Helicobacter pylori (H. pylori) serology testing is 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.
MEDICARE & MEDICAID COVERAGE RATIONALE

Medicare does not have a National Coverage Determination (NCD) for Helicobacter pylori (H. Pylori) serology testing. Local Coverage Determinations (LCDs) for Nevada do not exist at this time. Accessed January 2017.

Medicaid Services Manual
Section 800: Laboratory Services

The Nevada Medicaid Laboratory Services program is designed to provide laboratory services under a Clinical Laboratory Improvement Amendment of 1988 (CLIA) certified provider. These services include microbiology, serology, immunohematology, cytology, histology, chemical, hematology, biophysical, toxicology or other methods of “in-vitro” examination of tissues, secretions, excretions, or other human body parts. Clinical laboratory services are furnished primarily in three distinct settings: independent clinical laboratories, physician office laboratories and hospital-based laboratories. Such services shall maintain a high standard of quality and shall be provided within the limitations and exclusions specified within this chapter.

DESCRIPTION OF SERVICES

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):

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 the member specific benefit plan document 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.

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REFERENCES


## POLICY HISTORY/REVISION INFORMATION

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The foregoing Health Plan of Nevada/Sierra Health & Life Healthcare Operations protocol has been adopted from an existing UnitedHealthcare coverage determination guideline that was researched, developed and approved by the UnitedHealthcare Coverage Determination Committee.