

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 TX may use reasonable discretion interpreting and applying this policy to services being delivered in a particular case. Blue Cross and Blue Shield of TX 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: Nov. 19, 2024

Plan Effective Date: Jan. 1, 2025 (Blue Cross and Blue Shield of Texas Only)

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 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 dyspeptic symptoms,
 - b. For individuals with active peptic ulcer disease,
 - c. For individuals with past PUD without *H. Pylori* history,
 - d. For individuals with low-grade gastric mucosa-associated lymphoid tissue lymphoma,
 - e. For individuals with a history of endoscopic resection of early gastric cancer,
 - f. For individuals with gastric intestinal metaplasia,
 - g. For individuals with uninvestigated dyspepsia who are under the age of 60 years and without alarm features,
 - h. For individuals initiating chronic treatment with a non-steroidal anti-inflammatory drug,
 - i. For individuals with unexplained iron deficiency anemia,
 - j. For the evaluation of individuals with chronic immune thrombocytopenic purpura and suspected *H. pylori* infection,
 - k. For individuals with a family history of gastric cancer,
 - l. For individuals who are first-generation immigrants from high prevalence areas.

2. For individuals 18 years of age and older, urea breath testing **or** stool antigen testing to measure the success of eradication of *H. pylori* infection (follow-up measurement at least 4 weeks post-treatment) **may be reimbursable** in **any** of the following situations:
 - a. For individuals with an *H. pylori*-associated ulcer.
 - b. As part of the follow-up of for individuals with persistent symptoms of dyspepsia following appropriate antibiotic treatment for *H. pylori*.
 - c. For individuals with Gastric MALT Lymphoma.
 - d. For individuals who have undergone resection of early gastric cancer.

3. For individual 18 years of age and older undergoing endoscopic examination or who have alarm symptoms, 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**.

4. For individuals 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 with chronic immune thrombocytopenic purpura and suspected *H. pylori* infection.
 - b. To measure the success of eradication of *H. pylori* infection (follow-up measurement at least 4 weeks post-treatment).
5. For individuals less than 18 years of age, 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** in **any** of the following situations:
 - a. For individuals with gastric or duodenal ulcers;
 - b. For individuals with refractory iron deficiency anemia (when other causes have been ruled out).
6. 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 who do not have a history of peptic ulcer disease.
7. For individuals of all ages, serologic testing for *H. pylori* infection **is not reimbursable**.
8. 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.
9. 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**.
10. 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**.
11. Nucleic acid testing for *H. pylori* **is not reimbursable**.
- 12.

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:

- Abdelmalek, S., Hamed, W., Nagy, N., Shokry, K., & Abdelrahman, H. (2022). Evaluation of the Diagnostic Values and Utility of Helicobacter Pylori Stool Antigen Lateral Immunochromatography Assay.
- Allen, J. I., Katzka, D., Robert, M., & Leontiadis, G. I. (2015). 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*, *149*(4), 1088-1118. <https://doi.org/10.1053/j.gastro.2015.07.040>
- ASCP. (2016). *Do not request serology for H. pylori. Use the stool antigen or breath tests instead.* <https://www.aafp.org/pubs/afp/collections/choosing-wisely/318.html>
- Bhatt, D. L., Scheiman, J., Abraham, N. S., Antman, E. M., Chan, F. K., Furberg, C. D., Johnson, D. A., Mahaffey, K. W., & Quigley, E. M. (2008). 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*, *118*(18), 1894-1909. <https://doi.org/10.1161/circulationaha.108.191087>
- Chey, W. D., Leontiadis, G. I., Howden, C. W., & Moss, S. F. (2017). ACG Clinical Guideline: Treatment of Helicobacter pylori Infection. *Am J Gastroenterol*, *112*(2), 212-239. <https://doi.org/10.1038/ajg.2016.563>
- Dechant, F. X., Dechant, R., Kandulski, A., Selgrad, M., Weber, F., Reischl, U., Wilczek, W., Mueller, M., & Weigand, K. (2020). Accuracy of Different Rapid Urease Tests in Comparison with Histopathology in Patients with Endoscopic Signs of Gastritis. *Digestion*, *101*(2), 184-190. <https://doi.org/10.1159/000497810>
- El-Serag, H. B., Kao, J. Y., Kanwal, F., Gilger, M., LoVecchio, F., Moss, S. F., Crowe, S., Elfant, A., Haas, T., Hapke, R. J., & Graham, D. Y. (2018). Houston Consensus Conference on Testing for Helicobacter pylori Infection in the United States. *Clinical Gastroenterology and Hepatology*, *16*(7), 992-1002.e1006. <https://pubmed.ncbi.nlm.nih.gov/29559361/>
- FDA. (2002). 510k summary. https://www.accessdata.fda.gov/cdrh_docs/pdf/K014225.pdf
- FDA. (2012). *Summary of Safety and Effectiveness.* https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100025B.pdf

