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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 supersedes 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 noninvasive 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.

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 nonspecific 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 nonspecific 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, C¹⁴; 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.

Noncovered 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 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.

Sources of Information

- TrailBlazer Carrier Advisory Committee
- TrailBlazer Medicare B Newsletter, No. 020, October 1997
- Klein, Peter D., et al. 1996. "Noninvasive 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.

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

Number/ Date/ Change

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

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