

MARYLAND MEDICARE PART A

Policy No: 98-2

Topic: Breath Test for *Helicobacter Pylori* (*H. Pylori*)

Beginning Effective Date
September 11, 1998

Ending Effective Date
Not applicable at this time.

Description

- The breath test for *Helicobacter pylori* is a non-invasive diagnostic procedure utilizing analysis of breath samples to determine the presence of *Helicobacter pylori*. There are different specific tests available.
- The carbon-13 breath test consists of analysis of breath samples before and after ingestion of ¹³C-urea. ¹³C-urea will decompose to form ¹³CO₂ and NH₄ in the presence of urease, which is produced by *H. pylori* in the stomach. The ¹³CO₂ is absorbed in the blood, then exhaled in the breath. The exhaled breath sample is analyzed and compared with the baseline breath sample, which was obtained before the ingestion of the ¹³C-urea.
- The ¹⁴C-urea breath test is a radioisotope method for detecting *H. pylori* in the stomach. The breath test can detect *H. pylori* colonization with reported 95 percent accuracy. *H. pylori* is accepted as an etiologic factor in duodenal ulcers, peptic ulcer disease, gastric carcinoma, and primary B cell gastric lymphoma.

Policy Type

Local Medical Review Policy

Indications and Limitations of Coverage and/or Medical Necessity

- The tests available for the diagnosis of *Helicobacter pylori* infection differ with respect to sensitivity, specificity, invasiveness, cost, and in the additional information that they provide. The appropriate choice of test depends on the clinical situation. The following clinical scenarios are appropriate for use of the *H. pylori* breath test:
 - patients with classic relatively uncomplicated symptoms of peptic ulcer disease for whom antibiotic therapy is planned, if the *H. pylori* breath test is positive, and no gastrointestinal endoscopy is planned,
 - patients who have non-specific dyspeptic symptoms with a positive *H. pylori* serum antibody test, and no endoscopy is planned,
 - an upper gastrointestinal contrast X-ray series has been done which shows a duodenal ulcer or significant gastritis and/or duodenitis, and no endoscopy is planned, and/or;
 - there are persistent or recurrent symptoms six weeks after treatment for a documented *H. pylori* infection, and no endoscopy is planned.
- The *H. pylori* breath test is considered **not** medically necessary in the following situations:
 - Patients who are being screened for *H. pylori* infection in the absence of documented upper gastrointestinal tract symptoms and/or pathology,
 - Patients who have had an upper gastrointestinal endoscopy within the preceding six weeks or for whom an upper gastrointestinal endoscopy is planned,
 - Patients who have non-specific dyspeptic symptoms with a negative *H. pylori* serum antibody test, or;
 - Patients who are asymptomatic after treatment of an *H. pylori* infection (either proven or suspected). Except in the situation of a history of a major complication of ulcer disease such as bleeding, perforation, penetration, or multiple recurrences, in which case, an *H. pylori* breath test may be used to document eradication of the infection in lieu of a follow-up endoscopy. If a follow-up breath test is used to document eradication of *H. pylori* in the asymptomatic patient, it is expected that medical record documentation should verify the history of the previous complication.

- Based on cure rates for *H. pylori* infection with the currently accepted regimens utilizing antibiotics, repeat endoscopy or *H. pylori* breath test would be expected in less than thirty percent of patients with *H. pylori* infection associated with duodenal ulcer and/or gastritis/duodenitis.

HCPCS Section/Benefit Category

Pathology and Laboratory/Chemistry

Types of Bill

11X, 13X, 14X, 21X, 22X, 23X, 72X

Revenue Codes

33X, 34X	HCPCS 78999©
30X	HCPCS 83019©
254	HCPCS A4641

HCPCS Codes

78999©	Unlisted miscellaneous procedure, diagnostic nuclear medicine
83019©	<i>Helicobacter pylori</i> , breath test (including drug and breath sample collection kit)
A4641	Radiopharmaceutical diagnostic imaging agent, unlisted

ICD-9-CM Codes that Support Medical Necessity

Medicare is establishing the following limited coverage for *H. pylori* breath test:

531.00-531.01 Gastric ulcer; acute with hemorrhage
 531.10-531.11 Gastric ulcer, acute with perforation
 531.20-531.21 Gastric ulcer, acute with hemorrhage and perforation
 531.40-531.41 Gastric ulcer, chronic or unspecified with hemorrhage
 531.50-531.51 Gastric ulcer, chronic or unspecified with perforation
 531.60-531.61 Gastric ulcer, chronic or unspecified with hemorrhage and perforation

531.70-531.71 Gastric ulcer, chronic without mention of hemorrhage or perforation

531.90-531.91 Gastric ulcer, unspecified as acute or chronic, without mention of hemorrhage or perforation

532.00-532.01 Duodenal ulcer, acute with hemorrhage

532.10-532.11 Duodenal ulcer, acute with perforation

532.20-532.21 Duodenal ulcer, acute with hemorrhage and perforation

532.30-532.31 Duodenal ulcer, acute without mention of hemorrhage or perforation

532.40-532.41 Duodenal ulcer, chronic or unspecified with hemorrhage

532.50-532.51 Duodenal ulcer, chronic or unspecified with perforation

532.60-532.61 Duodenal ulcer, chronic or unspecified with hemorrhage and perforation

