BlueCross BlueShield of Alabama

Name of Policy:
Helicobacter Pylori Testing

Policy #: 258
Category: Medicine/Laboratory

Latest Review Date: February 2010
Policy Grade: **Effective 02/06/2013**: **Active Policy but no longer scheduled for regular literature reviews and updates.**

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

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 is non-ulcer dyspepsia alone is uncertain. Dyspepsia refers to a symptom complex of epigastric pain or discomfort. While some dyspepsia symptoms, such as a postprandial gnawing or burning relieved by foods or antacids are suggestive of ulcer, others, such as belching, bloating, and fullness are referred to as non-ulcer dyspepsia. Nevertheless, there is considerable overlap between ulcer and non-ulcer dyspepsia. Coincident with the increased understanding of the pathophysiology of H. Pylori has been the development of non-invasive methods of detection of H. Pylori. Invasive detection of H. Pylori involves endoscopy followed by culture and either direct histologic identification of the organism, or detection of the organism using the CLO (Campylobacter-like organism) test. 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, either fecal antigens or a UBT indicates active disease.

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, a more readily available and economical technique.

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

The availability of non-invasive testing that differentiates between past or present infection of H. Pylori has prompted reconsideration of the treatment algorithms for patients presenting with dyspepsia. H. Pylori testing has been investigated in the following clinical situations:

I. The Initial Work-up of Patients with Simple Dyspepsia Symptoms

Patients presenting with uncomplicated dyspepsia have commonly been treated with an empiric trial of antisecretory therapy, followed by endoscopy only if symptoms persisted. Initial endoscopy was reserved for those patients with "alarm symptoms" suggestive of possible malignancy, e.g., anemia, gastrointestinal bleeding, early satiety, or weight loss. In addition, due to the increasing incidence of gastric malignancy as people age, endoscopy as part of the initial work-up has been performed in patients over age 50 with new onset of dyspepsia. In new treatment

algorithms, H. Pylori testing has been used as a predictor of underlying peptic ulcer such that patients positive for H. Pylori would then undergo either:

a. Endoscopy followed by anti-H. Pylori therapy only when the peptic ulcer is confirmed; OR
b. Initial empiric therapy with anti-H. Pylori therapy followed by endoscopy only in those patients with persistent symptoms after treatment ("test and treat" strategy). In this setting, the H. Pylori test is used to determine which type of empiric therapy to use, i.e., antisecretory therapy alone or antisecretory therapy plus anti-H. Pylori therapy for those patients testing positive.

Cost effective analyses of these two treatment strategies have compared the potential decreased costs associated with reducing the number of endoscopies in those treated initially with anti-H. Pylori therapy versus the increased costs of unnecessarily treating some patients with antibiotics. As noted above, anti-H. Pylori therapy has not been definitively shown to benefit dyspepsia symptoms in the absence of ulcer. Additional concerns regarding the empiric use of anti-H. Pylori therapy are the complications of anti-H. Pylori therapy and the possible emergence of resistant strains of H. Pylori.

In patients with newly diagnosed H. Pylori infection without prior treatment, the differentiation between past or present infection is not relevant. Therefore, serologic tests are appropriate in the initial workup of the patient. In a patient with a prior history of treated H. Pylori with recurrent symptoms, a serologic test will not be informative. Therefore, either UBT or fecal antigen testing may be performed to diagnose a recurrence of H. Pylori infection.

II. UBT or Fecal Antigen Testing to Confirm Eradication of H. Pylori at the Conclusion of Therapy

Eradication rates of H. Pylori after antibiotic therapy vary from 80% to 90%. Since the purpose of this therapy is to eliminate H. Pylori in order to decrease the ulcer recurrence rate, there has been interest in documenting eradication. In this setting, breath testing or fecal antigen testing is appropriate to determine active infection. Prior to these technologies, confirmation of organism eradication required repeat endoscopic evaluation to obtain gastric antral biopsy specimens for histology of the CLO test. In most cases, it is unnecessary to document bacterial eradication with follow-up testing; monitoring of clinical symptoms is sufficient. However, patients with persistent symptoms after therapy and those at high risk for recurrence, such as patients with ulcers complicated by bleeding or perforation, may benefit from this testing to determine the necessity for additional anti-H. Pylori therapy.

