

Diagnostic Breath Analyses for Gastrointestinal Conditions

Policy Number: PG0356
Last Review: 02/01/2023

HMO AND PPO
ELITE (MEDICARE ADVANTAGE)
MARKETPLACE

GUIDELINES:

- This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder terms, conditions, exclusions, and limitations contract. It does not constitute a contract or guarantee regarding coverage or reimbursement/payment. Self-Insured group specific policy will supersede this general policy when group supplementary plan document or individual plan decision directs otherwise.
- Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.
- This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.

SCOPE:

- Professional
- Facility

DESCRIPTION:

Exhaled breath tests are noninvasive methods designed to measure certain gases and compounds found in exhaled breath and are being used for the diagnosis and management of multiple conditions including but not limited to lactose intolerance, small intestine bacterial overgrowth (SIBO) and to evaluate small bowel transit time/gastroparesis. Gastric emptying breath testing (GEBT) and hydrogen breath testing (HBT) are examples of tests used to diagnose certain gastrointestinal conditions.

GEBT was developed to aid in the diagnosis of gastroparesis (delayed gastric emptying). This condition is characterized by slow or non-movement of food from the stomach to the small intestine due to improper contractions of stomach muscles. Cardinal symptoms include nausea, vomiting, early satiety, bloating, and/or upper abdominal pain. Gastroparesis may result from conditions such as Parkinson's disease, diabetes or following intestinal surgery. Gastric scintigraphy is considered the gold standard for diagnosing gastroparesis.

Irritable bowel syndrome (IBS) is a chronic gastrointestinal (GI) disorder characterized by abdominal pain or discomfort, bloating, excessive flatulence, and disturbed defecation (e.g., diarrhea and/or constipation). Since there are no reliable biological markers for IBS, the diagnosis of IBS is based solely on middle and lower GI tract symptoms and involves the use of a symptom-based diagnostic system.

The cause for IBS is unknown, but proposed causative mechanisms include psychosocial factors and abnormalities in intestinal microflora balance, in GI motility or sensation, or in brain-gut nerve transmission. Symptoms may be exacerbated by stress, hormonal changes, food or mold hypersensitivity, fatty foods, dairy products, chocolate, or caffeinated, carbonated, or alcoholic beverages. Furthermore, IBS shares symptoms with, may be caused by, or may coexist with other GI conditions, including but not limited to small intestinal bacterial overgrowth (SIBO), in which the number of microbes in the small intestine is increased versus normal, and carbohydrate (e.g., lactose, fructose, sucrose, glucose) malabsorption or intolerance, in which the amount of the culprit carbohydrate ingested exceeds the ability of the GI system to digest or absorb it.

Patients with IBS symptoms may undergo tests to identify other conditions that may be responsible for the symptoms. SIBO may be identified by direct aspirate and culture of specimens from the jejunum of the small intestine (jejunal aspirate and culture), which is the reference standard test for SIBO but is invasive and costly.

A carbon dioxide (CO₂) breath test is an alternate test for SIBO. This test involves measuring breath CO₂ before and after ingesting a substrate conjugated with carbon-14 (14C) or carbon-13 (13C). Gut bacteria metabolize or deconjugate the substrate and release CO₂, thereby providing a measure of intestinal bacteria. The sensitivity and specificity of CO₂ breath tests vary widely in the studies in this report (30% to 94% and 14% to 94%, respectively), and 14C poses a radiation risk for children or pregnant women. Standard tests for identifying carbohydrate malabsorption or food insensitivity include the lactose tolerance test (LTT), trials of a low-lactose or a low-fiber diet, food challenges, and food-elimination diets. Other than the LTT, these methods are time-consuming and require considerable cooperation and compliance from patients.

The hydrogen breath test (HBT) has been investigated as a way to identify SIBO or carbohydrate malabsorption and involves obtaining breath samples before and at timed intervals after ingesting a carbohydrate substrate and analyzing these samples for hydrogen (H₂) content. Intestinal bacteria ferment the carbohydrate, producing the only source of bodily H₂, which is expelled in the breath. The pattern and degree of expelled H₂ may indicate the presence of particular gastrointestinal (GI) disorders. In patients with IBS, the HBT is performed to identify GI conditions that may be responsible for symptoms and may be treatable, potentially providing symptom relief.

