Cigna Medical Coverage Policy

Subject **Helicobacter Pylori Serology Testing**

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Coverage Policy

Cigna does not cover serology/antibody testing (CPT code 86677) for diagnosing Helicobacter pylori infection or ANY other indication because it is considered experimental, investigational, and unproven.

General Background

Helicobacter pylori (H. pylori) is a key causal factor in most peptic ulcer disease and a primary risk factor for gastric cancer. The pathogenic role of H. pylori in peptic ulcer disease, both duodenal and gastric, is well-recognized. Nearly 95% of patients with duodenal ulcers and 80 % of patients with gastric ulcers are found to be infected with H. pylori. Treatment for H. pylori infection includes varied combinations of antibiotics, proton pump inhibitors (PPIs), histamine H2 receptor antagonists and bismuth compounds. Eradication of H. pylori significantly lowers the recurrence rate of H. pylori-associated peptic ulcers.

H. Pylori Testing Methods

H. pylori infection can be confirmed by invasive or noninvasive methods. Invasive tests require upper esophagogastroduodenal (EGD) endoscopy, which is considered the reference method of diagnosis. During endoscopy, biopsy specimens of the stomach and duodenum are obtained, and the diagnosis of H. pylori can be made by urease testing, histology and/or culture. If possible, noninvasive testing is done before tissue testing. Noninvasive methods include H. pylori stool antigen (HpSA), serology, and urea breath testing (UBT). The clinical utility of these testing methods lies in their ability to accurately identify H. pylori infection, which allows for subsequent treatment and eradication. The UBT has been proven to be a safe and effective test for identifying the presence of H. pylori with established sensitivity and specificity ranges of 94–98%. The accuracy of the UBT is comparable to endoscopic biopsy and to HpSA testing which has a sensitivity and specificity of 92–98% (Islam, et al., 2005; Perri, et al., 2005).

Serological assays measure specific H. pylori immunoglobulin G (IgG) antibodies that can determine if an individual has been infected. Serological testing has been the mainstay of H. pylori diagnosis, particularly in primary care, due to the accessibility, rapid results and low cost of this testing method. However, some serological tests have not been locally validated and therefore have suboptimal sensitivity and specificity in practice. The value of noninvasive H. pylori testing is also related to the background prevalence of H. pylori infection. False-positives are more likely to occur in areas where H. pylori infections are less prevalent (Talley, et al., 2005a). Serological tests are also unreliable indicators of H. pylori status in patients who have received treatment for the infection. Because it cannot distinguish between current and past infection, serological testing has poor accuracy in settings of low and intermediate H. pylori prevalence, limiting its value in the United States (Vakil and Fendrick, 2005).

Serology testing for H. pylori pre-dates the UBT and the HpSA test, and has been reported to have decreased accuracy based on local validation with a wider sensitivity and specificity range of 80–95%. Since the positive predictive value of antibody testing is influenced by the prevalence of an infection, the PPV in areas of low prevalence such as much of the United States is poor. A positive test has little value in predicting the actual presence of an active infection. False-positives lead to inappropriate treatment, as well as lack of treatment response and encouragement of antibiotic resistance (Vakil and Fendrick, 2005). The low accuracy of serology testing results in the need for additional confirmatory non-invasive (i.e., UBT, HpSA), or invasive (i.e., endoscopy/biopsy) testing. Therefore the performance and clinical utility of this testing method compared to other non-invasive methods is lacking.

Professional Societies/Organizations
According to the American College of Gastroenterology (ACG) practice guidelines for the management of H. pylori infection, antibody testing (e.g., serum, whole blood, urine) is widely available but has poor positive predictive value in populations with a low prevalence of H. pylori infection, limiting its usefulness in clinical practice. Antibody testing is of limited benefit in documenting eradication of H. pylori, as results can remain positive years after successful cure of the infection. The UBT and fecal antigen test are reliable methods of identifying active H. pylori infection before and proving H. pylori eradication after antibiotic therapy (Chey, et al., 2007).

