BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:
Helicobacter Pylori Testing

Policy #: 258
Category: Medicine/Laboratory

Latest Review Date: July 2018
Policy Grade: **Effective 02/06/2013**: **Active Policy but no longer scheduled for regular literature reviews and updates.**

Background:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

Description of Procedure or Service:

The recognition of the role of the bacterium Helicobacter Pylori (H. Pylori) in the pathogenesis of peptic ulcer disease has revolutionized the therapy of peptic ulcer. Specifically, 80% to 95% of patients with duodenal ulcers and 70% to 90% of patients with gastric ulcers have coexisting H. Pylori gastritis. Eradication of H. Pylori infection using a variety of combinations of antibiotics, bismuth compounds, and acid suppression therapy has emerged as a basic treatment strategy for these ulcers. However, it is important to realize that the majority of patients positive for H. Pylori do not develop ulcer symptoms. In addition, the role of H. Pylori therapy in non-ulcer dyspepsia alone is uncertain. Dyspepsia refers to a group of symptoms which include epigastric pain or discomfort, indigestion, upset stomach, bloating or nausea. Some dyspepsia symptoms (e.g. postprandial gnawing or burning relieved by foods or antacids) are suggestive of ulcers. Other symptoms (e.g. belching, bloating, or fullness) may be related to non-ulcer dyspepsia. Nevertheless, there is considerable overlap between ulcer and non-ulcer dyspepsia. Invasive detection of H. Pylori involves upper GI endoscopy with a biopsy. Non-invasive methods include serologic identification of anti-H. Pylori antibodies, detection of H. Pylori antigens in the feces, or the urea breath test (UBT). While serologic tests indicate either past or present infection, fecal antigens and UBT indicates active disease.

Noninvasive Testing for H. pylori

Urea Breath Test (UBT)

Urea breath testing is based on the high urease activity of H. Pylori, which hydrolyzes urea to carbon dioxide and ammonia. In the urea breath test, the patient ingests urea labeled with a carbon isotope, either 13C or 14C, and then the concentration of the isotope is measured in the expired CO2. Analysis of the concentration of 13C requires the use of mass spectrometry, and the sample must be submitted to the manufacturer's reference laboratory for analysis. In contrast, 14C is radioactive, and while its use exposes the patient to a small dose of radiation, its presence can be measured using scintillation counting.

The sensitivity and specificity of the UBT is reported to be 88% and 95-100%, respectively. False positive results are uncommon. Patients being tested for H. pylori should discontinue PPIs, bismuth, and/or antibiotics prior to being tested. These medications could cause false negative results.

Fecal Antigen Test

H. Pylori antigens can be detected in the stool by applying antibodies to a diluted stool sample complexed to a detection molecule.

The sensitivity and specificity of the fecal antigen test is reported to be 94% and 97%, respectively. This testing can be affected by PPIs, bismuth, and/or antibiotics as well and should be discontinued prior to testing.

Serological Test

Serological testing for H. pylori does not dependably differentiate between active and past infections, and additionally, it requires validation at the local level. The sensitivity and specificity of serological testing has been reported to be 85% and 79% respectively.

Policy:

Effective for dates of service on and after September 10, 2018:

Blue Advantage will treat **Urea Breath Testing using the carbon isotope (13C or 14C) or fecal antigen testing for Helicobacter Pylori (H. Pylori)** as a **covered benefit** in patients who meet **one** of the following criteria below:

1. Evaluation of new onset dyspepsia in persons younger than 60 years of age **without** alarm symptoms (anemia, weight loss, vomiting, lymphadenopathy); OR
2. Evaluation of persons with persistent symptoms of dyspepsia despite 2 weeks of appropriate medication therapy for H. pylori; OR
3. Evaluation of persons with a prior history of untreated H. Pylori infection and with recurrent symptoms.
4. Before starting proton pump inhibitor therapy for dyspepsia; OR
5. Before bariatric surgery for obesity; OR
6. Re-evaluation to assess success of eradication of H. pylori infection (Note: testing to ensure eradication should occur no sooner than 4 weeks post treatment).

