HELICOBACTER PYLORI SEROLOGY TESTING

INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced. The terms of the federal, state or contractual requirements for benefit plan coverage may differ greatly from the standard benefit plan upon which this Medical Policy is based. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage supersedes this Medical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the contractual requirements for benefit plan coverage prior to use of this Medical Policy. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

BENEFIT CONSIDERATIONS

Before using this policy, please check the federal, state or contractual requirements for benefit coverage.

COVERAGE RATIONALE

*Helicobacter pylori (H. pylori)* serology testing is unproven and not medically necessary for diagnosing infection or evaluating treatment effectiveness.

The American Gastroenterological Association (AGA) no longer recommends serology-based testing for diagnosing infection or evaluating treatment effectiveness as it is unable to distinguish between active infection and previous exposure to *H. pylori*, does not confirm eradication and has a poor positive predictive value when compared to active infection tests such as the urea breath test or stool antigen test.

APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Coverage Determination Guidelines may apply.
**Helicobacter pylori (H. pylori)** is a common bacterium found in the lining of the stomach. *H. pylori* is found in about two-thirds of the world’s population, and infection causes the majority of peptic ulcers and is a risk factor for stomach cancer.

*H. pylori* infection can be diagnosed using invasive or noninvasive methods. Invasive methods require the use of endoscopy and include rapid urease testing, histology, culture and polymerase chain reaction. During endoscopy, biopsy specimens of the stomach and duodenum are obtained for analysis. Noninvasive methods do not use endoscopy and include urea breath test, stool antigen test and antibody testing. The urea breath test and stool antigen test identify active infection where the antibody test indicates only the presence of *H. pylori* at some time.

American College of Gastroenterology (ACG) and AGA guidelines recommend test, treat and retest to confirm eradication with an active infection test prior to prescribing a proton pump inhibitor (PPI), and for patients under the age of 55 with no alarm symptoms. Alarm symptoms can include gastrointestinal bleeding, anemia, early satiety, unexplained weight loss (>10% weight loss), progressive dysphagia, odynophagia, recurrent vomiting, family history of gastrointestinal cancer or previous esophagogastric malignancy. Noninvasive active testing methods recommended by ACG and AGA include urea breath test and stool antigen test (Chey et al., 2007).

Serology or antibody testing measures immunoglobulin G (IgG), IgA and/or IgM antibodies specific to *H. pylori* in serum, whole blood or urine. Serology testing is no longer recommended for diagnosing infection or evaluating treatment effectiveness as it is unable to distinguish between active infection and previous exposure to *H. pylori*, does not confirm eradication and has a poor positive predictive value in populations with low disease prevalence when compared to active infection tests (Centers for Disease Control, 2006; Chey et al., 2007).

### CLINICAL EVIDENCE

A meta-analysis by Loy et al. (1996) evaluated the performance characteristics of several commercially available quantitative serological assays for *H. pylori* and found their overall sensitivity and specificity to be 85% and 79%, respectively. Twenty-one studies of varying quality were included in the analysis. Test accuracy measured was significantly higher in studies with smaller proportions of infected patients. There was little evidence to suggest that any one test was more accurate than another. The authors reported that the overall accuracy of these tests may not be adequate for clinical decision-making.

National Institute for Health and Care Excellence (NICE) guidelines recommend testing for *H. pylori* using a carbon-13 urea breath test or a stool antigen test, or laboratory-based serology where its performance has been locally validated. The guidelines do not recommend the use of office-based serological tests because of their inadequate performance (NICE, 2014).

### Professional Societies

**American Association for Clinical Chemistry (AACC)**

The AACC does not recommend *H. pylori* antibody testing for routine diagnosis or for evaluation of treatment effectiveness (AACC website, 2014).

**American College of Gastroenterology (ACG)**

ACG guidelines on the management of *H. pylori* infection (Chey et al., 2007) address three nonendoscopic diagnostic testing methods: antibody test, urea breath test and stool antigen test. Antibody testing identifies an immunological reaction to the infection while the urea breath test and stool antigen test identify the presence of active *H. pylori* infection. The guidelines make the following recommendations regarding testing:

- Although antibody testing is widely available, it has a poor positive predictive value in populations with a low prevalence of *H. pylori* infection, limiting its usefulness in clinical practice.
  - The urea breath test and stool antigen test provide reliable means of identifying active *H. pylori* infection before antibiotic therapy.
  - Both the urea breath test and stool antigen test can be used to confirm eradication 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.

ACG guidelines for the management of dyspepsia (Talley and Vakil, 2005a) state that dyspeptic patients more than 55 years old, or those with alarm features, should undergo prompt endoscopy to rule out peptic ulcer disease,
esophagogastric malignancy and other rare upper gastrointestinal tract disease. Alarm features include bleeding, anemia, early satiety, unexplained weight loss (>10% body weight), progressive dysphagia, odynophagia, persistent vomiting, a family history of gastrointestinal cancer, previous esophagogastric malignancy, previous documented peptic ulcer, lymphadenopathy or an abdominal mass. In patients aged 55 years or younger with no alarm features, one option is a test and treat approach for *H. pylori* using a validated noninvasive test. The urea breath test and stool antigen test are the most accurate noninvasive diagnostic tools. Many serological tests have not been locally validated, and have suboptimal sensitivity and specificity in practice.

**American Gastroenterological Association (AGA)**

An AGA technical review on the management of dyspepsia (Talley et al., 2005b) states that tests for active *H. pylori* infection (stool antigen test and urea breath test) should be used rather than serology testing for both the initial diagnosis of infection and the confirmation of *H. pylori* eradication. This recommendation is based on the superior accuracy of tests for active *H. pylori* infection compared with serologic testing.

**U.S. FOOD AND DRUG ADMINISTRATION (FDA)**

The FDA has approved a number of serological tests for the detection of antibodies to *H. pylori*. See the following website for more information (use product code LYR):


**CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)**

Medicare does not have a National Coverage Determination (NCD) for Helicobacter pylori (*H. pylori*) serology testing. Local Coverage Determinations (LCDs) do not exist at this time. (Accessed November 11, 2016)

**REFERENCES**


**POLICY HISTORY/REVISION INFORMATION**

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