If a conflict arises between a Clinical Payment and Coding Policy and any plan document under which a member is entitled to Covered Services, the plan document will govern. If a conflict arises between a CPCP and any provider contract pursuant to which a provider participates in and/or provides Covered Services to eligible member(s) and/or plans, the provider contract will govern. "Plan documents" include, but are not limited to, Certificates of Health Care Benefits, benefit booklets, Summary Plan Descriptions, and other coverage documents. Blue Cross and Blue Shield of Texas may use reasonable discretion interpreting and applying this policy to services being delivered in a particular case. BCBSTX has full and final discretionary authority for their interpretation and application to the extent provided under any applicable plan documents.

Providers are responsible for submission of accurate documentation of services performed. Providers are expected to submit claims for services rendered using valid code combinations from Health Insurance Portability and Accountability Act approved code sets. Claims should be coded appropriately according to industry standard coding guidelines including, but not limited to: Uniform Billing Editor, American Medical Association, Current Procedural Terminology, CPT® Assistant, Healthcare Common Procedure Coding System, ICD-10 CM and PCS, National Drug Codes, Diagnosis Related Group guidelines, Centers for Medicare and Medicaid Services National Correct Coding Initiative Policy Manual, CCI table edits and other CMS guidelines.

Claims are subject to the code edit protocols for services/procedures billed. Claim submissions are subject to claim review including but not limited to, any terms of benefit coverage, provider contract language, medical policies, clinical payment and coding policies as well as coding software logic. Upon request, the provider is urged to submit any additional documentation.

Helicobacter pylori Testing

Policy Number: CPCPLAB018

Version 1.0

Approval Date: April 28, 2025

Plan Effective Date: August 8, 2025

Description

The plan has implemented certain lab management reimbursement criteria. Not all requirements apply to each product. Providers are urged to review Plan documents for eligible coverage for services rendered.

Reimbursement Information:

1. For individual who are 18 years of age and older, urea breath testing **OR** stool antigen testing to diagnose an *H. pylori* infection **may be reimbursable** in **any** of the following situations:
    a. For individuals with dyspepsia (see **Note 1**),
    b. For individuals with active peptic ulcer disease,
    c. For individuals with past PUD and who have had recurrent symptoms,
    d. For individuals with low-grade gastric mucosa-associated lymphoid tissue lymphoma,
    e. For individuals with a history of resection of early gastric cancer,
    f. For individuals with gastric intestinal metaplasia,
    g. For individuals initiating chronic treatment with or who have been on a long-term aspirin or a non-steroidal anti-inflammatory drug treatment,
    h. For individuals with unexplained iron deficiency anemia,
    i. For individuals with idiopathic thrombocytopenic purpura,
    j. For individuals with a family history of gastric cancer,
    k. For individuals who are first-generation immigrants from high prevalence areas.

2. For individual who are18 years of age and older and who are undergoing endoscopic examination or who have alarm symptoms (see **Note 2**), a biopsy-based endoscopic histology test and **either** a rapid urease test **or** a culture with susceptibility testing to diagnose an *H. pylori* infection **may be reimbursable.**

3. For individuals who are less than 18 years of age, urea breath testing **OR** stool antigen testing to diagnose an *H. pylori* infection **may be reimbursable** in **any** of the following situations:
    a. For individuals who have gastric or duodenal ulcers or erosions.
    b. For individuals who have a family history of gastric cancer.

4. For individuals who are less than 18 years of age and who have refractory iron deficiency anemia, a biopsy-based endoscopic histology test and **either** a rapid urease test **or** a culture with susceptibility testing to diagnosis an *H. pylori* infection **may be reimbursable.**

5. For all individuals who have tested positive for *H. pylori*, urea breath testing **or** stool antigen testing to measure the success of eradication of *H. pylori* infection, with testing performed at least four weeks post-treatment **may be reimbursable.**

6. For individuals with a refractory *H. pylori* infection, susceptibility testing (culture or nucleic acid based) **may be reimbursable.**

7. Urea breath testing **or** stool antigen testing to diagnose an *H. pylori* infection **is not reimbursable** for **any** of the following situations**:**
    a. For asymptomatic individuals of all ages;
    b. For individuals 18 years and older with typical symptoms of gastroesophageal reflux disease (i.e., heartburn, regurgitation) who do not have a history of peptic ulcer disease.

