Clinical Policy: Helicobacter Pylori Serology Testing

Reference Number: CP.MP.153 Coding Implications
Last Review Date: 10/20 Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Helicobacter pylori (H. pylori) is the most prevalent chronic bacterial infection and is associated with peptic ulcer disease, chronic gastritis, gastric adenocarcinoma, and gastric mucosa associated lymphoid tissue (MALT) lymphoma. Noninvasive tests for the diagnosis of H. pylori include urea breath testing (UBT), stool antigen testing, and serology.[1]

Policy/Criteria
I. It is the policy of health plans affiliated with Centene Corporation® that H. pylori serology testing is **not medically necessary** for diagnosing infection or evaluating treatment effectiveness.

Background
The most common causes of peptic ulcer disease (PUD) are H. pylori infection and use of nonsteroidal anti-inflammatory drugs (NSAIDs). H. pylori infection causes progressive functional and structural gastroduodenal damage.[4] Accurate diagnosis of H. pylori infection is a crucial part in the effective management of many gastroduodenal diseases. Several invasive and non-invasive diagnostic tests are available for the detection of H. pylori and each test has its usefulness and limitations in different clinical situations.[8]

Urea breath tests and stool antigen tests are the most widely used non-invasive tests for identifying H. pylori infection, as well as most accurate. In addition, they can be used to confirm cure. Serologic tests are a convenient but less accurate alternative and cannot be used to confirm cure.[2]

The urea breath test is the noninvasive test of choice for the diagnosis of H. pylori, with high sensitivity (95%) and specificity (95% to 100%) for the detection of active H. pylori infections.[4] Urea breath tests require the ingestion of urea labeled with the nonradioactive isotope carbon 13 or carbon 14. Specificity and sensitivity approach 100%. Urea breath testing is an option for test of cure and should be performed four to six weeks after completion of eradication therapy. Proton pump inhibitors (PPIs) must be stopped for at least two weeks before the test, and accuracy is lower in patients who have had distal gastrectomy.[2]

Stool antigen tests using monoclonal antibodies are as accurate as urea breath tests if a validated laboratory-based monoclonal test is used. Like urea breath tests, stool antigen tests detect only active infection and can also be used as a test of cure. PPIs should be stopped for two weeks before testing, but stool antigen tests are not as affected by PPI use.[2]

Serologic antibody testing detects immunoglobulin G specific to H. pylori in serum and cannot distinguish between an active infection and a past infection.[2] Most common serologic tests are based on an enzyme-linked immunosorbent assay (ELISA) technology. As with any test,

prevalence of the H. pylori infection and the pretest probability influence the positive or negative predictive values. Overall, where the prevalence of H. pylori infection and the pretest probability are low, the negative predictive value of a serologic test is high whereas false positives are more frequent, with the opposite in high prevalence/high pretest probability cases (i.e., the positive predictive value is high but there is increased prevalence of false negative results).[4] Antibody testing cannot be used as a test of cure.

American Society for Clinical Pathology
Serologic evaluation of patients to determine the presence/absence of H. pylori infection is no longer considered clinically useful. Alternative noninvasive testing methods (e.g., the urea breath test and stool antigen test) exist for detecting the presence of the bacteria and have demonstrated higher clinical utility, sensitivity, and specificity.

The American Gastroenterological Association (AGA)
The 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.[7]

The American College of Gastroenterology
All patients with active PUD, a past history of PUD (unless previous cure of H. pylori infection has been documented), low-grade gastric MALT lymphoma, or a history of endoscopic resection of early gastric cancer should be tested for H. pylori 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. Other indications to test patients for H. pylori infection may include, patients taking long-term low-dose aspirin, patients initiating chronic treatment with an NSAID, patients with unexplained iron deficiency anemia despite an appropriate evaluation and adults with idiopathic thrombocytopenic purpura. Any individual who tests positive should be offered eradication therapy.[3] Patients with a history of PUD who have previously been treated for H. pylori infection should undergo eradication testing with a urea breath test or fecal antigen test.[3]

Coding Implications
This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2020, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT® Codes	Description
86677	Antibody; Helicobacter pylori

HCPCS Codes	Description
N/A	

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

ICD-10-CM Code	Description
N/A	

Reviews, Revisions, and Approvals	Date	Approval Date
Policy developed	12/17	12/17
Removed from background of policy the statement "Serology testing is useful in screening and epidemiological studies." and indications for testing in individuals without alarm symptoms.	04/18	
References reviewed and updated.	11/18	11/18
References reviewed and updated.	11/19	11/19
References reviewed and updated. Replaced "member" with "member/enrollee" in all instances.	10/20	10/20

References

1. Crowe SE. Indications and diagnostic tests for Helicobacter pylori infection. Nov 17. In: UpToDate, Waltham, MA. Abrams SA (Ed). Accessed 10/1/20.
2. Fashner J, Gitu AC. Diagnosis and Treatment of Peptic Ulcer Disease and H. pylori Infection. Am Fam Physician. 2015 Feb 15;91(4):236-242
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4. Dore MP, Pes GM, Bassotti G, Usai-Satta P. Dyspepsia: When and How to Test for Helicobacter pylori Infection. Gastroenterol Res Pract. 2016;2016:8463614. doi: 10.1155/2016/8463614. Epub 2016 Apr 28
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6. Wang YK, Kuo FC, Liu CJ, et al. Diagnosis of Helicobacter pylori infection: Current options and developments. World J Gastroenterol. 2015 Oct 28;21(40):11221-35. doi: 10.3748/wjg.v21.i40.11221.
7. Talley NJ, Vakil NB, Moayyedi P. American Gastroenterological Association technical review on the evaluation of dyspepsia. Gastroenterology. 2005 Nov;129(5):1756-80.
8. Pourakbari B, Ghazi M, Mahmoudi S, et al. Diagnosis of Helicobacter pylori infection by invasive and noninvasive tests. Braz J Microbiol. 2013 Nov 15;44(3):795-8. doi: 10.1590/S1517-83822013005000052. eCollection 2013.
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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

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Note: For Medicaid member/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare member/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.

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