Currently, there are two UBTs approved by the FDA: the 13C-based test (Meretek) and the radioactive 14C-based test (Tri-Med). They have similar performance characteristics. Although the 14-C test is radioactive, the dose can be low and the test is less expensive. This test should not be given to children or women of child-bearing potential. Both of these tests are qualitative, not quantitative.

Policy:

The **Urea Breath Test (UBT) using the carbon isotope (13C or 14C) or the fecal antigen test to detect Helicobacter Pylori (H. Pylori)** infection **meets** Blue Cross and Blue Shield of Alabama's medical criteria for coverage in patients who meet these criteria:

1. Patients with a prior history of treated H. Pylori infection **(ICD-9 code: 041.86)** and with recurrent symptoms.
2. As a follow-up to determine H. Pylori eradication in patients with peptic ulcer **(ICD-9 codes: 533.00-533.91)** 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%).

Serologic testing for H. Pylori meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage as a part of the initial workup of a patient with newly diagnosed dyspepsia **(ICD-9 code: 536.8)** to guide appropriate empiric therapy or as part of the preoperative evaluation of patients undergoing bariatric surgery (Roux-en-y gastric bypass).

The **UBT or fecal antigen test does not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage, including but not limited to the following conditions:

1. Routine screening of asymptomatic persons for H. Pylori infection. **(ICD-9 code: 041.86)**
2. As part of the initial work up in patients < 50 years of age with newly diagnosed dyspepsia **(ICD-9 code: 536.8)** 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 **(ICD-9 codes: 533.00-533.91)** 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.

The **simultaneous use of the UBT and the fecal antigen test for H. Pylori infection does not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage because concurrent testing with both methods is not necessary.

Blue Cross and Blue Shield of Alabama 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 Cross and Blue Shield of Alabama administer benefits based on the

members' contract and corporate 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%). The infection is less common in more affluent Caucasians (< 40 years = 20%).

In 1994, the National Institutes of Health (NIH) Consensus Development Conference issued a statement on H. Pylori in peptic ulcer disease. They stated that all patients with gastric or duodenal ulcers who are infected with H. Pylori should be treated with antimicrobials. They also stated that antimicrobial therapy should not be given to asymptomatic H. Pylori-infected patients without ulcers or H. Pylori-infected patients with nonulcer dyspepsia. They noted that anti-H. Pylori therapy has an equivocal effect in patients with non-ulcer dyspepsia and thus many patients will be unnecessarily treated. Many patients find the multi-drug and multi-dose anti-H. Pylori therapy confusing, cumbersome, and unpleasant.

However, since its publication in 1994, the conclusions of this conference have been widely challenged. There have been some more recently published studies that suggest that empiric treatment with anti-H. Pylori therapy in patients with simple dyspepsia who have tested positive for H. Pylori ("test and treat") is cost effective compared to initial endoscopy or endoscopy only in patients positive for H. Pylori. This use of empiric anti-H. Pylori therapy in patients without imaging confirmation of peptic ulcer contradicts the 1994 NIH statement. Some of the studies that look at this are summarized below.

Fendrich et al (1995) reported that endoscopy, though costly, provided diagnosis and treatment and potentially reduced the number of patients inappropriately treated. However, the safety and effectiveness of less expensive, less invasive diagnostic and treatment strategies support initial non-invasive care of symptomatic patients thought to have PUD.

Ofman et al (1997) also reported that in H. Pylori-seropositive patients with dyspepsia, initial anti-H. Pylori therapy is the most cost-effective management strategy. Randomized studies of these strategies that evaluate outcomes and patient preferences are needed to optimize management decisions.

