of Tennessee

Policy

Reimbursement Policy

Helicobacter Pylori Testing

I. Policy Description

Helicobacter pylori (*H. pylori*) is a spiral-shaped, gram-negative bacteria that thrives while living in acidic environments, growing in close association with the stomach lining. H. *pylori* infection causes chronic inflammation (infection) in the stomach and is associated with conditions such as peptic ulcer disease, chronic gastritis, gastric adenocarcinoma, and gastric mucosa associated lymphoid tissue (MALT) lymphoma.[1]

II. Indications and/or Limitations of Coverage

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request. Specifications pertaining to Medicare and Medicaid can be found in the "Applicable State and Federal Regulations" section of this policy document.

1) For individuals who are 18 years of age and older, urea breath testing **or** stool antigen testing to diagnose an *H. pylori* infection **MEETS COVERAGE CRITERIA** in **any** of the following situations:

   a) For individuals with dyspepsia (see Note 1).

   b) For individuals with active peptic ulcer disease (PUD).

   c) For individuals with past PUD and who have had recurrent symptoms.

   d) For individuals with low-grade gastric mucosa-associated lymphoid tissue (MALT) lymphoma.

   e) For individuals with a history of resection of early gastric cancer (EGC).

   f) For individuals with gastric intestinal metaplasia (GIM).

For individuals initiating chronic treatment with or who have been on a long-term aspirin or non-steroidal anti-inflammatory drug (NSAID) treatment.

   g) For individuals with unexplained iron deficiency anemia.

h) For individuals with idiopathic thrombocytopenic purpura (ITP).

i) For individuals with a family history of gastric cancer.

j) For individuals who are first-generation immigrants from a high prevalence area.

For individuals who are 18 years of age and older and who are undergoing endoscopic examination or who have alarm symptoms (see Note 2), a biopsy-based endoscopic histology test and **either** a rapid urease test **or** a culture with susceptibility testing to diagnose an *H. pylori* infection **MEETS COVERAGE CRITERIA**.

2) For individuals who are less than 18 years of age, urea breath testing **or** stool antigen testing to diagnose an *H. pylori* infection **MEETS COVERAGE CRITERIA** in **any** of the following situations:

   a) For individuals who have gastric or duodenal ulcers or erosions.

For individuals who have a family history of gastric cancer.

3) For individuals who are less than 18 years of age and who have refractory iron deficiency anemia, a biopsy-based endoscopic histology test and **either** a rapid urease test **or** a culture with susceptibility testing to diagnose an *H. pylori* infection **MEETS COVERAGE CRITERIA.**

4) For all individuals who have tested positive for *H. pylori*, urea breath testing **or** stool antigen testing to measure the success of eradication of *H. pylori* infection, with testing performed at least four weeks post-treatment, **MEETS COVERAGE CRITERIA**.

5) For individuals with a refractory *H. pylori* infection, susceptibility testing (culture or nucleic acid based) **MEETS COVERAGE CRITERIA.**

6) Urea breath testing **or** stool antigen testing to diagnose an *H. pylori* infection **DOES NOT MEET COVERAGE CRITERIA** for **any** of the following situations:

   a) For asymptomatic individuals of all ages.

   b) For individuals 18 years and older with typical symptoms of gastroesophageal reflux disease (i.e., heartburn, regurgitation) who do not have a history of peptic ulcer disease (PUD).

7) For individuals of all ages, serologic testing for *H. pylori* infection **DOES NOT MEET COVERAGE CRITERIA**.

8) For individuals less than 18 years of age, a biopsy-based endoscopic histology test and a rapid urease test **or** a culture with susceptibility testing to diagnose an *H. pylori* infection **DOES NOT MEET COVERAGE CRITERIA** in **any** of the following situations:

   a) For children with functional abdominal pain.

   b) As part of an initial investigation in children with iron deficiency anemia.

   c) When investigating causes of short stature.

9) For individuals with recent use of antibiotics, proton pump inhibitors (PPIs), or bismuth, the urea breath test, stool antigen, **or** biopsy-based testing to diagnose an *H. pylori* infection **DOES NOT MEET COVERAGE CRITERIA**.

10) To diagnose an H. pylori infection, concurrent testing with **any** combination of the urea breath test, stool antigen testing, **and/or** biopsy-based testing **DOES NOT MEET COVERAGE CRITERIA**.

11) For all other situations not described above, nucleic acid testing for *H. pylori* **DOES NOT MEET COVERAGE CRITERIA**.