- FDA. (2023). PyloPlus UBT System.
<https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm?db=pma&i d=409747>
- Ferwana, M., Abdulmajeed, I., Alhajiahmed, A., Madani, W., Firwana, B., Hasan, R., Altayar, O., Limburg, P. J., Murad, M. H., & Knawy, B. (2015). Accuracy of urea breath test in *Helicobacter pylori* infection: meta-analysis. *World J Gastroenterol*, *21*(4), 1305-1314. <https://doi.org/10.3748/wjg.v21.i4.1305>
- Gisbert, J. P., de la Morena, F., & Abaira, V. (2006). Accuracy of monoclonal stool antigen test for the diagnosis of *H. pylori* infection: a systematic review and meta-analysis. *Am J Gastroenterol*, *101*(8), 1921-1930.
<https://doi.org/10.1111/j.1572-0241.2006.00668.x>
- Gupta, S., Li, D., El Serag, H. B., Davitkov, P., Altayar, O., Sultan, S., Falck-Ytter, Y., & Mustafa, R. A. (2020). AGA Clinical Practice Guidelines on Management of Gastric Intestinal Metaplasia. *Gastroenterology*, *158*(3), 693-702.
<https://doi.org/10.1053/j.gastro.2019.12.003>
- Halland, M., Haque, R., Langhorst, J., Boone, J. H., & Petri, W. A. (2021). 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*, *40*(5), 1023-1028. <https://doi.org/10.1007/s10096-020-04137-7>
- Hassan, A. M., Faraj, H. H. A., & Mohammad, H. F. (2021). Comparison between stool antigen test and urea breath test for diagnosing of *Helicobacter pylori* infection among Children in Sulaymaniyah City. *Mustansiriya Medical Journal*, *20*(1), 6.
<https://www.mmjonweb.org/article.asp?issn=2070-1128;year=2021;volume=20;issue=1;spage=6;epage=11;aulast=Hassan>
- Hussein, R. A., Al-Ouqaili, M. T. S., & Majeed, Y. H. (2021). Detection of *Helicobacter Pylori* infection by invasive and non-invasive techniques in patients with gastrointestinal diseases from Iraq: A validation study. *PLoS One*, *16*(8), e0256393. <https://doi.org/10.1371/journal.pone.0256393>
- Jensen, P., Feldman, Mark. (2023). *Acute and chronic gastritis due to Helicobacter pylori*. <https://www.uptodate.com/contents/acute-and-chronic-gastritis-due-to-helicobacter-pylori>
- Katellaris, P., Hunt, R., Bazzoli, F., Cohen, H., Fock, K. M., Gemilyan, M., Malfertheiner, P., Mégraud, F., Piscocya, A., Quach, D., Vakil, N., Vaz Coelho, L. G., LeMair, A., & Melberg, J. (2023). *Helicobacter pylori* World Gastroenterology Organization Global Guideline. *J Clin Gastroenterol*, *57*(2), 111-126.
<https://doi.org/10.1097/mcg.0000000000001719>
- Kato, S., Shimizu, T., Toyoda, S., Gold, B. D., Ida, S., Ishige, T., Fujimura, S., Kamiya, S., Konno, M., Kuwabara, K., Ushijima, K., Yoshimura, N., & Nakayama, Y. (2020). The updated JSPGHAN guidelines for the management of *Helicobacter pylori* infection in childhood. *Pediatr Int*, *62*(12), 1315-1331.
<https://doi.org/10.1111/ped.14388>