UBT and fecal antigen testing have also been used to confirm H. Pylori eradication after therapy and thus may replace endoscopy in patients with persistent symptoms or patients at high risk for recurrent ulcers. Those high-risk patients with persistent H. Pylori may benefit from additional courses of anti-H. Pylori therapy. Testing for eradication of H. Pylori in patients whose symptoms have resolved is not medically necessary.

Slomianski et al (1995) looked at the use of the 13C UBT to confirm eradication of H. Pylori. 118 H. Pylori infected patients had a 13C UBT at baseline and 6 weeks after triple therapy. All patients had a positive baseline UBT. In 101/118 patients (86%), H. Pylori was eradicated. Of these 101 patients, 95 had a negative UBT at 6 weeks. The 13C UBT had a 6-week post-treatment sensitivity of 97%, specificity of 71%, PPV of 94%, and NPV of 88%. They concluded that the 13C UBT is a sensitive indicator of H. Pylori eradication 6 weeks after treatment.

In 1998, the American College of Gastroenterology published guidelines for the management of H. Pylori infection in adults. Some of the recommendations are summarized below:

1. Diagnostic testing for H. Pylori infection should only be performed if treatment is intended.
2. Testing for H. Pylori infection is indicated in patients with active peptic ulcer disease, a past history of documented peptic ulcer, or gastric MALT lymphoma.
3. Testing for H. Pylori infection is not indicated in asymptomatic individuals without a past history of peptic ulcer disease, or in patients on long-term treatment with a proton pump inhibitor for gastroesophageal reflux disease (GERD).
4. There is no conclusive evidence that eradication of H. Pylori infection will reverse the symptoms of non-ulcer dyspepsia. Patients may be tested for H. Pylori on a case-by-case basis, and treatment offered to those with a positive result.
5. The diagnostic test to use in a particular patient depends on the clinical setting, particularly if upper GI endoscopy is performed.
6. Currently, routine post-treatment testing is only recommended in patients with a history of ulcer complications, gastric MALT lymphoma, or early gastric cancer. Patients with recurrent symptoms after treatment of H. Pylori infection will also need further evaluation.

In October 2005, the American College of Gastroenterology and its Practice Parameters Committee published new guidelines for the management of dyspepsia. Some of these revised guidelines are highlighted below.

1. In dyspeptic patients ≤ age 55 years, with no alarm features, there are 2 approximately equivalent management options:
    a. An empiric trial of acid suppression with a proton pump inhibitor (PPI) for 4-8 weeks. This option is preferred when there is a low prevalence of H. Pylori in the population. If the patient fails to respond or relapses rapidly on stopping antisecretory therapy, then the test and treat strategy is best applied before referral for EGD; OR
    b. Test and treat for H. Pylori using a validated non-invasive test and a trial of acid suppression if eradication is successful but symptoms do not resolve. This option is preferred when there is a moderate to high prevalence of H. Pylori infection (≥ 10%) in the population.

2. A notable disadvantage of test and treat is that even with curing the H. Pylori infection, only a minority of patients report symptom improvement. This can be

confusing to the clinician. However, endoscopy and targeted medical therapy does no better. In patients with peptic ulcer disease, eradication of H. Pylori infection does not relieve all symptoms in 1/3 of patients.

3. The choice of H. Pylori test is critical. Many serological tests have suboptimal sensitivity and specificity. The urea breath test and stool antigen test are currently the most accurate non-invasive diagnostic tools.

The ACG referenced the following article by Loy, et al, in the discussion of serological tests.

Loy et al (1996) published the results of a literature search on the accuracy of common commercial serological kits for H. Pylori and to ascertain factors affecting accuracy. They reviewed about 12 commercial serological kits from 21 studies. The results of their analyses suggested that different commercial kits did not have significantly different accuracy. Overall, the sensitivity = 85% and the specificity = 79%. The authors concluded that the overall accuracy of these kits may not be adequate for clinical decision-making in all patient groups.

Peng et al (2005) compared the accuracy of the 13C-UBT with conventional invasive methods to diagnose H. Pylori infection in 100 patients. The 100mg UBT capsule had 100% sensitivity and specificity. The 50mg UBT capsule had 96.4% sensitivity and 100% specificity. The accuracy of the CLO test was 92%, histology was 91%, and culture was 89%. They concluded that capsule UBT has a higher accuracy than the other 3 tests.