The American Gastroenterological Association (AGA) medical position statement on the evaluation of dyspepsia states that noninvasive H. pylori testing is optimally performed by a 13C-urea breath test or stool antigen test (Talley, 2005b).

Use Outside of the US
The European Helicobacter Study Group (EHSG) promotes multidisciplinary research and organizes consensus conferences to explore issues surrounding H. pylori infection. The Fourth Maastricht/Florence Consensus Conference included 44 experts from 24 countries who issued the following recommendations regarding diagnostic testing for H. pylori (Malfertheiner, et al., 2012):

1. The diagnostic accuracy of the stool antigen test (SAT) is equivalent to the UBT if a validated laboratory-based monoclonal test is used
2. The serological tests are not all equivalent. Only validated IgG serology tests should be used owing to variability in the accuracy of different commercial tests. Evidence level: 1b; Grade of recommendation: B
3. In patients treated with PPIs: if possible, PPI should be stopped for two weeks before testing by culture, histology, rapid urease test, UBT or stool test. Evidence level: 1b; Grade of recommendation: A
4. If it is not possible, validated IgG serology can be performed. Evidence level: 2b; Grade of recommendation:

Joint evidence-based guidelines from the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN), and the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN) include the following regarding H. pylori testing methods (Koletzko, et al., 2011):

1. It is recommended that the initial diagnosis of H. pylori infection be based on either a positive histopathology plus a positive rapid urease test or a positive culture.
2. The 13C-urea breath test (UBT) is a reliable noninvasive test to determine whether H. pylori has been eradicated.
3. A validated enzyme-linked immunosorbent assay (ELISA) test for detection of H pylori antigen in stool is a reliable noninvasive test to determine whether H pylori has been eradicated.
4. Tests based on the detection of antibodies (IgG, IgA) against H. pylori in serum, whole blood, urine, and saliva are not reliable for use in the clinical setting.
5. It is recommended that clinicians wait at least 2 weeks after stopping proton pump inhibitor (PPI) therapy and 4 weeks after stopping antibiotics to perform biopsy-based and noninvasive tests (UBT, stool test) for H pylori.

According to the National Institute for Clinical Excellence (NICE) guidelines for the management of dyspepsia in adults, H. pylori can be initially detected using either a carbon-13 urea breath test (UBT), stool antigen test or laboratory-based serology where its performance has been locally validated. (NICE, 2004).

Summary
Esophagogastroduodenal (EGD) endoscopy with biopsy is considered the reference method for the diagnosis of Helicobacter pylori (H. pylori). The overall body of literature suggests that noninvasive testing with the urea breath test (UBT) is as clinically useful as endoscopy in managing select patients with uncomplicated upper gastrointestinal symptoms. H. pylori stool antigen (HpSA) testing provides an acceptable alternative to UBT. Serological testing has suboptimal sensitivity and specificity and a lower positive predictive value than breath testing and stool antigen testing in areas of low H. pylori prevalence. Serological testing also cannot distinguish between active and resolved infection, limiting its clinical utility in confirming eradication of H. pylori at the conclusion of therapy. Serology-based testing has not been shown to improve patient outcomes, as a positive test often requires confirmation with a proven testing method. Profesional societies such as the American College of Gastroenterology (ACG) and the American Gastroenterological Association (AGA) no longer recommend the use of serologic testing. As such, this testing method is unproven for the diagnostic management of H. pylori.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement
3) ICD-10-CM Diagnosis Codes are for informational purposes only and are not effective until 10/01/2015.

Experimental/Investigational/Unproven/Not Covered:

CPT* Codes	Description
86677	Antibody; Helicobacter pylori

ICD-9-CM Diagnosis Codes	Description
	All codes

ICD-10-CM Diagnosis Codes	Description
	All codes

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