Blue Advantage will treat **serologic testing for H. Pylori** as a **covered benefit** in patients who meet one of the following criteria below:

1. Evaluation of new onset dyspepsia in patients younger than 60 years of age **without** alarm symptoms (anemia, weight loss, vomiting, lymphadenopathy); OR
2. Before bariatric surgery for obesity

Blue Advantage will treat **Urea Breath Testing using the carbon isotope (13C or 14C), fecal antigen testing, or serological testing for Helicobacter Pylori (H. Pylori)** as a **non-covered benefit** and **investigational for all other indications, including but not limited to, the following:**

1. Assessing the risk of developing dementia
2. Dyspepsia associated with alarm markers (Endoscopy is recommended)
3. Evaluating infantile colic
4. Managing recurrent aphthous stomatitis
5. New onset dyspepsia in persons aged 60 years or older (upper GI endoscopy is indicated because of concern for gastric neoplasia)
6. Screening of asymptomatic person for H. pylori infection

Blue Advantage will treat **any combination of simultaneous urea breath testing, fecal antigen testing, and/or serological testing for H. pylori** as a **non-covered benefit and as not medically necessary.**

Effective for dates of service on or after February 10, 2006 and prior to September 10, 2018:

Blue Advantage will treat the **Urea Breath Test (UBT) using the carbon isotope (13C or 14C) or the fecal antigen test to detect Helicobacter pylori (H. pylori)** infection as a **covered** benefit in patients who meet these criteria:

1. Patients with a prior history of treated H. pylori infection and with recurrent symptoms.
2. As a follow-up to determine H. pylori eradication in patients with peptic ulcer and either:
   a. Persistent symptoms after an initial course of anti-H. pylori therapy; OR
   b. High risk factors for ulcer recurrence, such as documented peptic ulcers complicated by bleeding, perforation, or obstruction.
3. In dyspeptic patients ≤ age 55 years with **no** alarm symptoms (e.g., weight loss, bleeding, dysphagia, anemia, abdominal mass, jaundice, family history of gastric cancer, personal history of peptic ulcer, anorexia, early satiety, etc.) in populations where there is a moderate to high prevalence of H. pylori infection (≥ 10%).

Blue Advantage will treat **serologic testing for H. pylori** as a **covered** benefit as a part of the initial workup of a patient with newly diagnosed dyspepsia to guide appropriate empiric therapy or as part of the preoperative evaluation of patients undergoing bariatric surgery (Roux-en-y gastric bypass).

Blue Advantage will treat the **UBT or fecal antigen test** as a **non-covered** benefit, including but not limited to the following conditions:

1. Routine screening of asymptomatic persons for H. pylori infection.
2. As part of the initial work up in patients < 50 years of age with newly diagnosed dyspepsia to guide appropriate empiric therapy; serologic testing is sufficient.
3. As a routine follow-up test to determine H. pylori eradication in patients with peptic ulcer but without persistent symptoms or high risk factors for recurrence.
4. As part of the initial work up of patients with dyspepsia and at increased risk for gastric malignancy, i.e., patients over age 50 and those with “alarm” symptoms of anorexia, early satiety, weight loss, anemia, or gastrointestinal bleeding. These patients are candidates for immediate endoscopy.

Blue Advantage will treat the **simultaneous use of the UBT and the fecal antigen test for H. pylori infection** as a **non-covered** benefit because concurrent testing with both methods is not necessary.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most

appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

Prevalence of H. Pylori infection correlates best socio-economic status rather than race. In the United States, probability of being infected is greater for older persons (>50 years = >50%), minorities (African Americans 40-50%) and immigrants from developing countries (Latino > 60%, Eastern Europeans > 50%).

Urea Breath Test

In 2013, Ling evaluated the diagnostic accuracy and clinical utility of the 13C UBT in adult patients with ulcer like dyspepsia who have no alarm features. A literature search was performed using Ovid MEDLINE, Ovid MEDLINE In-Process and Other Non-Indexed Citations, Ovid Embase, the Wiley Cochrane Library, and the Centre for Reviews and Dissemination database, for studies published between 2003 and 2012. From 19 diagnostic studies, the ^{13}C UBT summary estimates were 98.1% (95% confidence interval [CI], 96.3-99.0) for sensitivity and 95.1% (95% CI, 90.3-97.6) for specificity. In 6 studies that compared the ^{13}C UBT with serology, the 1^{13}C UBT sensitivity was 95.0% (95% CI, 90.1-97.5) and specificity was 91.6 % (95% CI, 81.3-96.4). The sensitivity and specificity for serology were 92.9% (95% CI, 82.6-97.3) and 71.1% (95% CI, 63.8-77.5), respectively. In 1 RCT, symptom resolution, medication use, and physician visits were similar among the ^{13}C UBT, serology, gastroscopy, or empirical treatment arms. However, patients tested with ^{13}C UBT reported higher dyspepsia-specific quality of life scores. A noted limitation was processing of the ^{13}C UBT results can vary according to many factors. Further, the studies showed significant heterogeneity and used different composite reference standards. The authors concluded that the 13C UBT is an accurate test with high sensitivity and specificity. Compared with serology, it has higher specificity.