8. For individuals of all ages, serologic testing for *H. pylori* infection **is not reimbursable**.

9. For individuals less than 18 years of age, a biopsy-based endoscopic histology test and a rapid urease test **or** a culture with susceptibility testing to diagnose an *H.* pylori infection **is not reimbursable** in **any** of the following situations:
    a. For children with functional abdominal pain;
    b. As part of initial investigation in children with iron deficiency anemia;
    c. When investigating causes of short stature.

10. For individuals with recent use of antibiotics, proton pump inhibitors, or bismuth, the urea breath test, stool antigen **or** biopsy-based testing to diagnose an *H. pylori infection* **is not reimbursable**.

11. To diagnose an *H. pylori* infection, concurrent testing with **any** combination of the urea breath test, stool antigen testing, **and/or** biopsy-based testing **is not reimbursable.**

12. For all other situations not described above, nucleic acid testing for *H. pylori* **is not reimbursable**.

NOTES:

Note 1: "Dyspepsia refers to bothersome upper abdominal symptoms that are often meal related. The predominant symptoms are fullness (or bloating) after meals, early satiety (inability to finish a normal-sized meal because of postprandial discomfort), or epigastric pain (or burning) that may or may not be related to meals. If dyspepsia is chronic, epigastric pain is a less common feature than postprandial fullness or satiety. Pain is not required to make a diagnosis of dyspepsia." (2)

Note 2: Alarm features of dyspepsia: vomiting, gastrointestinal bleeding, unexplained iron deficiency, or weight loss. (3)

Procedure Codes

The following is not an all-encompassing code list. The inclusion of a code does not guarantee it is a covered service or eligible for reimbursement.

Codes
83009, 83013, 83014, 86318, 86677, 87070, 87077, 87081, 87149, 87150, 87153, 87181, 87186, 87205, 87338, 87339, 87513, 88305, 0008U

References:

1. Lamont JT. Indications and diagnostic tests for Helicobacter pylori infection. July 13, 2023. https://www.uptodate.com/contents/indications-and-diagnostic-tests-for-helicobacter-pylori-infection2. Longstreth G, Lacy, Brian. Approach to the adult with dyspepsia. Updated January 16, 2025. https://www.uptodate.com/contents/approach-to-the-adult-with-dyspepsia
3. Chey WD, Howden CW, Moss SF, et al. ACG Clinical Guideline: Treatment of Helicobacter pylori Infection. *Official journal of the American College of Gastroenterology | ACG*. 2024;119(9):1730-1753. doi:10.14309/ajg.0000000000002968
4. Siao D, Somsouk M. Helicobacter pylori: evidence-based review with a focus on immigrant populations. *Journal of general internal medicine*. Mar 2014;29(3):520-8. doi:10.1007/s11606-013-2630-y
5. Jensen P, Feldman, Mark. Acute and chronic gastritis due to Helicobacter pylori. Updated September 5, 2023. https://www.uptodate.com/contents/acute-and-chronic-gastritis-due-to-helicobacter-pylori
6. Singh V, Mishra S, Rao GR, et al. Evaluation of nested PCR in detection of Helicobacter pylori targeting a highly conserved gene: HSP60. *Helicobacter*. Feb 2008;13(1):30-4. doi:10.1111/j.1523-5378.2008.00573.x
7. Patel SK, Pratap CB, Jain AK, Gulati AK, Nath G. Diagnosis of Helicobacter pylori: what should be the gold standard? *World journal of gastroenterology*. Sep 28 2014;20(36):12847-59. doi:10.3748/wjg.v20.i36.12847
8. Dechant FX, Dechant R, Kandulski A, et al. Accuracy of Different Rapid Urease Tests in Comparison with Histopathology in Patients with Endoscopic Signs of Gastritis. *Digestion*. 2020;101(2):184-190. doi:10.1159/000497810
9. Pohl D, Keller PM, Bordier V, Wagner K. Review of current diagnostic methods and advances in Helicobacter pylori diagnostics in the era of next generation sequencing. *World journal of gastroenterology*. Aug 28 2019;25(32):4629-4660. doi:10.3748/wjg.v25.i32.4629
10. Hussein RA, Al-Ouqaili MTS, Majeed YH. Detection of Helicobacter Pylori infection by invasive and non-invasive techniques in patients with gastrointestinal diseases from Iraq: A validation study. *PLoS One*. 2021;16(8):e0256393. doi:10.1371/journal.pone.0256393
11. Hassan AM, Faraj HHA, Mohammad HF. Comparison between stool antigen test and urea breath test for diagnosing of Helicobacter pylori infection among Children in Sulaymaniyah City. *Mustansiriya Medical Journal*. 2021;20(1):6.

