MEDICAL POLICY	Fecal Analysis of Gastrointestinal Microbiome (All Lines of Business Except Medicare)
Effective Date: 1/1/2023  1/1/2023 Medical Officer Date	Medical Policy Number: 1 Medical Policy Committee Approved Date: 7/15; 4/16; 5/17; 6/18; 8/19; 3/2020; 1/2021; 1/2022; 12/2022

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:

All lines of business except Medicare (*unless otherwise directed by a Medicare medical policy. Note that investigational services are considered "**not medically necessary**" for Medicare members.)*

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

POLICY CRITERIA

I. Fecal analysis of the following analytes is considered **not medically necessary and not covered** for all indications, including but not limited to the following:

   A. Beta-glucuronidase;
   B. Cholesterol
   C. Fecal secretory IgA
   D. Total short chain fatty acids
   E. Long chain fatty acids
   F. n-Butyrate Concentration
   G. Commensal bacterial levels (e.g. Lactobacillus, Bifidobacterium, E. coli)
   H. Triglycerides

I. Phospholipids
J. N-Butyrate
K. Chymotrypsin
L. Fecal fats
M. Fecal yeasts
N. Meat fibers
O. Vegetable fibers
P. pH

II. Fecal analysis panels (see Policy Guidelines), including one or more of the analytes in criterion I.A-N above are considered **not medically necessary and not covered** as a diagnostic tool for all indications, including but not limited to:

A. Intestinal dysbiosis
B. Irritable bowel syndrome
C. Malabsorption
D. Small intestinal overgrowth of bacteria (SIBO)

Link to Policy Summary

POLICY GUIDELINES

Examples of fecal analysis panels include:

- GI Effects Comprehensive Stool Profile, by Genova Diagnostics
- Comprehensive Digestive Stool Analysis (CDSA), by Genova Diagnostics
- GA-map Dysbiosis Test by BIOHIT Healthcare

BILLING GUIDELINES

Please bill the most appropriate unlisted code for GI microbiome fecal analysis panels. If any of the following codes are billed individually as part of a GI panel, this is considered unbundling and the claim will deny as incorrect coding:

For Microbiology Fecal Profiles:

87045	87102	87328
87046	87177	87329
87075	87209	

Comprehensive Fecal Profile:

82274	82653	82715
82542	82656	82725

82784	87046	87328
83520	87075	87329
83993	87102	87336
84311	87177	
87045	87209	

CPT/HCPCS CODES

All Lines of Business Except Medicare

Unlisted Codes

All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy, then it will be **denied as not covered.**

81599	Unlisted multianalyte assay with algorithmic analysis
89240	Unlisted miscellaneous pathology test

DESCRIPTION

Gastrointestinal Microbiome

The human gastrointestinal (GI) microbiome comprises of a diverse collective of bacteria, archaea, fungi, protozoa, and viruses that may differ based on age, sex, race/ethnicity, diet, and location of the host.[1] Research has shown that these colonies play vital roles in the health of the host, including energy homeostasis, metabolism, get epithelial health, immunologic activity, and neurobehavioral development.[2] Changes in GI microbiome are associated with diseases such as inflammatory bowel disease, asthma, obesity, metabolic syndrome, cardiovascular disease, immun.-mediated conditions, and neurodevelopmental conditions. Recent interest in the human microbiome have led to research initiatives such as the Human Microbiome Project, funded by the National Institutes of Health. Treatments to correct gut microbiome imbalances are under investigation to prevent and treat a number of associated diseases and syndromes.

Intestinal dysbiosis

Intestinal dysbiosis refers to a microbial imbalance inside the GI tract, leading to conditions such as small intestinal bacterial overgrowth (SIBO), malabsorption, irritable bowel syndrome and fungal overgrowth. It is purported that intestinal dysbiosis and imbalanced microflora are correlated with local and systemic health issues and that treating the gut may help treat a myriad of other GI and non-GI health issues.[3]

Gastrointestinal Fecal Panels

Gastrointestinal (GI) fecal panels are stool tests intended to detect multiple GI microbes and offer diagnoses for microbiome-associated diseases. The panels review microbial targets as well as immune and digestive markers associated with issues in GI function such as maldigestion, inflammation, dysbiosis, metabolite imbalance, and infection. Tests purport the ability to diagnose gut conditions, such as irritable bowel syndrome, metabolic disorders, such as pre-diabetes, and kidney diseases, such as kidney stones.[3] Comprehensive panels include analytes for digestion (e.g. triglycerides, meat and vegetable fibers), absorption (e.g. cholesterol, total fecal fat), microbiology (levels of lactobacilli, E Coli, etc.), immunology (e.g. calprotectin, IgA), and metabolism (e.g. N-butyrate, pH).[4]

REVIEW OF EVIDENCE

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of fecal analysis of gastrointestinal ecology. Below is a summary of the available evidence identified through November of 2022.

Clinical Validity

In 2016, Emmanuel and colleagues published results of a retrospective study relating fecal biomarker results to data from patient-completed questionnaires to determine rates of biomarker results capable of suggesting potentially treatable causes of irritable bowel syndrome (IBS) symptomatology.[5] Rome III criteria for IBS were found in 3553 records in Genova Diagnostics' database. Abnormal biomarker results were present in 94% of cases. The study found significant difference in fecal biomarker patterns occurring by age and IBS phenotype. The retrospective design of this study is a limitation, potentially leading to selection biases. The authors suggest that fecal biomarker testing may be appropriate for patients with IBS to differentiate causes of symptoms.

In 2014, Goepp and colleagues published results of a retrospective study on the frequency of abnormal fecal biomarker results in patients with IBS symptoms.[6] The authors reviewed 2256 records and found that 82.8% had at least one abnormal value. 73.1% of records indicated low growth of beneficial bacteria such as Lactobacillus and Bifidobacterium. Fecal analyses in 14.3% of records showed abnormally elevated eosinophil protein X levels, 12.1% showed elevated calprotectin, and 7.5% showed low pancreatic elastase. Authors concluded that abnormal fecal biomarkers are highly prevalent in patients with IBS symptoms and additional independent clinical trials are needed on fecal biomarker testing.

A number of other retrospective reviews were published on fecal testing for GI symptoms and indications.[7-9] These studies found associations with certain analytes and indications such as Crohn disease and IBS, but all suffered from limitations of retrospective study design and single center/database records.

Clinical Utility

No studies were identified on the diagnostic accuracy of fecal analysis vs 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.

POLICY SUMMARY

There is insufficient evidence in medical literature to support the use of comprehensive GI microbiome screens. The panels represent a non-targeted approach which is not medically necessary based on evidence-based medicine. The comprehensive screens rarely lead to actionable data over targeted testing. Randomized trials on the clinical utility of these panels are needed to determine efficacy of patient-centered outcomes. Therefore, fecal analysis panels of the GI microbiome are considered investigational.

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days' notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

REFERENCES

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