In 2015, Ferwana et al performed a meta-analysis on the accuracy of urea breath test to diagnose H pylori infection in patients with dyspepsia. A total of 23 studies met the eligibility criteria. Fourteen studies (61%) evaluated 13C UBT and 9 studies (39%) evaluated 14C UBT. There was significant variation in the type of reference standard tests used across studies. Pooled sensitivity was 0.96 (95% CI: 0.95-0.97) and pooled specificity was 0.93 (95%CI: 0.91-0.94). Likelihood ratio for a positive test was 12 and for a negative test was 0.05 with an area under the curve of 0.985. Meta-analyses were associated with a significant statistical heterogeneity that remained unexplained after subgroup analysis. There was evidence of moderate bias. The authors concluded by stating that UBT has high diagnostic accuracy for detecting H. pylori infection in patients with dyspepsia.

Fecal Antigen Test

In 2016, Saha et al evaluated the application of a stool antigen test to assess the burden of H pylori (HP) infection in dyspepsia patients. This prospective study was conducted to find out the prevalence of HP infection based on stool antigen testing in 50 dyspeptic patients who had also undergone upper gastrointestinal (GI) endoscopy. Using stool antigen testing, a total of 30 (60%) samples tested were positive for the HP antigen. Using endoscopy, only 15 of the 30 positive samples were suggestive of HP infection. The authors found HP stool antigen testing to be

superior to upper GI endoscopy for detecting HP infection. They recommended initial testing for HP stool antigen in dyspeptic patients before initiating treatment and before carrying out any invasive procedure such as endoscopy.

Serologic Testing
In 2013, Iqbal et al evaluated the percentage agreement between serology and histology for detection of H. pylori infection. Fifty subjects were selected by non-probability purposive sampling from laboratory data who had serological testing of H. pylori IgG antibody, prior to histological evaluation of endoscopic gastric or/and duodenal biopsies. Serological Quantification of H. pylori IgG was carried out with HpG screen ELISA kit (Genesis Diagnostics, UK), using an enzyme linked immunosorbent assay for detection of IgG antibodies against H. pylori. Manufacturer's recommended cutoff value was used and results were considered positive when greater than 7 U/ml. For histological diagnosis, an expert histopathologist characterized the presence of spiral bacteria in the mucosal layer or the surface of epithelial cells on microscopic examination, as a positive test. An agreement of 0.72 was found by Kappa statistics between serology and histopathology results and a good diagnostic accuracy (86%) of serological testing was observed for the diagnosis of H. pylori infection. A substantial agreement was found between serology and histopathology results to detect the H. pylori infection. Laboratory-based serologic testing using ELISA technology to detect IgG antibodies is inexpensive, noninvasive and convenient method to detect the H. pylori infection in primary care setting.

Gastric Bypass
In 2018, Mocanu et al aimed to systematically review the effect of H pylori on bariatric surgery outcomes. A comprehensive literature review was conducted which consisted of 7 studies with 255,435 patients. Meta-analysis showed no significant difference in the rates of bleeding, leak, hospital length of stay, and wight loss between H pylori positive and H pylori negative patients. However, it was found that H pylori was the largest independent predictor of marginal ulceration in those who had Roux en-Y gastric bypass, with a tenfold increase versus H pylori negative patients. The authors concluded that H pylori is associated with increased marginal ulceration rates, but has little impact on other bariatric surgery outcomes.

