

**Contractor's Policy Number**

98-02-R4

**Contractor Name**

CareFirst of Maryland Inc., Medicare Part A

**Contractor Number**

00190

**Contractor Type**

Fiscal Intermediary

**LMRP Title**

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

**AMA CPT Copyright Statement**

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**HCFA National Coverage 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) (7). This section excludes routine physical examinations.
- 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.

**Primary Geographic Jurisdiction**

Maryland

Washington, DC

**Secondary Geographic Jurisdiction**

Alabama, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Missouri, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Wisconsin, Washington state, and Wyoming

**HCFA Region**

Region III

**HCFA Consortium**

Northeast

**Original Policy Effective Date**

09/11/1998

**Original Policy Ending Date**

**Revision Effective Date**

01/22/2003

**Revision Ending Date**

**LMRP 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  $^{13}\text{C}$ -urea.  $^{13}\text{C}$ -urea will decompose to form  $^{13}\text{CO}_2$  and  $\text{NH}_4$  in the presence of urease, which is produced by *H. pylori* in the stomach. The  $^{13}\text{CO}_2$  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  $^{13}\text{C}$ -urea.

- The  $^{13}\text{C}$ -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.

### **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.

### **CPT/HCPCS Section & Benefit Category**

Radiology

Pathology and Laboratory/Chemistry

### **Types of Bill**

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

### **Revenue Codes**

30X, 34X, 636

### **CPT/HCPCS Codes**

Note: Providers are reminded to refer to the long descriptors of the CPT codes in their CPT book. The AMA and CMS require the use of short *descriptors* in policies published on the web.

78267            *Breath test, C<sup>1</sup>•; attain/analysis*

78268            *Breath test, analysis*

83013            *H. pylori; analysis*  
 83014            *H. pylori drug admin/collect*

### **ICD-9-CM Codes that Support Medical Necessity**

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

#### **Covered for:**

- 531.00 Gastric ulcer; acute with hemorrhage; without mention of obstruction
- 531.01            with obstruction
- 531.10            acute with perforation; without mention of obstruction
- 531.11            with obstruction
- 531.20-            acute with hemorrhage and perforation, without mention of obstruction
- 531.21 ,            with obstruction
- 531.30-            acute without mention of hemorrhage or perforation; without mention of obstruction
- 531.31            with obstruction
- 531.40-            chronic or unspecified with hemorrhage, without mention of obstruction
- 531.41            with obstruction
- 531.50-            chronic or unspecified with perforation, without mention of obstruction
- 531.51            with obstruction
- 531.60-            chronic or unspecified with hemorrhage and perforation; without mention of obstruction
- 531.61            with obstruction
- 531.70-            chronic without mention of hemorrhage or perforation; without mention of obstruction
- 531.71            with obstruction
- 531.90            unspecified as acute or chronic, without mention of

hemorrhage or perforation; without mention of obstruction

531.91 with obstruction

532.00 Duodenal ulcer, acute with hemorrhage; without mention of obstruction

532.01 with obstruction

532.10 acute with perforation; without mention of obstruction

532.11 with obstruction

532.20 acute with hemorrhage and perforation, without mention of  
obstruction

532.21 with obstruction

532.30 acute without mention of hemorrhage or perforation,  
without mention of  
obstruction

532.31 with obstruction

532.40 chronic or unspecified with hemorrhage; without mention of  
obstruction

532.41 with obstruction

532.50 chronic or unspecified with perforation; without mention of  
obstruction

532.51 with obstruction

532.60 chronic or unspecified with hemorrhage and  
perforation; without mention  
of obstruction

532.61 with obstruction

532.70 chronic without mention of hemorrhage or perforation;  
without mention of obstruction

532.71 with obstruction

532.90 unspecified as acute or chronic, without mention of  
hemorrhage or perforation; without mention of obstruction

532.91 with obstruction

534.0 Gastrojejunal ulcer; acute with hemorrhage; without mention of  
obstruction

534.01 with obstruction

534.10 acute with perforation; without mention of obstruction

- 534.11 with obstruction
- 534.20 acute with hemorrhage and perforation; without mention of obstruction
- 534.21 with obstruction
- 534.30 acute without mention of hemorrhage or perforation; without mention of obstruction
- 534.31 with obstruction
- 534.40 chronic or unspecified with hemorrhage; without mention of obstruction
- 534.41 with obstruction
- 534.50 chronic or unspecified with perforation; without mention of obstruction
- 534.51 with obstruction
- 534.60 chronic or unspecified with hemorrhage and perforation; without mention of obstruction
- 534.61 with obstruction
- 534.70 chronic without mention of hemorrhage or perforation; without mention of obstruction
- 534.71 with obstruction
- 534.90 unspecified as acute or chronic, without mention of hemorrhage or perforation; without mention of obstruction
- 534.91 with obstruction
- 535.00 Acute gastritis; without mention of hemorrhage
- 535.01 with hemorrhage
- 535.10 Atrophic gastritis, without mention of hemorrhage
- 535.11 with hemorrhage
- 535.50 Unspecified gastritis and gastroduodenitis, without mention of hemorrhage
- 535.51 with hemorrhage
- 535.60 Duodentis, without mention of hemorrhage
- 535.61 with hemorrhage
- 536.8 Dyspepsia and other specified disorders of function of stomach
- 789.01 Abdominal pain; right left upper quadrant

789.02 left upper quadrant  
789.06 Abdominal pain; epigastric

### **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.

### **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.

### **Documentation Requirements**

- Documentation supporting the medical necessity should be legible, maintained in the patient’s medical records, and available to Medicare upon request.

### **Other Comments**

- Commercially available kits for administering the <sup>13</sup>C-urea breath test are reimbursable based on invoice price for the kit. The kit and <sup>13</sup>C-urea containing drug must be approved by the FDA. Because of the precise way the <sup>13</sup>C-urea must be administered and the breath samples collected, <sup>13</sup>C-urea is not considered self-administrable.
- Services related to the explanation of the test to the patient, and supervision of the administration of the <sup>13</sup>C-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.

## **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 <sup>13</sup>C-urea Breath Test." *The American Journal of Gastroenterology* Vol. 91 (April): pp. 690-694.
- Slomianski, Arie, M.D., et al. 1995. "[<sup>13</sup>C] Urea Breath Test to Confirm Eradication of *Helicobacter Pylori*." *The American Journal of Gastroenterology* Vol. 90 (February): pp. 224-226.

## **Advisory Committee Notes**

- 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 specialty(ies).

Advisory Committee meeting date:

## **Start Date of Comment Period**

03/31/1998

## **Ending Date of Comment Period**

04/30/1998

## **Start Date of Notice Period**

08/11/1998

## **Revision History**

<u>Number</u>	<u>Date</u>	<u>Change</u>
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- 98-2-R4      01/22/2003      Descriptors changed to short descriptors, unranked ICD-9 codes.
- 98-2-R3      08/10/2001      The policy was revised to accommodate changes in *CPT 2001* with the addition of 78267 and 78268. (See 08/10/2001 Provider Bulletin)
- 98-2-R2      04/09/01      The policy was revised to accommodate changes in *CPT 2000* with the addition of 83013 and 83014. (See 04/09/2001 Provider Bulletin)
- 98-2-R1      11/17/2000-      Policy modified to accommodate ICD-9-CM codes  
531.30-531.31 erroneously omitted in the original policy.

**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](http://www.marylandmedicare.com)**

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