HBTs do not appear to provide a clinical benefit for diagnosis of IBS or for management of patients with IBS. There are a number of variables that influence HBT results, besides possible SIBO or carbohydrate malabsorption, and therefore these tests do not provide a definitive diagnosis for patients with symptoms of IBS or help to determine the underlying cause of those symptoms.

POLICY:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans and Paramount Medicaid Advantage

Hydrogen breath test to detect lactose malabsorption (91065) does not require prior authorization when the coverage criteria below is met.

Hydrogen breath test for diagnosing for any other gastric indication is noncovered.

CO₂ breath test for diagnosing bile acid, fat, or lactose malabsorption is non-covered.

Gastric emptying breath testing is non-covered for all indications, i.e. 13C-Spirulina Platensis Gastric Emptying Breath Test

COVERAGE CRITERIA:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans and Paramount Medicaid Advantage

Hydrogen breath test is covered to detect lactose intolerance/deficiency for all of the following:

- persistent symptoms (eg, abdominal pain, bloating, diarrhea, gas, nausea); and
- after a 2-week trial of a lactose-free diet.

The following breath tests are non-covered (not an all-inclusive list):

- Hydrogen breath testing
 - Irritable bowel syndrome (IBS);
 - Small bowel transit time/gastroparesis;
 - Small intestinal bacterial overgrowth (SIBO);
- Carbon Dioxide (CO₂) breath testing
 - Lactose malabsorption;
 - Bile acid malabsorption;
 - Fat malabsorption
- Methane breath testing is considered not medically necessary and is not covered for the diagnosis or management of any gastrointestinal condition, including carbohydrate or other malabsorption syndromes.
- Gastric emptying breath test (GEBT) is considered experimental and investigational for gastroparesis and

for all other indications because of insufficient evidence of its effectiveness. While these test has the advantage of avoiding radiation associated with scintigraphy, further studies are needed before they can be routinely recommended for evaluation of delayed gastric emptying.

- The measurements of exhaled volatile organic compounds are considered experimental and investigational for detection of cancer in the digestive tract (including colorectal, gastro-esophageal, liver, and pancreatic cancers), and inflammatory bowel diseases because of insufficient evidence of its effectiveness.

CODING/BILLING INFORMATION:

The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

CPT CODES	
91065	Breath hydrogen or methane test (e.g., for detection of lactase deficiency, fructose intolerance, bacterial overgrowth, or oro-cecal gastrointestinal transit)
0106U	Gastric emptying, serial collection of 7 timed breath specimens, non-radioisotope carbon-13 (13C) spirulina substrate, analysis of each specimen by gas isotope ratio mass spectrometry, reported as rate of 13CO2 excretion

REVISION HISTORY EXPLANATION: ORIGINAL EFFECTIVE DATE: 06/24/2016

Date	Explanation & Changes
06/24/2016	<ul style="list-style-type: none"> • Policy created to reflect most current clinical evidence per TAWG
12/22/2020	<ul style="list-style-type: none"> • Medical policy placed on the new Paramount Medical Policy Format
02/02/2023	<ul style="list-style-type: none"> • Changed medical policy title from Diagnostic Breath Analyses to Diagnostic Breath Analyses for Gastrointestinal Conditions • Paramount added the noncovered procedure code 0106U • Policy reviewed/updated to reflect most current clinical evidence • No changes to policy statement
03/11/2024	<ul style="list-style-type: none"> • Medical policy placed on the new Paramount Medical Policy Format

Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to <https://www.paramounthealthcare.com/providers/medical-policies/policy-library>

REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals> <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs>

American Medical Association, *Current Procedural Terminology (CPT®)* and associated publications and services <https://www.ama-assn.org/amaone/cpt-current-procedural-terminology>

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update>

U.S. Preventive Services Task Force, <https://www.uspreventiveservicestaskforce.org/uspstf/> Industry Standard Review

Hayes, Inc., <https://www.hayesinc.com/>

Industry Standard Review