In 2016, Chaves et al prospectively evaluated the incidence of inflammatory lesions in the stomach after bariatric surgery and to correlate it with H pylori infection. The study included 216 patients undergoing Roux en-Y gastric bypass. All patients underwent endoscopic procedures to detect H. pylori prior to surgery. Positive cases were treated with antibiotics and a proton inhibitor pump with follow up in the 6^{th} and 12^{th} month after surgery. Most patients were female (68.1%), with grade III obesity (92.4%). Preoperative endoscopy revealed gastritis in 96.8%, with H. pylori infection in 40.7% (88/216). A biopsy was carried out in 151 patients, revealing H. pylori in 60/151, related to signs of inflammation in 90% (54/60). In the 6th and 12th month after surgery, the endoscopy and the histopathological exam showed a normal gastric pouch in 84% of patients and the incidence of H. pylori was 11% and 16%, respectively. The presence of inflammation was related to H. pylori infection ($p<0,001$). The authors concluded that when inflammatory disease is present in the new gastric reservoir, it is directly related to H. pylori infection.

Dementia
In 2013, Baudron et al published a prospective community based cohort study to determine if H. pylori infection was associated with dementia. They also evaluated the risk of developing dementia in a longitudinal population-based cohort of elderly adults living in the community. A total of 603 non-institutionalized individuals aged 65 and older living in the southwest of France followed from 1989 to 2008 were included in this study. A descriptive and comparative analysis including dementia prevalence, according to H. pylori status (serology), was made at baseline. Cox proportional hazard models were used to study the risk of developing dementia according to H. pylori status assessed on sera samples from elderly adults initially free of dementia and followed for 20 years. A neurologist diagnosed dementia according to Diagnostic and Statistical Manual of Mental Disorders Third Edition criteria. At baseline, 391 (64.8 %) subjects (348 women, mean age of 73.9 ± 6.5 years) were sero-positive for H. pylori. Dementia prevalence was higher in the infected group (5.4 % versus 1.4 %, p = 0.02). After 20 years of follow-up, 148 incident cases of dementia were diagnosed. After controlling for age, sex, educational level, apolipoprotein E4 status, cardiovascular risk factors, and Mini-Mental State Examination score, H. pylori infection was determined to be a risk factor for developing dementia (hazard ratio = 1.46, p = 0.04). Although the authors concluded that this longitudinal population-based study provided additional epidemiological support to the hypothesis of an association between dementia and H. pylori infection, further research is needed.

In 2015, Tsolaki et al published a study to determine the association between various forms of dementia, primary open angle glaucoma and H pylori. The study included 156 patients who were divided into groups (dementia group, glaucoma group, and 2 control groups). All patients underwent neuropsyschological evaluation to detect dementia, an eye exam to detect glaucoma, and H pylori diagnostic testing. The authors reported there were positive correlations found between H pylori infection and dementia. They further state that continued research in this field might further clarify the link between dementia, glaucoma and H pylori.

In 2018, Fani et al studied the association between H pylori serology and dementia risk in a population based cohort. The authors measured H pylori serum IgG titers in 4215 non-demented participants of the Rotterdam Study between 1997-2002. The mean age of the participants was 69 years. They determined the association between H. pylori at baseline and dementia incidence until 2015, per natural log (U/mL) increase in titer, and for seropositive/seronegative, using Cox models adjusting for cohort, sex, age, education, and cardiovascular risk factors. During a median follow up of 13.3 years, 529 participants developed dementia, of which 463 had Alzheimer's disease. H. pylori was not associated with risk of dementia (hazard ratio [95% confidence interval] for antibody titer: 1.04 [0.90-1.21]; for seropositivity 1.03 [0.86-1.22]), or Alzheimer's disease. The authors also state that available evidence of H pylori infection increasing the risk of dementia are inconsistent, and longitudinal studies are sparse.

Infantile Colic
In 2012, Ali published a case control study in Saudi Arabia to determine whether Helicobacter pylori is associated with infantile colic. A total of 55 patients with infantile colic who were 2 weeks to 4 months of age and who fulfilled modified Wessel criteria (i.e., crying and fussy behavior) and a total of 30 healthy controls with no history of colic who were matched by country of origin, age, sex, and ethnicity to the 55 colicky infants. The main outcome measure

was H pylori infection determined by H pylori stool antigen testing. Of the 55 patients presenting with infantile colic, 45 (81.8%) tested positive for H pylori; of the 30 healthy controls, 7 (23.3%) tested positive for H pylori (odds ratio, 15.3 [95% CI, 17.9-29.8]).The author concluded that H pylori infection is associated with infantile colic and may be a causative factor.

