
Helicobacter Pylori Serological Testing

MEDICAL POLICY NUMBER: 303

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INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

SCOPE: Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

PLAN PRODUCT AND BENEFIT APPLICATION

Commercial

Medicaid/OHP*

Medicare**

*Medicaid/OHP Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

**Medicare Members

Note that investigational services are considered “**not medically necessary**” for Medicare members.

COVERAGE CRITERIA

The use of serological antibody testing for *Helicobacter pylori* is considered **not medically necessary** for all indications.

Link to [Evidence Summary](#)

POLICY CROSS REFERENCES

None

The full Company portfolio of current Medical Policies is available online and can be [accessed here](#).

POLICY GUIDELINES

BACKGROUND

Helicobacter pylori (*H. pylori*)

H. pylori is a chronic bacterial infection associated with conditions such as peptic ulcer disease, chronic gastritis, gastric adenocarcinoma, and gastric mucosa associated lymphoid tissue lymphoma. *H. pylori* generally has no symptoms in up to 90% of people infected. It is estimated that 50% of the world’s population is infected with the bacteria, more commonly found in developing nations. Route of infection is unknown, although it seems that person-to-person transmission through fecal/oral or oral/oral exposure is most likely. *H. pylori* is treated with antibiotic regimens.¹

Diagnostic testing

H. Pylori can be diagnosed through endoscopy using biopsy urease tests, histology, or bacterial culture. Non-invasive options are also available, including urea breath tests, stool antigen tests, and serology. Urea breath tests and stool antigen tests test for active infections, while serology can be positive in patients with active or prior infection.

Serologic tests

Serologic tests use ELISA tests to detect IgG antibodies for *H pylori*. They are noninvasive and inexpensive, but require validation at the local level, limiting their value in routine practice.

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of serologic testing to diagnose *Helicobacter pylori*. Below is a summary of the available evidence identified through March 2022.

Systematic reviews

In 2018, Cochrane published a systematic review of non-invasive diagnostic tests for *H pylori* infection, including urea breath test, serology, and stool antigen testing.² The review identified 101 studies that met inclusion criteria, involving 11,003 participants. Of the included diagnostic accuracy studies, 34 evaluated serology, totalling 4242 participants. For serological testing, the diagnostic odds ratio was 47.4 (95% confidence interval [CI], 25.5 to 88.1), and the sensitivity (95% CI) estimated at a fixed specificity of 0.90 was 0.84 (95% CI, 0.74 to 0.91). Direct comparison of urea breath test versus serological testing showed a diagnostic odds ratio of 0.68 (95% CI, 0.12 to 3.70; p=0.56). There was limited data for direct comparison of stool antigen test versus serological test. The authors concluded that urea breath tests had higher diagnostic accuracy compared to serology, but further comparative studies of high methodological quality are needed to determine accuracy.

Prospective studies

In 2013, Pourakbari and colleagues published the results of a prospective study comparing rapid urease tests (RUT), serology, histopathology, and stool antigen tests with PCR for the detection of *H pylori*.³ The

study included 89 participants. Fifty-three participant biopsies were found to be *H pylori* positive through ureC PCR. Correlation of RUT, serology, histopathology, and stool antigen tests with PCR was 0.82, 0.32, 0.91, and 0.63. Serology (IgG) had a sensitivity, specificity, and test accuracy of 50%, 83.3%, and 65%. The authors concluded that RUT and histopathology and as accurate as the PCR of biopsy and stool antigen tests are considered an appropriate noninvasive diagnostic test for *H pylori*, whereas serology was not recommended.

CLINICAL PRACTICE GUIDELINES

American College of Gastroenterology (ACG)

In 2007, the ACG published practice guidelines for the management of *H pylori* infection. The guidelines state the following: Antibody testing is inexpensive and widely available but poor PPV [positive predictive value] in populations with a low prevalence of *H. pylori* infection limits its usefulness in clinical practice.”⁴ They recommend urea breath tests and fecal antigen tests as noninvasive diagnostic tools.

In 2017, the ACG updated their guidelines, continuing to recommend urea breath tests for diagnosing *H pylori* infection and testing post-treatment.⁵

UpToDate

In 2020, UpToDate published guidelines on diagnostic tests for *H pylori* infection. They state, “Serologic tests require validation at the local level, which is impractical in routine practice. In addition, concerns over its accuracy have limited its use. Guidelines recommend that serologic testing should not be used in low prevalence populations as the low accuracy of serology would result in inappropriate treatment in significant numbers of patients.”⁶

EVIDENCE SUMMARY

Due to the fact that serological testing for *H pylori* infection will produce positive results from both active infection and past exposure, antibody testing has poor positive predictive value. Clinical guidelines therefore recommend against serological testing for *H pylori* in low prevalence populations, such as the United States, in order to prevent inappropriate treatment.

MEDICARE ADVANTAGE

Note: The Company policy for *PHA Medicare Medical Policy Development and Application* (MP50) provides details regarding Medicare’s definition of medical necessity and the hierarchy of Medicare references and resources during the development of medical policies, as well as the Plan’s use of evidence-based processes for policy development.

As of 5/2022, no specific Medicare coverage policy or guidance (e.g., manual, national coverage determination [NCD], local coverage determination [LCD] article [LCA], etc.) was identified which addresses helicobacter Pylori serological testing. In the absence of a NCD, LCD, or other Medicare policy, Medicare regulatory guidelines do allow Medicare Advantage Organizations (MAOs) to make

their own coverage determinations, as long as the MAO applies an objective, evidence-based process, based on authoritative evidence. (*Medicare Managed Care Manual, Ch. 4, §90.5*) Thus, the Company medical policy criteria may be applied for medical necessity decision-making.

BILLING GUIDELINES AND CODING

CODES*		
CPT	86677	Antibody; Helicobacter pylori

*Coding Notes:

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- See the non-covered and prior authorization lists on the Company [Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website](#) for additional information.
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as “medically unlikely edits” (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

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5. Chey WD, Leontiadis GI, Howden CW, Moss SF. ACG Clinical Guideline: Treatment of Helicobacter pylori Infection. *Official journal of the American College of Gastroenterology | ACG*. 2017;112(2):212-239. https://journals.lww.com/ajg/Fulltext/2017/02000/ACG_Clinical_Guideline_Treatment_of_Helicobacter.12.aspx
6. Lamont JT FM, Grover S. Indications and diagnostic tests for Helicobacter pylori infection. UpToDate. <https://www.uptodate.com/contents/indications-and-diagnostic-tests-for->

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POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.