- Keller, J., Hammer, H. F., Afolabi, P. R., Benninga, M., Borrelli, O., Dominguez-Munoz, E., Dumitrascu, D., Goetze, O., Haas, S. L., & Hauser, B. (2021). 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*. <https://doi.org/10.1002/ueg2.12099>
- Ko, C. W., Siddique, S. M., Patel, A., Harris, A., Sultan, S., Altayar, O., & Falck-Ytter, Y. (2020). AGA Clinical Practice Guidelines on the Gastrointestinal Evaluation of Iron Deficiency Anemia. *Gastroenterology*, *159*(3), 1085-1094. <https://doi.org/10.1053/j.gastro.2020.06.046>
- Korkmaz, H., Findik, D., Ugurluoglu, C., & Terzi, Y. (2015). Reliability of stool antigen tests: investigation of the diagnostic value of a new immunochromatographic *Helicobacter pylori* approach in dyspeptic patients. *Asian Pac J Cancer Prev*, *16*(2), 657-660. <https://pubmed.ncbi.nlm.nih.gov/25684503/>
- L. Jones, N., Koletzko, S., Goodman, K., Bontems, P., Cadranet, S., Casswall, T., Czinn, S., Gold, B., Guarner, J., Elitsur, Y., Homan, M., Kalach, N., Kori, M., Madrazo, A., Megraud, F., Papadopoulou, A., & Rowland, M. (2017). *Joint ESPGHAN/NASPGHAN guidelines for the management of Helicobacter pylori in children and adolescents (update 2016)* (Vol. 64). https://naspghan.org/files/Joint_ESPGHAN_NASPGHAN_Guidelines_for_the.33.pdf
- Lamont, J. T. (2023). *Indications and diagnostic tests for Helicobacter pylori infection - UpToDate* <https://www.uptodate.com/contents/indications-and-diagnostic-tests-for-helicobacter-pylori-infection>
- Longstreth, G., Lacy, Brian. (2022, 07/22/2022). *Approach to the adult with dyspepsia*. <https://www.uptodate.com/contents/approach-to-the-adult-with-dyspepsia>
- Loy, C. T., Irwig, L. M., Katelaris, P. H., & Talley, N. J. (1996). Do commercial serological kits for *Helicobacter pylori* infection differ in accuracy? A meta-analysis. *Am J Gastroenterol*, *91*(6), 1138-1144.
- Malferteiner, P., Megraud, F., Morain, C. A., Atherton, J., Axon, A. T. R., Bazzoli, F., Gensini, G. F., Gisbert, J. P., Graham, D. Y., Rokkas, T., El-Omar, E. M., & Kuipers, E. J. (2012). Management of *Helicobacter pylori* infection—the Maastricht IV/ Florence Consensus Report. *Gut*, *61*(5), 646. <https://doi.org/10.1136/gutjnl-2012-302084>
- Malferteiner, P., Megraud, F., Morain, C. A., Gisbert, J. P., Kuipers, E. J., Axon, A. T., Bazzoli, F., Gasbarrini, A., Atherton, J., Graham, D. Y., Hunt, R., Moayyedi, P., Rokkas, T., Rugge, M., Selgrad, M., Suerbaum, S., Sugano, K., & El-Omar, E. M. (2017). Management of *Helicobacter pylori* infection—the Maastricht V/Florence Consensus Report. *Gut*, *66*(1), 6. <https://doi.org/10.1136/gutjnl-2016-312288>
- Marrero Rolon, R., Cunningham, S. A., Mandrekar, J. N., Polo, E. T., & Patel, R. (2022). 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*, *59*(5). <https://doi.org/10.1128/jcm.03040-20>