Recurrent aphthous stomatitis

In 2016, Gomes et al stated that recurrent aphthous stomatitis (RAS) is a recurrent painful ulcerative disorder that commonly affects the oral mucosa. Local and systemic factors such as trauma, food sensitivity, nutritional deficiencies, systemic conditions, immunological disorders and genetic polymorphisms are associated with the development of the disease. Helicobacter pylori is a gram-negative, microaerophilic bacteria, that colonizes the gastric mucosa and it was previously suggested to be involved in RAS development. These investigators reviewed all previous studies that investigated the association between RAS and H. pylori. A search in PubMed (Medline) databases was made of articles published up until July 2015 using the following keywords: Helicobacter pylori or H. pylori and RAS or recurrent aphthous stomatitis. A total of 15 experimental studies that addressed the relationship between infection with H. pylori and the presence of RAS and 3 reviews, including a systematic review and a meta-analysis were included in this review. The studies reviewed used different methods to assess this relationship, including PCR, nested PCR, culture, ELISA and urea breath test (UBT). A large variation in the number of patients included in each study, as well as inclusion criteria and laboratorial methods was observed; H. pylori can be detected in the oral mucosa or ulcerated lesion of some patients with RAS. The quality of the all studies included in this review was assessed using levels of evidence based on the University of Oxford's Center for Evidence Based Medicine Criteria. The authors concluded that although the eradication of the infection may affect the clinical course of the oral lesions by undetermined mechanisms, RAS ulcers are not associated with the presence of the bacteria in the oral cavity and there is no evidence that H. pylori infection drives RAS development.

Summary of Evidence

For individuals undergoing testing for H. pylori for the risk of developing dementia, dyspepsia with alarm markers, evaluating infantile colic, managing recurrent aphthous stomatitis, new onset dyspepsia older than 60 years, and the screening of asymptomatic patients for HP infection, the evidence consists of cohort studies and case control studies. Overall, the evidence is weak and only hypotheses are presented in several of the studies. High quality and long term data are needed to determine the net health outcome.

Practice Guidelines and Position Statements

American College of Gastroenterology (ACG)

In 2017, the ACG and the Canadian Association of Gastroenterology published a joint guideline on the management of dyspepsia.

The summary and strength of recommendations are in Table 1.

Table 1: Management of dyspepsia

We suggest dyspepsia patients aged 60 or over have an endoscopy to exclude upper gastrointestinal neoplasia.	Conditional recommendation, very low quality evidence.
We do not suggest endoscopy to investigate alarm features for dyspepsia patients under the age of 60 to exclude upper GI neoplasia.	Conditional recommendation, moderate quality evidence
We recommend dyspepsia patients under the age of 60 should have a non-invasive test for *H. pylori* , and therapy for *H. pylori* infection if positive.	Strong recommendation, high quality evidence
We recommend dyspepsia patients under the age of 60 should have empirical PPI therapy if they are *H. pylori* -negative or who remain symptomatic after *H. pylori* eradication therapy.	Strong recommendation, high quality evidence.
We suggest dyspepsia patients under the age of 60 not responding to PPI or *H. pylori* eradication therapy should be offered prokinetic therapy.	Conditional recommendation very low quality evidence.
We suggest dyspepsia patients under the age of 60 not responding to PPI or *H. pylori* eradication therapy should be offered TCA therapy.	Conditional recommendation low quality evidence.
We recommend FD patients that are *H. pylori* positive should be prescribed therapy to treat the infection.	Strong recommendation, high quality evidence.
We recommend FD patients who are *H. pylori* -negative or who remain symptomatic despite eradication of the infection should be treated with PPI therapy.	Strong recommendation, moderate quality evidence.
We recommend FD patients not responding to PPI or *H. pylori* eradication therapy (if appropriate) should be offered TCA therapy.	Conditional recommendation, moderate quality evidence.
We suggest FD patients not responding to PPI, *H. pylori* eradication therapy or tricyclic antidepressant therapy should be offered prokinetic therapy.	Conditional recommendation, very low quality evidence
We suggest FD patients not responding to drug therapy should be offered psychological therapies.	Conditional recommendation, very low quality evidence.
We do not recommend the routine use of complementary and alternative medicines for FD.	Conditional Recommendation, very low quality evidence.
We recommend against routine motility studies for patients with FD.	Conditional recommendation, very low quality evidence.
We suggest motility studies for selected patients with FD where gastroparesis is strongly suspected.	Conditional recommendation, very low quality evidence.

