



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 Overgrowth (SIBO) | Hydrogen/methane breath test covered only when ordered by 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

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: Evidence on the validity of the lactulose breath test for the diagnosis of SIBO is conflicting. In 1990, Corazza and colleagues performed complete microbiological analyses of jejunal aspirates in 77 patients thought to have SIBO. Those results were then compared to glucose and lactulose breath tests. In the results, the investigators reported sensitivities of 62% and 68% for glucose and lactulose, respectively and specificities of 44% and 83% (Corazza, et al. 1990). See [Evidence Table](#) More recently, however, Ghoshal and colleagues performed both glucose and lactulose breath tests on 83 patients on two separate days and reported that, when compared to culture of small bowel aspirate, both glucose and lactulose breath tests had lower sensitivities (glucose 44%, lactulose 31%) and higher specificities (glucose 80%, lactulose 86%). The authors propose several theories to explain the low sensitivities, including non-hydrogen producing patients, and patients with high basal breath hydrogen levels despite adequate preparation (Ghoshal, et al. 2006). See [Evidence Table](#) While none of the studies measured safety outcomes or recorded adverse events, most of the literature identifies breath tests as simple, safe, and lacking invasiveness (Dukowicz, et al. 2007). Despite these advantages, there is a lack of uniformity regarding their protocol and interpretation. Furthermore, hydrogen and methane levels are affected by a number of factors including smoking, exercise, chewing gum, breath mints, and antibiotic use. Above all else, differences in bacterial flora among patients can determine responses to breath testing with about 10-15% of patients lacking bacteria capable of producing hydrogen. Ultimately, the absence of an established interpretation of the gold standard, limits the ability to firmly establish the diagnostic accuracy of breath tests for diagnosing SIBO leaving the validity of the test in question. 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:

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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.

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, 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} | 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: <i>trio-smart® Breath Test for Aiding Diagnosis of Small Intestinal Bacterial Overgrowth (SIBO)</i> |