12. Abdelmalek S, Hamed W, Nagy N, Shokry K, Abdelrahman H. Evaluation of the Diagnostic Values and Utility of Helicobacter Pylori Stool Antigen Lateral Immunochromatography Assay. 2022;
13. Gisbert JP, de la Morena F, Abraira V. Accuracy of monoclonal stool antigen test for the diagnosis of H. pylori infection: a systematic review and meta-analysis. *The American journal of gastroenterology*. Aug 2006;101(8):1921-30. doi:10.1111/j.1572-0241.2006.00668.x
14. Opekun AR, Zierold C, Rode A, et al. Clinical Performance of the Automated LIAISON® Meridian H. pylori SA Stool Antigen Test. *Biomed Res Int*. 2020;2020:7189519. doi:10.1155/2020/7189519
15. Korkmaz H, Findik D, Ugurluoglu C, Terzi Y. Reliability of stool antigen tests: investigation of the diagnostic value of a new immunochromatographic Helicobacter pylori approach in dyspeptic patients. *Asian Pacific journal of cancer prevention : APJCP*. 2015;16(2):657-60.
16. Ferwana M, Abdulmajeed I, Alhajiahmed A, et al. Accuracy of urea breath test in Helicobacter pylori infection: meta-analysis. *World journal of gastroenterology*. Jan 28 2015;21(4):1305-14. doi:10.3748/wjg.v21.i4.1305
17. Loy CT, Irwig LM, Katelaris PH, Talley NJ. Do commercial serological kits for Helicobacter pylori infection differ in accuracy? A meta-analysis. *The American journal of gastroenterology*. Jun 1996;91(6):1138-44.
18. Nezami BG, Jani M, Alouani D, Rhoads DD, Sadri N. Helicobacter pylori Mutations Detected by Next-Generation Sequencing in Formalin-Fixed, Paraffin-Embedded Gastric Biopsy Specimens Are Associated with Treatment Failure. *J Clin Microbiol*. Jul 2019;57(7)doi:10.1128/jcm.01834-18
19. Yang F, Xu YL, Zhu RF. Helicobacter pylori infection and the risk of colorectal carcinoma: a systematic review and meta-analysis. *Minerva medica*. Oct 2019;110(5):464-470. doi:10.23736/s0026-4806.19.05942-1
20. Wang T, Li X, Zhang Q, et al. Relationship between Helicobacter pylori infection and osteoporosis: a systematic review and meta-analysis. *BMJ open*. Jun 27 2019;9(6):e027356. doi:10.1136/bmjopen-2018-027356
21. Zhou BG, Yang HJ, Xu W, Wang K, Guo P, Ai YW. Association between Helicobacter pylori infection and nonalcoholic fatty liver disease: A systematic review and meta-analysis of observational studies. *Helicobacter*. Jun 2019;24(3):e12576. doi:10.1111/hel.12576
22. Halland M, Haque R, Langhorst J, Boone JH, Petri WA. Clinical performance of the H. PYLORI QUIK CHEK™ and H. PYLORI CHEK™ assays, novel stool antigen tests for diagnosis of Helicobacter pylori. *Eur J Clin Microbiol Infect Dis*. May 2021;40(5):1023-1028. doi:10.1007/s10096-020-04137-7
23. Marrero Rolon R, Cunningham SA, Mandrekar JN, Polo ET, Patel R. Clinical Evaluation of a Real-Time PCR Assay for Simultaneous Detection of Helicobacter pylori and Genotypic Markers of Clarithromycin Resistance Directly from Stool. *J Clin Microbiol*. Apr 20 2022;59(5)doi:10.1128/jcm.03040-20
24. Nguyen Wenker T, Peng FB, Emelogu I, et al. The Predictive Performance of Contemporary Guideline Recommendations for Helicobacter pylori Testing in a United States Population. *Clin Gastroenterol Hepatol*. Jul 2023;21(7):1771-1780. doi:10.1016/j.cgh.2022.10.009

