HELICOBACTER PYLORI TESTING

Policy Number: CMP - 046
Effective Date: January 1, 2018

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BACKGROUND

*Helicobacter pylori* (*H. pylori*) is a gram-negative rod bacteria that is uniquely adapted to survive in the highly acidic gastric environment. To survive in the harsh, acidic environment of the stomach, *H. pylori* secretes an enzyme called urease, which converts the chemical urea to ammonia. The production of ammonia around *H. pylori* neutralizes the acidity of the stomach, making it more hospitable for the bacterium. In addition, the shape of *H. pylori* allows it to burrow into the mucus layer, which is less acidic than the lumen of the stomach. *H. pylori* can also attach to the cells that line the inner surface of the stomach.

*H. pylori* infection with the bacterium is common. The Centers for Disease Control and Prevention (CDC) estimates that approximately two-thirds of the world’s population harbors the bacterium, with infection rates much higher in developing countries than in developed nations.
Disease Conditions

Although *H. pylori* infection does not cause illness in all infected people, it is a major risk factor for the development of chronic active gastritis, peptic ulcer disease, gastric cancer, and probably some forms of gastric lymphoma. Colonization of the stomach with *H. pylori* has been accepted as an important cause of stomach cancer and of gastric mucosa-associated lymphoid tissue (MALT) lymphoma.

Gastric Cancer

Infection with *H. pylori* is the primary identified cause of gastric cancer. Other factors that increase the risk for gastric cancer include chronic gastritis; older age; male sex; a diet high in salted, smoked, or poorly preserved foods and low in fruits and vegetables; tobacco smoking; pernicious anemia; a history of stomach surgery for benign conditions; and a family history of stomach cancer. Multiple studies have shown that individuals infected with *H. pylori* have an increased risk of gastric adenocarcinoma.

Gastric MALT

Gastric MALT lymphoma, a rare type of non-Hodgkin lymphoma, is characterized by the slow multiplication of B lymphocytes (an immune cell) in the stomach lining. In normal circumstances, the stomach lining lacks lymphoid tissue, but this tissue may be developed in response to *H. pylori* colonization. In rare cases, this tissue may give rise to MALT. Nearly all patients with gastric MALT lymphoma have signs of *H. pylori* infection and the risk of developing this tumor is more than six times higher in infected people than in uninfected people.

Diagnosis

According to the American College of Gastroenterology, the established indications for diagnosis and treatment of *H. pylori* are:

- Active peptic ulcer disease (gastric or duodenal ulcer)
- Confirmed history of peptic ulcer disease (not previously treated for *H. pylori* infection)
- Gastric MALT lymphoma (low grade)
- After endoscopic resection of early gastric cancer
- Uninvestigated dyspepsia (depending upon *H. pylori* prevalence) - Test and treat strategy, especially for those under 55 who have no alarm features.

Alarm features identified by the College of Gastroenterology include bleeding, anemia, early satiety, unexplained weight loss, progressive dysphagia, odynophagia, recurrent vomiting, family history of GI cancer, and previous esophagogastic malignancy.

It is not necessary to perform *H. pylori* testing in the following situations:

- In the absence of documented gastritis or duodenal pathology (i.e. Patients who have had a normal upper GI endoscopy within the preceding six weeks).
- Patients for whom an upper GI endoscopy is planned either for initial diagnosis or follow-up.
- Patients who are asymptomatic after treatment of *H. pylori* infection, unless there is a documented family history of gastric cancer or it is necessary to resume NSAIDS or ulcerogenic medications.
- Patients with dyspepsia requiring endoscopy and biopsy or to monitor response to therapy.
- Patients with new onset, uncomplicated dyspeptic symptoms.
Testing

Testing for *H. pylori* can be divided into invasive specimen collection (biopsy and/or culture), non-invasive specimen collection (gram stain, rapid urease testing, serologic tests, breath tests) and assay for stool antigens (HpSA). The choice of specific testing depends on the clinical presentation of the patient and whether or not the patient requires endoscopy for evaluation. When medically necessary, more than one test may be needed to achieve the best diagnostic accuracy.

Invasive Tests

Invasive tests for *H. pylori* detection involve endoscopic biopsies of stomach tissue. Esophagogastroduodenoscopy (EGD) is used to obtain specimens of gastric mucosa. If endoscopy is indicated for the clinical evaluation of the patient, collection of biopsy specimens for histologic examination, urease activity and/or culture may be considered.

Non-Invasive Tests

Non-Invasive Specimen Collection (blood, breath, stool, etc) do not require endoscopy and are generally serological qualitative or semi-quantitative tests.