Kaplan (2005) published a report on the gastrointestinal management of the bariatric surgery patient. The stomach is a frequent site of complications after weight loss surgery, and little is known about what factors predispose to gastric complications. Ulcerations are thought to results primarily from local ischemia around the anastomosis, but the possible role of H. Pylori is not known. Many clinicians prefer to negate any potential contribution of H. Pylori by eradicating the organism preoperatively. The author evaluates each patient serologically for H. Pylori and treats positive results with a single course of combination therapy. In patients at high risk for H. Pylori infection or in whom serological testing may not be reliable (e.g., within 1 year after a course of therapy), it may be helpful to complement serology with H. Pylori breath testing or stool antigen testing.

The American College of Gastroenterology in August 2007 updated the guidelines on the management of H. Pylori. Chey and Wong along with members of the Practice Parameters Committee of the ACG published these guidelines with the following information being considered new:

- A subset of patients with functional dyspepsia derives benefit from H. Pylori eradication. Emerging evidence suggests an association between H. Pylori and unexplained iron deficiency anemia.
- In populations with a low pretest probability of H. Pylori infection, nonendoscopic tests such as the urea breath test and fecal antigen test offer superior positive predictive value compared with antibody tests.
- Eradication rates with a PPI, clarithromycin, and amoxicillin are decreasing worldwide. Fourteen-day courses of therapy are more effective than seven-days treatment regimens.

- Newer treatments such as sequential therapy require validation in the United States before they can be recommended as a standard first-line therapy.
- A PPI, levofloxacin, and amoxicillin for 10 days appear to be more effective and better tolerated than a PPI, bismuth, tetracycline, and metronidazole in patients with persistent H. Pylori infection but require validation in North America.

February 2010 Update
In the 2007 update of the American College of Gastroenterology Guideline on the Management of H. Pylori Infection Chen et al provided the following information on diagnosis and serologic testing. The Guideline remains the same for testing for H. Pylori, testing should only be performed if there is to be treatment for positive results. Antibody testing relies upon the detection of IgG antibodies specific to H. Pylori in serum, whole blood, or urine. IgG antibodies to H. Pylori typically become present approximately 21 days after infection and can remain present long after eradication. The advantages of the antibody tests are their low cost, widespread availability, and rapid results. There are several factors that limit the usefulness of antibody testing in clinical practice. A meta-analysis evaluated the performance characteristics of several commercially available quantitative serological assays and found their overall sensitivity and specificity to be 85% and 79%, respectively, with no differences between the different assays. It is important to understand that the PPV of antibody testing is greatly influenced by the prevalence of H. Pylori infection. Antibody tests are of little benefit in documenting eradication as results can remain positive for years following successful cure of the infection. Therefore, a negative antibody test suggests the absence of infection, a positive test is not better than a coin toss in predicting the presence of active infection. In low prevalence populations, antibody tests should be avoided or positive results should be confirmed with a test that identifies active infection such as the UBT or FAT prior to initiating eradication therapy.

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

Approved by Governing Bodies:
Not applicable

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

ITS: Home Policy provisions apply
BellSouth/AT&T contracts: No special consideration
FEP contracts: FEP does not consider investigational. Review for medical necessity.
Wal-Mart: Special benefit consideration may apply. Refer to member's benefit plan.
Pre-certification requirements: Not 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
	87338	Infectious agent antigen detection by enzyme immunoassay technique, qualitative or semi-quantitative, multiple step method; Helicobacter Pylori, stool
ICD-9 Procedure:	**89.39**	Other non-operative measurements and examinations (includes urea breath test)

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Policy History:

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Key Points updated with ACG guidelines, no policy change, February 2008 **(1)**
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Medical Policy Administration Committee, February 2010
Medical Policy Group, February 2013: **Effective 02/06/2013**: **Active Policy but no longer scheduled for regular literature reviews and updates.**