532.70-532.71 Duodenal ulcer, chronic without mention of hemorrhage or perforation

532.90-532.91 Duodenal ulcer, unspecified as acute or chronic, without mention of hemorrhage or perforation

534.00-534.01 Gastrojejunal ulcer, acute with hemorrhage

534.10-534.11 Gastrojejunal ulcer, acute with perforation

534.20-534.21 Gastrojejunal ulcer, acute with hemorrhage and perforation

534.30-534.31 Gastrojejunal ulcer, acute without mention of hemorrhage or perforation

534.40-534.41 Gastrojejunal ulcer, chronic or unspecified with hemorrhage

534.50-534.51 Gastrojejunal ulcer, chronic or unspecified with perforation

534.60-534.61 Gastrojejunal ulcer, chronic or unspecified with hemorrhage and perforation

534.70-534.71 Gastrojejunal ulcer, chronic without mention of hemorrhage or perforation

534.90-534.91 Gastrojejunal ulcer, unspecified as acute or chronic, without mention of hemorrhage or perforation

535.00-535.01 Gastritis and duodenitis, acute with or without mention of hemorrhage

535.10-535.11 Chronic gastritis, with or without mention of hemorrhage

535.50-535.51 Gastritis and duodenitis, unspecified, with or without mention of hemorrhage

535.60-535.61 Duodenitis

536.8 Dyspepsia and other specified disorders of function of stomach

789.01-789.02 Abdominal pain, right and left upper quadrant

789.06 Abdominal pain, epigastric

Non-covered ICD-9-CM Code(s)

All diagnoses not listed in the “ICD-9-CM Codes that Support Medical Necessity” section of this policy.

HCFA National Policy

- Establishment of national policy supercedes all previous contractor policy statements, including Local Medical Policy coverage guidelines.
- Title XVIII of the Social Security Act, section 1862 (a) (1) (A). this section allows coverage and payment for only those services that are considered to be medically reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member.
- Title XVIII of the Social Security Act, section 1862 (a) (7). This section excludes routine physical examinations.

Reasons for Denial

- The service does not follow the guidelines of this policy,
- The service is for screening purposes,
- The service is not medically necessary, and;
- The medical record does not verify that the service described by the HCPCS code was provided.

Sources of Information

- TrailBlazer Carrier Advisory Committee
- TrailBlazer Medicare B Newsletter, No. 020, October 1997
- Klein, Peter D., et al. 1996. “Non-invasive Detection of *Helicobacter*

Pylori Infection in Clinical Practice: The ¹³C-urea Breath Test.” The American Journal of Gastroenterology Vol. 91 (April): pp. 690-694.

- Slomianski, Arie, M.D., et al. 1995. “[¹³C] Urea Breath Test to Confirm Eradication of *Helicobacter Pylori* .” The American Journal of Gastroenterology Vol. 90 (February): pp. 224-226.

Coding Guidelines

- To report the ¹³C-urea breath test kit, use the unlisted HCPCS code J3490,
- To report the ¹³C-urea breath test service, use the unlisted HCPCS code 84999,
- To report the ¹•C-urea breath test, use radiopharmaceutical HCPCS A4641, and;
- To report the ¹•C-urea breath test, use the unlisted nuclear medicine HCPCS code 78999.

Note: As with all unlisted procedure codes, a description must be admitted with the claim before consideration for coverage and payment may be made.

Documentation Requirements

- Documentation supporting the medical necessity should be legible, maintained in the patient’s medical records, and available to Medicare upon request.
- This policy does not reflect the sole opinion of the intermediary or the carrier medical directors.

Other Comments

- Commercially available kits for administering the ¹³C-urea breath test are reimbursable based on invoice price for the kit. The kit and ¹³C-urea containing drug must be approved by the FDA. Because of the precise way the ¹³C-urea must be administered and the breath samples collected, ¹³C-urea is not considered self-administrable.
- Services related to the explanation of the test to the patient, and supervision of the administration of the ¹³C-urea, should be billed as evaluation and management services by the physician administering the test. Normally, if the

test is administered during the overall evaluation of the patient for the clinical problem requiring the test, the time and effort of the physician in administering the test should be taken into consideration in determining the level of evaluation and management service to be billed.

- This policy does not reflect the sole opinion of the intermediary, carrier, or Intermediary/Carrier Medical Directors. Although the final decision rests with the intermediary, this policy was developed in cooperation with the Carrier Advisory Committee (CAC), which includes representatives from the appropriate specialties.

Start Date of Comment Period

March 31, 1998

Start Date of Notice Period

August 11, 1998

Revision Date

Revision Number

THIS BULLETIN SHOULD BE SHARED WITH ALL HEALTH CARE PRACTITIONERS AND MANAGERIAL MEMBERS OF THE PROVIDER/SUPPLIER STAFF. BULLETINS ISSUED AFTER OCTOBER 1, 1999 ARE AVAILABLE AT NO-COST FROM OUR WEBSITE AT www.marylandmedicare.com

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