25. Talley NJ. American Gastroenterological Association medical position statement: evaluation of dyspepsia. *Gastroenterology*. Nov 2005;129(5):1753-5. doi:10.1053/j.gastro.2005.09.019
26. Allen JI, Katzka D, Robert M, Leontiadis GI. American Gastroenterological Association Institute Technical Review on the Role of Upper Gastrointestinal Biopsy to Evaluate Dyspepsia in the Adult Patient in the Absence of Visible Mucosal Lesions. *Gastroenterology*. Oct 2015;149(4):1088-118. doi:10.1053/j.gastro.2015.07.040
27. Gupta S, Li D, El Serag HB, et al. AGA Clinical Practice Guidelines on Management of Gastric Intestinal Metaplasia. *Gastroenterology*. 2020;158(3):693-702. doi:10.1053/j.gastro.2019.12.003
28. Ko CW, Siddique SM, Patel A, et al. AGA Clinical Practice Guidelines on the Gastrointestinal Evaluation of Iron Deficiency Anemia. *Gastroenterology*. 2020;159(3):1085-1094. doi:10.1053/j.gastro.2020.06.046
29. Shah SC, Iyer PG, Moss SF. AGA Clinical Practice Update on the Management of Refractory Helicobacter pylori Infection: Expert Review. *Gastroenterology*. Apr 2021;160(5):1831-1841. doi:10.1053/j.gastro.2020.11.059
30. Chey WD, Leontiadis GI, Howden CW, Moss SF. ACG Clinical Guideline: Treatment of Helicobacter pylori Infection. *The American journal of gastroenterology*. Feb 2017;112(2):212-239. doi:10.1038/ajg.2016.563
31. NICE. Gastro-oesophageal reflux disease and dyspepsia in adults: investigation and management. Dyspepsia and Gastro-Oesophageal Reflux Disease: Investigation and Management of Dyspepsia, Symptoms Suggestive of Gastro-Oesophageal Reflux Disease, or Both https://www.nice.org.uk/guidance/cg184
32. NICE. Dyspepsia and gastro-oesophageal reflux disease in adults. https://www.nice.org.uk/guidance/qs96/resources/dyspepsia-and-gastrooesophageal-reflux-disease-in-adults-investigation-and-management-2098972399813
33. Bhatt DL, Scheiman J, Abraham NS, et al. ACCF/ACG/AHA 2008 expert consensus document on reducing the gastrointestinal risks of antiplatelet therapy and NSAID use: a report of the American College of Cardiology Foundation Task Force on Clinical Expert Consensus Documents. *Circulation*. Oct 28 2008;118(18):1894-909. doi:10.1161/circulationaha.108.191087
34. Katelaris P, Hunt R, Bazzoli F, et al. Helicobacter pylori World Gastroenterology Organization Global Guideline. *J Clin Gastroenterol*. Feb 1 2023;57(2):111-126. doi:10.1097/mcg.0000000000001719
35. Keller J, Hammer HF, Afolabi PR, et al. European guideline on indications, performance and clinical impact of 13C-breath tests in adult and pediatric patients: An EAGEN, ESNM, and ESPGHAN consensus, supported by EPC. *UEG Journal*. 2021;doi:10.1002/ueg2.12099
36. Homan M, Jones NL, Bontems P, et al. Updated joint ESPGHAN/NASPGHAN guidelines for management of Helicobacter pylori infection in children and adolescents (2023). *J Pediatr Gastroenterol Nutr*. Sep 2024;79(3):758-785. doi:10.1002/jpn3.12314
37. Kato S, Shimizu T, Toyoda S, et al. The updated JSPGHAN guidelines for the management of Helicobacter pylori infection in childhood. *Pediatr Int*. Dec 2020;62(12):1315-1331. doi:10.1111/ped.14388