FD, functional dyspepsia; *H. pylori* , *Helicobacter pylori* ; PPI, proton pump inhibitor; TCA, tricyclic antidepressant.

Also in 2017, the ACG updated their clinical guidelines regarding the treatment of Helicobacter pylori.

The indications to test for, and to treat, H. pylori infection are in Table 2.

Table 2: Indications to test for and treat H. Pylori

Since all patients with a positive test of active infection with *H. pylori* should be offered treatment, the critical issue is which patients should be tested for the infection	strong recommendation, quality of evidence: not applicable
All patients with active peptic ulcer disease (PUD), a past history of PUD (unless previous cure of H. pylori infection has been documented), low-grade gastric	strong recommendation, quality of evidence: high for active or history of PUD, low for MALT lymphoma, low for history of endoscopic resection of EGC

mucosa-associated lymphoid tissue (MALT) lymphoma, or a history of endoscopic resection of early gastric cancer (EGC) should be tested for H. pylori infection. Those who test positive should be offered treatment for the infection	
In patients with uninvestigated dyspepsia who are under the age of 60 years and without alarm features, non-endoscopic testing for *H. pylori* infection is a consideration. Those who test positive should be offered eradication therapy	Conditional recommendation, quality of evidence: high for efficacy, low for the age threshold
When upper endoscopy is undertaken in patients with dyspepsia, gastric biopsies should be taken to evaluate for *H. pylori* infection. Infected patients should be offered eradication therapy	Strong recommendation, high quality of evidence
Patients with typical symptoms of gastroesophageal reflux disease (GERD) who do not have a history of PUD need not be tested for *H. pylori* infection. However, for those who are tested and found to be infected, treatment should be offered, acknowledging that effects on GERD symptoms are unpredictable	strong recommendation, high quality of evidence
In patients taking long-term low-dose aspirin, testing for *H. pylori* infection could be considered to reduce the risk of ulcer bleeding. Those who test positive should be offered eradication therapy	conditional recommendation, moderate quality of evidence
Patients initiating chronic treatment with a non-steroidal anti-inflammatory drug (NSAID) should be tested for *H. pylori* infection	strong recommendation, moderate quality of evidence
Those who test positive should be offered eradication therapy. The benefits of testing and treating *H. pylori* in patients already taking NSAIDs remains unclear	conditional recommendation, low quality of evidence
Patients with unexplained iron deficiency (ID) anemia despite an appropriate evaluation should be tested for *H. pylori* infection. Those who test positive should be offered eradication therapy	conditional recommendation, high quality of evidence
Adults with idiopathic thrombocytopenic purpura (ITP) should be tested for *H. pylori* infection. Those who test positive should be offered eradication therapy	conditional recommendation, very low quality of evidence
There is insufficient evidence to support routine testing and treating of *H. pylori* in asymptomatic individuals with a family history of gastric cancer or patients with lymphocytic gastritis, hyperplastic gastric polyps and hyperemesis gravidarum	no recommendation, very low quality of evidence

Key Words:

Helicobacter Pylori (H. Pylori), urea breath test (UBT), 13C isotope, 14C isotope, dyspepsia, peptic ulcer disease, fecal antigen test, serological testing

Approved by Governing Bodies:

The FDA has approved multiple tests for urea breath testing and fecal antigen testing.

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

Coding:

CPT Codes:

78267	Urea breath test, C-14 (isotopic); acquisition for analysis
78268	Urea breath test, C-14 (isotopic); analysis
83009	Helicobacter Pylori, blood test analysis for urease activity, non-radioactive isotope (e.g., C-13)
83013	Helicobacter Pylori; breath test analysis for urease activity, non-radioactive isotope (e.g., C-13)
83014	Helicobacter Pylori; drug administration
86677	Antibody; Helicobacter pylori
87338	Infectious agent antigen detection by enzyme immunoassay technique, qualitative or semi-quantitative, multiple step method; Helicobacter Pylori, stool

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Medical Policy Group **(4):** Updates to Description, Policy, Key Points, Key Words, Approved by Governing Bodies, Current Coding and References. Updated policy section by adding bariatric surgery under UBT/fecal antigen testing, updated age for evaluation of new onset dyspepsia to younger than 60, added additional IV criteria. Added Key Word serological testing. Added CPT code 86677 to Current Coding.
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