

Policy: MP364

Section: Medical Policy

Subject: Fecal Analysis for Diagnosis of Intestinal Dysbiosis

Applicable Lines of Business

Commercial	X	CHIP	X
Medicare	X	ACA	X
Medicaid	X		

I. Policy: Fecal Analysis for Diagnosis of Intestinal Dysbiosis

II. Purpose/Objective:

To provide a policy of coverage regarding: Fecal Analysis for Diagnosis of Intestinal Dysbiosis

III. Responsibility:

- A. Medical Directors
- B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.

- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION: Intestinal dysbiosis is believed to occur when the microorganisms in the digestive tract are out of balance. This condition is hypothesized to cause diseases of the digestive tract, including but not limited to, poor nutrient absorption, intestinal bacteria overgrowth, and irritable bowel syndrome (IBS). Many direct-to-consumer tests are available (e.g., Ombre, Viome, Thorne, Wellnicity, Floré, Biohm, Verisana)

See Also: AHS G2060 Fecal Analysis in the Diagnosis of Intestinal Dysbiosis and Fecal Microbiota Transplant Testing

Fecal analysis by culture or by nucleic acid amplification testing prior to fecal microbiota transplant is considered medically necessary. **(Please see MP290 Fecal Microbiota Transplantation)**

EXCLUSIONS:

Fecal analysis of components such as, but not limited to triglycerides, short and long chain fatty acids, cholesterol, identification and quantitation of fecal yeast, lactobacilli, bifidobacteria, meat and vegetable fibers, and chymotrypsin, etc, as a diagnostic test for the evaluation of intestinal dysbiosis, irritable bowel syndrome, malabsorption, or small intestinal overgrowth of bacteria is considered **Unproven** and therefore **NOT COVERED**. There is insufficient evidence in the published, peer-reviewed medical literature to establish the benefits of this testing at this time.

Direct-to-Consumer microbiome tests including but not limited to, Ombre, Viome, Thorne, Wellnicity, Floré, Biohm, Verisana are considered **unproven** and are therefore **NOT COVERED**.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

Medicaid Business Segment:

Any requests for services that do not meet criteria set in the PARP may be evaluated on a case by case basis.

CODING ASSOCIATED WITH: Fecal Analysis for Diagnosis of Intestinal Dysbiosis

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

0430U Gastroenterology, malabsorption evaluation of alpha-1-antitrypsin, calprotectin, pancreatic elastase and reducing substances, feces, quantitative. { *Malabsorption Evaluation Panel, Mayo Clinic/Mayo Clinic Laboratories* }

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:

Emmanuel A, Landis D, Peucker M, et al. Faecal biomarker patterns in patients with symptoms of irritable bowel syndrome. *Frontline Gastroenterol.* Oct 2016;7(4):275-282.

Goepf J, Fowler E, McBride T, et al. Frequency of abnormal fecal biomarkers in irritable bowel syndrome. *Glob Adv Health Med.* May 2014;3(3):9-15.

Casen, C., Vebo, H. C., Sekelja, M., Hegge, F. T., Karlsson, M. K., Cierniejewska, E, et al. Deviations in human gut microbiota: a novel diagnostic test for determining dysbiosis in patients with IBS or IBD. *Aliment Pharmacol Ther*, 2015;42(1), 71-83

Andoh A, Kuzuoka H, Tsujikawa T, et al. Multicenter analysis of fecal microbiota profiles in Japanese patients with Crohn's disease. *J Gastroenterol*. Dec 2012;47(12):1298-1307.

Guinane, C. M., & Cotter, P. D. Role of the gut microbiota in health and chronic gastrointestinal disease: understanding a hidden metabolic organ. *Therap Adv Gastroenterol*, 2013;6(4), 295-308.

Sobhani I, Tap J, Roudot-Thoraval F, et al. Microbial dysbiosis in colorectal cancer (CRC) patients. *PLoS One*. Jan 27 2011;6(1):e16393.

Joossens M, Huys G, Cnockaert M, et al. Dysbiosis of the faecal microbiota in patients with Crohn's disease and their unaffected relatives. *Gut*. May 2011;60(5):631-637.

Langhorst J, Eisenbruch S, Koelzer J, et al. Noninvasive markers in the assessment of intestinal inflammation in inflammatory bowel diseases: performance of fecal lactoferrin, calprotectin, and PMN elastase, CRP, and clinical indices. *Am J Gastroenterol*. Jan 2008;103(1):162-169.

Lo Presti, A., Zorzi, F., Del Chierico, F, et al. Fecal and Mucosal Microbiota Profiling in Irritable Bowel Syndrome and Inflammatory Bowel Disease. *Front Microbiol*, 2019;10, 1655.

Jeffery IB, Das A, O'Herlihy E, et al. Differences in Fecal Microbiomes and Metabolomes of People With vs Without Irritable Bowel Syndrome and Bile Acid Malabsorption. *Gastroenterology*. Mar 2020; 158(4): 1016-1028.e8

This policy will be revised as necessary and reviewed no less than annually.

Devised: 8/22

Revised:

Reviewed: 8/23, 8/24

CMS UM Oversight Committee Approval: 12/23; 11/8/24

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.