

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Combined Hydrogen/Methane Breath Test

- Diagnosing Small Intestinal Bacterial Overgrowth (SIBO)
- Fructose or Lactose Intolerance

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Criteria

For Medicare Members

Source	Policy	
CMS Coverage Manuals	None	
National Coverage Determinations (NCD)	Diagnostic Breath Analyses (100.5)	
Local Coverage Determinations (LCD)	None	
Local Coverage Article	None	

For Non-Medicare Members

Services	Criteria used
Diagnosing Small Intestinal Bacterial	Hydrogen/methane breath test covered only when ordered by
Overgrowth (SIBO)	Gastroenterologist for possible SIBO
Fructose or Lactose Intolerance	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies

If requesting this service, please send the following documentation to support medical necessity:

Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Small intestinal bacterial overgrowth (SIBO) is characterized by a malabsorption syndrome due to abnormally large amounts of bacteria within the small intestine (Gasbarrini, et al. 2007). Symptoms include diarrhea, abdominal pain or cramps, nausea, constipation, acid reflux, bloating, flatulence, dehydration and fatigue. SIBO can also cause more severe symptoms including steatorrhea, anemia, bleeding or bruising, night blindness, bone pain, fractures, leaky gut syndrome, autoimmune reactions, weight loss and "failure to thrive". Due largely to uncertainty with regard to definition and detection, the true prevalence of SIBO and its relationship to a number of clinical disorders remains unclear (Dukowicz, et al. 2007).

Direct aspiration and culture of jejunal fluid have traditionally been considered the "gold standard" for SIBO diagnosis. With results expressed as colony-forming units per milliliter of jejunal fluid (cfu/ml), a SIBO diagnosis is © 2014, Kaiser Foundation Health Plan of Washington. All Rights Reserved.

most commonly defined as >105 cfu/ml, however, the thresholds vary throughout the literature (Abu-Shanab and Quigley 2009; Dukowicz, et al. 2007). To add to this, aspiration and culture is expensive, invasive and difficult to perform requiring the passage of a tube under fluoroscopic guidance through the nose, throat, esophagus and stomach. Breath tests, on the other hand, escape these limitations and have been proposed as a simple tool for diagnosing SIBO. Based on the fact that only bacteria in the gastrointestinal tract can ferment unabsorbed carbohydrates and metabolize them into hydrogen and/or methane, the gases are absorbed into the bloodstream and subsequently excreted in the breath (Levitt, et al. 2006; Simren and Stotzer 2006). Put simply, breath tests measure the levels of hydrogen and/or methane gas in a breath (Ghoshal, et al. 2006).

Breath tests can be performed at home or in a clinic and require that the patient fast for 12 hours prior to testing, after which, the patient provides a baseline sample breath. After establishing a baseline measurement, the patient ingests a small amount of substrate, either lactulose or glucose, and subsequently, provides breath samples every 15 minutes for three to five hours. At this time, hydrogen/methane breath tests have not been standardized with protocols differing in dose and concentration of the test substrate, and duration of test time intervals (Bures, et al. 2010). In the same way, there have been no accepted criteria for what constitutes a positive result.

Hydrogen/methane breath tests have not been approved by the Food and Drug Administration (FDA).

Medical Technology Assessment Committee (MTAC)

Combined Hydrogen/Methane Breath Test

6/16/2014: MTAC REVIEW

Evidence Conclusion: There is insufficient evidence to establish the diagnostic accuracy of the combined hydrogen/methane breath test for diagnosing SIBO. There is insufficient evidence to conclude that the hydrogen breath test is not harmful to patients. There is insufficient evidence to determine the impact of the test on patient management.

Articles: There is extensive literature on the use of breath testing to diagnose SIBO with many publications addressing the prevalence of SIBO among patients with irritable bowel syndrome. Generally speaking, there is a greater body of published literature on the use of hydrogen breath testing with less literature specifically addressing the use of methane breath tests and combination hydrogen and methane breath tests. Two studies were identified that assess the utility and accuracy of SIBO. The following studies were selected for critical appraisal: Corazza GR, Menozzi MG, Strocchi A, et al. The diagnosis of small bowel bacterial overgrowth: reliability of jejunal culture and inadequacy of breath hydrogen testing. Gastroenterology. 1990;98(2):302-309. See Evidence Table Ghoshal UC, Ghoshal U, Das K et al. Utility of hydrogen breath tests in diagnosis of small intestinal bacterial overgrowth in malabsorption syndrome, and its relationship with oro-cecal transit time. Indian J Gastroenterology. 2006;25(1):6-10. See Evidence Table.

The use of Combined Hydrogen/Methane Breath Test for Diagnosing Small Intestinal Bacterial Overgrowth (SIBO) does not meet the *Kaiser Permanente Medical Technology Testing Criteria*.

trio-smart® Breath Test for Aiding Diagnosis of Small Intestinal Bacterial Overgrowth (SIBO) 10/25/2023: INTC REVIEW

Evidence Conclusion:

There is insufficient evidence regarding the effectiveness and safety of the trio-smart® breath test for aiding diagnosis of small intestinal bacterial overgrowth (SIBO) in patients with gastrointestinal symptoms.

• The existing evidence regarding how the trio-smart® breath test effectively aids in the diagnosis of SIBO is of insufficient quantity and/or quality.

Rationale: In patients with gastrointestinal symptoms, there is no clinical validity or clinical utility evidence on the trio-smart® breath test for aiding diagnosis of SIBO.

Evidence Summary:

 A Hayes, Inc. Evidence Analysis Research Brief (June 2023) noted that there currently is not enough published peer-reviewed literature to evaluate the evidence related to the trio-smart[®] breath test for diagnosis of SIBO in a full assessment. There were no relevant clinical validity or clinical utility studies identified in the Hayes, Inc. review of abstracts.

- In our supplemental search of the published literature for studies not identified by Hayes, Inc., we did not find any full-text, peer-reviewed articles addressing the clinical question.
- In the absence of peer-reviewed data, no conclusion is drawn regarding the effectiveness and safety of the trio-smart[®] breath test in aiding SIBO diagnosis in patients with gastrointestinal symptoms.

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trio-smart® product website (More About trio-smart®)

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Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT [®] Codes	Description
91065	Breath hydrogen or methane test (eg, for detection of lactase deficiency, fructose intolerance,

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bacterial overgrowth, or oro-cecal gastrointestinal transit)

*Note: Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

**To verify authorization requirements for a specific code by plan type, please use the Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
07/01/2014	07/01/2014 ^{MPC} , 05/05/2015 ^{MPC} , 03/01/2016 ^{MPC} , 01/03/2017 ^{MPC} , 11/07/2017 ^{MPC} , 09/04/2018 ^{MPC} , 09/03/2019 ^{MPC} , 09/01/2020 ^{MPC} , 09/07/2021 ^{MPC} , 09/06/2022 ^{MPC} , 09/05/2023 ^{MPC} , 10/01/2024 ^{MPC}	11/02/2023

MPC Medical Policy Committee

Revision History	Description
12/06/2016	Added language to cover test if ordered only by GI for possible SIBO
11/02/2023	Added October 25, 2023 INTC Review: trio-smart® Breath Test for Aiding Diagnosis of Small
	Intestinal Bacterial Overgrowth (SIBO)