June 2010

Medical Policy Group, February 2013

Medical Policy Group, February 2014

Medical Policy Group, February 2015

Medical Policy Group, January 2016

Medical Policy Group, December 2016

Medical Policy Group, January 2018

Medical Policy Group, January 2019

Medical Policy Group, December 2019

Medical Policy Group, December 2020

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.