Fecal Analysis of Gastrointestinal Microbiome

MEDICAL POLICY NUMBER: 1

Effective Date: 12/1/2023

Last Review Date: 11/2023

Next Annual Review: 12/2024

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 Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. 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. 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.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PLAN PRODUCT AND BENEFIT APPLICATION

☒ **Commercial** ☒ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP 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.

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

COVERAGE CRITERIA

I. Fecal analysis of the following analytes is considered **not medically necessary** 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** 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 Evidence Summary

POLICY CROSS REFERENCES

None

The full Company portfolio of current Medical Policies is available online and can be accessed here.

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

BACKGROUND

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]

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

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.

EVIDENCE 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 not medically necessary.

BILLING GUIDELINES AND CODING

CPT 82274 should be billed once regardless of the number of specimens required to complete the test. The test should be reported with one date of service reflecting the date the test was completed, even if specimens are collected on different dates.

For Microbiology Fecal Profiles:

- 87045
- 87046
- 87075
- 87102
- 87177
- 87209
- 87328
- 87329

Comprehensive Fecal Profile:

- 82274
- 82542
- 82653
- 82656
- 82715
- 82725
- 82784
- 83520
- 83993
- 84311
- 87045
- 87046

- 87075
- 87102
- 87177
- 87209
- 87328
- 87329
- 87336

CODES*		
CPT	81599	Unlisted multianalyte assay with algorithmic analysis
	89240	Unlisted miscellaneous pathology test

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

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POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.
8/2023	Interim Update. Updated Billing Guideline. No changes to code configuration.
12/2023	Annual update. No changes to criteria.