38. Malfertheiner P, Megraud F, Morain CA, et al. Management of Helicobacter pylori infection—the Maastricht V/Florence Consensus Report. *Gut*. 2017;66(1):6. doi:10.1136/gutjnl-2016-312288
39. Malfertheiner P, Megraud F, Morain CA, et al. Management of Helicobacter pylori infection—the Maastricht IV/ Florence Consensus Report. *Gut*. 2012;61(5):646. doi:10.1136/gutjnl-2012-302084
40. Neunert C, Terrell DR, Arnold DM, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia. *Blood Advances*. 2020;3(23):3829-3866. doi:10.1182/bloodadvances.2019000966
41. El-Serag HB, Kao JY, Kanwal F, et al. Houston Consensus Conference on Testing for Helicobacter pylori Infection in the United States. *Clinical Gastroenterology and Hepatology*. 2018/07/01 2018;16(7):992-1002.e6.
42. FDA. Summary of Safety and Effectiveness. https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100025B.pdf
43. FDA. 510k summary. https://www.accessdata.fda.gov/cdrh_docs/pdf/K014225.pdf
44. Biosciences M. BreathTek® UBT for H. pylori. Updated July 1, 2024. https://www.meridianbioscience.com/diagnostics/disease-areas/gastrointestinal/h-pylori/breathtek-ubt-for-h-pylori
45. FDA. PyloPlus UBT System - P170022/S003. Updated January 11, 2024. https://www.fda.gov/medical-devices/recently-approved-devices/pyloplus-ubt-system-p170022s003

Policy Update History:

Approval Date	Effective Date; Summary of Changes
04/28/2025	08/08/2025; Document updated with literature review. The following changes were made to Reimbursement Information: #1a changed “dyspeptic” to “dyspepsia (see Note 1)”; #1c replaced “without H. pylori history” with “ and who have had recurrent symptoms”; #1e removed “endoscopic”; removed #1g due to repetition with #1a; former #1h (now #1g), added “and who have been on a” and “aspirin”; former #1j, changed “chronic immune” to “idiopathic” and removed “and suspected H. pylori infection. Removed former #2 (follow up testing now found in new #5) Former #4, now #3, removed chronic ITP, follow up (now in #5), added ulcers/erosions and family history. Former #5, now #4, removed gastric ulcers (noninvasive testing now allowed in #3), reworded criteria since it now only pertains to those with refractory IDA. New #5 and #6: “5) For all individuals who have tested positive for H. pylori, urea breath testing or stool antigen testing to measure the success of eradication of H. pylori infection, with testing performed at least four weeks post-treatment, may be reimbursable. 6) For individuals with a refractory H. pylori

	infection, susceptibility testing (culture or nucleic acid based) may be reimbursable." Former #6.b., now #7.b., added "(i.e., heartburn, regurgitation)". Allowance of nucleic acid based susceptibility testing in #6 results in changes to #12, addition of "for all other situations not described above". New Note 1 and Note 2: "Note 1: "Dyspepsia refers to bothersome upper abdominal symptoms that are often meal related. The predominant symptoms are fullness (or bloating) after meals, early satiety (inability to finish a normal-sized meal because of postprandial discomfort), or epigastric pain (or burning) that may or may not be related to meals. If dyspepsia is chronic, epigastric pain is a less common feature than postprandial fullness or satiety. Pain is not required to make a diagnosis of dyspepsia." Note 2: Alarm features of dyspepsia: vomiting, gastrointestinal bleeding, unexplained iron deficiency, or weight loss." References revised.
02/05/2025	05/15/2025; Added code 87513. No other changes.
09/13/2024	01/01/2025: New policy.