- Moayyedi, P., Lacy, B. E., Andrews, C. N., Enns, R. A., Howden, C. W., & Vakil, N. (2017). ACG and CAG Clinical Guideline: Management of Dyspepsia. *Am J Gastroenterol*, 112(7), 988-1013. <https://doi.org/10.1038/ajg.2017.154>
- Neunert, C., Terrell, D. R., Arnold, D. M., Buchanan, G., Cines, D. B., Cooper, N., Cuker, A., Despotovic, J. M., George, J. N., Grace, R. F., Kühne, T., Kuter, D. J., Lim, W., McCrae, K. R., Pruitt, B., Shimanek, H., & Vesely, S. K. (2020). American Society of Hematology 2019 guidelines for immune thrombocytopenia. *Blood Advances*, 3(23), 3829-3866. <https://doi.org/10.1182/bloodadvances.2019000966>
- Nezami, B. G., Jani, M., Alouani, D., Rhoads, D. D., & Sadri, N. (2019). Helicobacter pylori Mutations Detected by Next-Generation Sequencing in Formalin-Fixed, Paraffin-Embedded Gastric Biopsy Specimens Are Associated with Treatment Failure. *J Clin Microbiol*, 57(7). <https://doi.org/10.1128/jcm.01834-18>
- Nguyen Wenker, T., Peng, F. B., Emelogu, I., Mallepally, N., Kanwal, F., El-Serag, H. B., & Tan, M. C. (2023). The Predictive Performance of Contemporary Guideline Recommendations for Helicobacter pylori Testing in a United States Population. *Clin Gastroenterol Hepatol*, 21(7), 1771-1780. <https://doi.org/10.1016/j.cgh.2022.10.009>
- NICE. (2015). *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>
- NICE. (2019). *Gastro-oesophageal reflux disease and dyspepsia in adults: investigation and management* <https://www.nice.org.uk/guidance/cg184>
- Opekun, A. R., Zierold, C., Rode, A., Blocki, F. A., Fiorini, G., Saracino, I. M., Vaira, D., & Sutton, F. M. (2020). Clinical Performance of the Automated LIAISON® Meridian H. pylori SA Stool Antigen Test. *Biomed Res Int*, 2020, 7189519. <https://doi.org/10.1155/2020/7189519>
- Patel, S. K., Pratap, C. B., Jain, A. K., Gulati, A. K., & Nath, G. (2014). Diagnosis of Helicobacter pylori: what should be the gold standard? *World J Gastroenterol*, 20(36), 12847-12859. <https://doi.org/10.3748/wjg.v20.i36.12847>
- Pohl, D., Keller, P. M., Bordier, V., & Wagner, K. (2019). Review of current diagnostic methods and advances in Helicobacter pylori diagnostics in the era of next generation sequencing. *World J Gastroenterol*, 25(32), 4629-4660. <https://doi.org/10.3748/wjg.v25.i32.4629>
- Siao, D., & Somsouk, M. (2014). Helicobacter pylori: evidence-based review with a focus on immigrant populations. *J Gen Intern Med*, 29(3), 520-528. <https://doi.org/10.1007/s11606-013-2630-y>
- Singh, V., Mishra, S., Rao, G. R., Jain, A. K., Dixit, V. K., Gulati, A. K., Mahajan, D., McClelland, M., & Nath, G. (2008). Evaluation of nested PCR in detection of Helicobacter pylori targeting a highly conserved gene: HSP60. *Helicobacter*, 13(1), 30-34. <https://doi.org/10.1111/j.1523-5378.2008.00573.x>
- Talley, N. J. (2005). American Gastroenterological Association medical position statement: evaluation of dyspepsia. *Gastroenterology*, 129(5), 1753-1755. <https://doi.org/10.1053/j.gastro.2005.09.019>

Wang, T., Li, X., Zhang, Q., Ge, B., Zhang, J., Yu, L., Cai, T., Zhang, Y., & Xiong, H. (2019). Relationship between *Helicobacter pylori* infection and osteoporosis: a systematic review and meta-analysis. *BMJ Open*, *9*(6), e027356. <https://doi.org/10.1136/bmjopen-2018-027356>

Yang, F., Xu, Y. L., & Zhu, R. F. (2019). *Helicobacter pylori* infection and the risk of colorectal carcinoma: a systematic review and meta-analysis. *Minerva Med*, *110*(5), 464-470. <https://doi.org/10.23736/s0026-4806.19.05942-1>

Zhou, B. G., Yang, H. J., Xu, W., Wang, K., Guo, P., & Ai, Y. W. (2019). Association between *Helicobacter pylori* infection and nonalcoholic fatty liver disease: A systematic review and meta-analysis of observational studies. *Helicobacter*, *24*(3), e12576. <https://doi.org/10.1111/hel.12576>

Policy Update History:

Approval Date	Effective Date; Summary of Changes
11/19/2024	01/01/2025: Added new CPT code 87513 effective 01/01/2025.
09/13/2024	01/01/2025: New policy.