NOTES:

Note 1: "Dyspepsia refers to bothersome upper abdominal symptoms that are often meal related. The predominant symptoms are fullness (or bloating) after meals, early satiety (inability to finish a normal-sized meal because of postprandial discomfort), or epigastric pain (or burning) that may or may not be related to meals. If dyspepsia is chronic, epigastric pain is a less common feature than postprandial fullness or satiety. Pain is not required to make a diagnosis of dyspepsia."[2]

Note 2: Alarm features of dyspepsia: vomiting, gastrointestinal bleeding, unexplained iron deficiency, or weight loss.[3]

III. Applicable State and Federal Regulations

DISCLAIMER: If there is a conflict between this Policy and any relevant, applicable government policy for a particular member [e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs) for Medicare and/or state coverage for Medicaid], then the government policy will be used to make the determination. For the most up-to-date Medicare policies and coverage, please visit the Medicare search website: https://www.cms.gov/medicare-coverage-database/search.aspx. For the most up-to-date Medicaid policies and coverage, visit the applicable state Medicaid website.

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Food and Drug Administration (FDA)

Many labs have developed specific tests that they must validate and perform in house. These laboratory-developed tests (LDTs) are regulated by the Centers for Medicare and Medicaid (CMS) as high-complexity tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). LDTs are not approved or cleared by the U. S. Food and Drug Administration; however, FDA clearance or approval is not currently required for clinical use.

On Feb 22, 2012, the FDA approved the BreathTek UBT for *H. pylori* Kit created by Otsuka America Pharmaceutical, Inc. TheBreathTek UBT for *H. pylori* Kit (BreathTek UBT Kit) is intended for use in the qualitative detection of urease associated with *H. pylori* in the human stomach and is indicated as an aid in the initial diagnosis and post-treatment monitoring of *H. pylori* infection in adults, and pediatric patients three to 17 years old. The test may be used for monitoring treatment if used at four weeks following completion of therapy. The FDA notes its sensitivity and specificity to be 0.958 and 0.992 respectively.[42]

On Jan 17, 2002, the FDA approved the BreathTek UBiT for *H. pylori* created by Meretek Diagnostics Inc. The scientific basis underlying the BreathTek UBT and the BreathTek UBiT UBT kit is identical. The urea breath test is FDA cleared for use in individuals 18 years of age and older.[43]

The BreathTek product line was bought by Meridian Biosciences and as of July 1, 2024 the entire BreathTek line, including BreathTek UBT and the BreathTek UBiT have been discontinued.[44]

On February 18, 2020, the FDA approved the PyloPlus UBT System created by ARJ Medical Inc. PyloPlus detects urease associated with *H. pylori* in the stomach and is indicated as an aid in the initial diagnosis of *H. pylori* infection in adults 18 years and older.[45]

IV. Applicable CPT/HCPCS Procedure Codes

CPT	Code Description
83009	Helicobacter pylori, blood test analysis for urease activity, non-radioactive isotope (eg, C-13)
83013	Helicobacter pylori; breath test analysis for urease activity, non-radioactive isotope (eg, C-13)
83014	Helicobacter pylori; drug administration
86318	Immunoassay for infectious agent antibody(ies), qualitative or semiquantitative, single step-method (eg, reagent strip);
86677	Antibody; Helicobacter pylori

87070	Culture, bacterial; any other source except urine, blood or stool, aerobic, with isolation and presumptive identification of isolates
87077	Culture, bacterial; aerobic isolate, additional methods required for definitive identification, each isolate
87081	Culture, presumptive, pathogenic organisms, screening only;
87149	Culture, typing; identification by nucleic acid (DNA or RNA) probe, direct probe technique, per culture or isolate, each organism probed
87150	Culture, typing; identification by nucleic acid (DNA or RNA) probe, amplified probe technique, per culture or isolate, each organism probed
87153	Culture, typing; identification by nucleic acid sequencing method, each isolate (eg, sequencing of the 16S rRNA gene)
87181	Susceptibility studies, antimicrobial agent; agar dilution method, per agent (eg, antibiotic gradient strip)
87186	Susceptibility studies, antimicrobial agent; microdilution or agar dilution (minimum inhibitory concentration [MIC] or breakpoint), each multi-antimicrobial, per plate
87205	Smear, primary source with interpretation; Gram or Giemsa stain for bacteria, fungi, or cell types
87338	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; Helicobacter pylori, stool
87339	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; Helicobacter pylori
87513	Infectious agent detection by nucleic acid (DNA or RNA); Helicobacter pylori (H. pylori), clarithromycin resistance, amplified probe technique
88305	Level IV - Surgical pathology, gross and microscopic examination - Stomach
0008U	Helicobacter pylori detection and antibiotic resistance, DNA, 16S and 23S rRNA, gyrA, pbp1, rdxA and rpoB, next generation sequencing, formalin-fixed paraffin-embedded or fresh tissue or fecal sample, predictive, reported as positive or negative for resistance to clarithromycin, fluoroquinolones, metronidazole, amoxicillin, tetracycline, and rifabutin Proprietary test: AmHPR H. Antibiotic Resistance Panel Lab/Manufacturer: American Molecular Laboratories, Inc

Procedure codes appearing in Medical Policy documents are included only as a general reference tool for each policy. They may not be all-inclusive.

V. Evidence-based Scientific References

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