BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 2.04.26 Fecal Analysis in the Diagnosis of Intestinal Dysbiosis

Annual Effective Policy Date: April 1, 2024

Original Policy Date: September 2011

Related Policies:

None

Fecal Analysis in the Diagnosis of Intestinal Dysbiosis

Description

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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.

OBJECTIVE

The objective of this evidence review is to determine whether the use of fecal analysis in the management of a variety of intestinal disorders improves the net health outcome.

POLICY STATEMENT

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 *Escherichiacoli* 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*)
- *N*-butyrate
- 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)
- Fecal secretory immunoglobulin A.

POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

Due to the nonspecific nature of the Current Procedural Terminology (CPT) codes used to identify different components of fecal analysis, identification of these claims may require identification of those laboratories that specialize in the analysis for the evaluation of intestinal dysbiosis. Because there are a limited number of laboratories that provide this type of fecal analysis, these services may be provided by out-of-area providers. Also, a review of these services may be approached through a retrospective review looking for specific patterns of testing.

FDA REGULATORY STATUS

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 (CLIA). Laboratories that offer laboratory-developed tests must be licensed by the CLIA 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.

RATIONALE

Summary of Evidence

For individuals with gastrointestinal conditions such as suspected intestinal dysbiosis, irritable bowel syndrome (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. 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 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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strengths of evidence ratios, and include a description of management of conflict of interest.

American Gastroenterological Association

The American Gastroenterological Association (AGA) published clinical practice guidelines (2019) on laboratory evaluation of functional diarrhea and diarrhea-predominant irritable bowel syndrome (IBS) in adults.[9,] Related to fecal analysis, the AGA suggests the use of fecal calprotectin or fecal lactoferrin to screen for IBS in individuals presenting with chronic diarrhea (conditional recommendation; low-quality evidence).

In 2020, the AGA published a clinical practice update on small intestinal bacterial overgrowth (SIBO).[10,] On the topic of fecal analysis, the guideline states, "there is insufficient evidence to support the use of inflammatory markers, such as fecal calprotectin to detect SIBO." No other fecal markers are explicitly mentioned.

U.S. Preventive Services Task Force Recommendations

No U.S. Preventive Services Task Force (USPSTF) recommendations have been identified.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
September 2011	New policy	
June 2013	Replace policy	Policy updated with literature search, references updated; no change in policy statement.
June 2014	Replace policy	Policy updated with literature review, reference 13 added. No change in policy statement.
June 2015	Replace policy	Policy updated with literature review, adding reference 2. No changes to policy statement.
June 2016	Replace policy	Policy updated with literature review through November 16, 2015; no references added. Policy statement unchanged.
March 2017	Replace policy	Policy updated with literature review; reference 2 added. Policy statement unchanged.
March 2018	Archive policy	Policy updated with literature review through October 25, 2017; no references added. Policy statement unchanged. Policy archived.
March 2020	Reinstate/replace policy	Policy updated with literature review through October 14, 2019; no references added. Policy reactivated. Policy statement unchanged.
March 2021	Replace policy	Policy updated with literature review through November 9, 2020; no references added. Policy statement unchanged.
March 2022	Replace policy	Policy statement unchanged.
March 2023	Replace policy	Policy updated with literature review through October 26, 2022; references added. Policy statements unchanged.
March 2024	Replace policy	Policy updated with literature review through October 24, 2023; no references added. Policy statements unchanged.