

**Prior Authorization Review Panel
MCO Policy Submission**

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness (PHW)	Submission Date: 08/01/2024
Policy Number: PA.CP.MP.153	Effective Date: 05/2018 Revision Date: 06/26/2024
Policy Name: Helicobacter Pylori Serology Testing	
Type of Submission – <u>Check all that apply</u>: ☐ New Policy ☐ Revised Policy* ☐ Annual Review – No Revisions ☐ Statewide PDL ☒ Retiring Policy	
*All revisions to the policy <u>must</u> be highlighted using track changes throughout the document. Please provide any clarifying information for the policy below: Retiring policy. Concert related policies are loaded in InterQual.	
Name of Authorized Individual (Please type or print): Dr. Craig A. Butler, MD.	Signature of Authorized Individual: <i>Craig A Butler MD</i>

Clinical Policy: Helicobacter Pylori Serology Testing

Reference Number: PA.CP.MP.153

Effective Date: 05/2018

Date of Last Revision: 09/2023

[Coding Implications](#)

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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 PA Health & Wellness 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 (88% to 95%) and specificity (95% to 100%) for the detection of active H. pylori infections.^{1,4} 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.²

American Society for Clinical Pathology

Per the 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.¹¹

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

The American College of Gastroenterology states that 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. 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 2022, 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	

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed	04/18	06/18
Annual Review. References reviewed and updated	12/18	01/08/2019
Annual Review. References reviewed and updated	06/2020	8/7/2020
Annual Review. References reviewed and updated	8/31/2021	
Annual review completed. Background updated and minor rewording with no clinical significance. Changed “Last Review Date” in header to “Date of Last Revision” and changed “Date” in Revision log to “Revision Date”. References reviewed and updated. Reviewed by specialist.	2/21/2023	
Annual review completed. Background updated and minor rewording with no clinical significance. References reviewed and updated. Reviewed by external specialist.	09/28/2023	
Retiring policy. Concert related policies are loaded in InterQual.	06/2024	7/31/2024

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