The urea breath test or stool test is recommended for initial testing for *H. pylori* because they are non-invasive, accurate and cost-effective. Although the serological test for *H. pylori* antigen is non-invasive and cost-effective, it is not recommended for initial evaluation or for determination of eradication after treatment for *H. pylori* according to the American College of Gastroenterology.¹⁵

Serological testing may be appropriate for the patient with non-specific dyspeptic symptoms in order to rule in or out *H. Pylori* infection. This test is not appropriate to determine treatment outcome because the test is limited to the detection of antibodies and therefore cannot accurately detect active infection because high levels of antibodies persist for months after treatment. Serology is not used for follow-up testing or to determine cure.

Urea Breath Test

The urea breath test for is a non-invasive diagnostic procedure utilizing analysis of breath samples to determine the presence of *H. pylori* in the stomach. The *H. pylori* breath test consists of analysis of breath samples before and after ingestion of labeled C-urea. Breath tests can detect the continued presence of *H. pylori* after treatment, (which is not the case with serology, where the presence of antibodies can exist for long periods of time).

Urea Breath Tests are indicated in patients who:

- Continue to have symptoms of dyspepsia after completing a treatment regimen which includes appropriate antibodies and no endoscopy is planned.
- Have symptoms that continue four weeks after the treatment regimen has been completed.
- Patients that have a history of hemorrhage, or outlet obstruction from peptic ulcer disease.
- Patients with a history of ulcer on chronic NSAID or on anticoagulant therapy.

Breath tests are not considered medically necessary for 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 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).

**Stool Testing**

The stool test describes an in vitro qualitative procedure for the detection of H. pylori antigens in human stool. A fresh or appropriately stored stool specimen is processed and tested by enzyme immunoassay technique. Test results can aid in the diagnosis of H. pylori as well as response to therapy. The stool test is appropriate for the patient with non-specific dyspeptic symptoms. In contrast to the serum antibody test, the stool antigen test returns to normal (negative) after successful treatment, and may determine treatment outcome.

Indications for stool antigen testing include the initial detection of H. pylori and follow-up of patients who continue to have symptoms after completing a treatment regimen that includes appropriate antibiotics. The stool test for H. pylori antigen is also appropriate for the patient with non-specific dyspeptic symptoms. In contrast to the serum antibody test, the stool antigen test returns to normal (negative) after successful treatment, and may be used to determine treatment outcome and whether eradication has occurred.

**Serological Testing**

Serological testing for antibodies to H. pylori is inexpensive, convenient and simple, but, because antibody levels persist some months after treatment, it is not useful for assessing therapeutic effectiveness.\(^{15}\)

Confirmation of successful H. pylori cure may be necessary:

- In Patients with an H. pylori-associated ulcer
- Individuals with persistent dyspeptic symptoms despite the test-and-treat strategy
- Those with H. pylori-associated MALT lymphoma
- Individuals who have undergone resection of early gastric cancer

**POLICY**

For the following CPT code(s) in Table 1, the patient should have a diagnosis (ICD-10-CM) code(s) listed in the attached files below.

**Table 1. HCPCS Codes (Alphanumeric, CPT\(^{\circ}\) AMA)**

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<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>78267</td>
<td>Urea breath test, c-14 (isotopic); acquisition for analysis</td>
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<tr>
<td>78268</td>
<td>Urea breath test, c-14 (isotopic); analysis</td>
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<td>83009</td>
<td>Helicobacter pylori, blood test analysis for urease activity, non-radioactive isotope (eg, C-13)</td>
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<td>83013</td>
<td>Helicobacter pylori; breath test analysis for urease activity, non-radioactive isotope (eg, C-13)</td>
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<td>83014</td>
<td>Helicobacter pylori; drug administration</td>
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<td>86677</td>
<td>Antibody; Helicobacter pylori</td>
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<tr>
<td>HCPCS Code</td>
<td>Description</td>
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<td>87338</td>
<td>Infectious agent antigen detection by enzyme immunoassay technique, qualitative or semiquantitative, multiple-step method; <em>Helicobacter pylori</em>, stool</td>
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<td>87339</td>
<td>Infectious agent antigen detection by enzyme immunoassay technique, qualitative or semiquantitative, multiple-step method; <em>Helicobacter pylori</em></td>
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**ICD-10 Diagnosis Codes (Proven)**

CMP-046 H Pylori ICD10_v2.2
REFERENCES


POLICY HISTORY/REVISION HISTORY

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
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<td>01/21/2017</td>
<td>Updated ICD10 codes as per CMS recommendations. Removed ICD9 code file</td>
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<td>12/03/2015</td>
<td>Annual Policy Review Completed – changes made:</td>
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<td>Added ICD9 diagnosis codes related to malignant neoplasm:</td>
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<td>Idiopathic Thrombocytopenic Purpura (ITP)- 287.31</td>
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