

If a conflict arises between a Clinical Payment and Coding Policy (“CPCP”) 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. BCBSIL may use reasonable discretion interpreting and applying this policy to services being delivered in a particular case. BCBSIL 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 (“HIPAA”) approved code sets. Claims should be coded appropriately according to industry standard coding guidelines including, but not limited to: Uniform Billing (“UB”) Editor, American Medical Association (“AMA”), Current Procedural Terminology (“CPT®”), CPT® Assistant, Healthcare Common Procedure Coding System (“HCPCS”), ICD-10 CM and PCS, National Drug Codes (“NDC”), Diagnosis Related Group (“DRG”) guidelines, Centers for Medicare and Medicaid Services (“CMS”) National Correct Coding Initiative (“NCCI”) 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

Enterprise Medical Policy Committee Approval Date: January 25, 2022

Plan Effective Date: May 1, 2022

Description

BCBSIL 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. Urea Breath testing OR stool antigen testing for *H. pylori* infection **may be reimbursable** for adult patients (>18y) in the following situations:
 - a. In the evaluation of a patient with suspected *H. pylori* infection and the following situations:
 - i. dyspeptic symptoms, or
 - ii. active peptic ulcer disease (PUD), or
 - iii. past PUD without *H. pylori* history, or
 - iv. low-grade gastric mucosa-associated lymphoid tissue (MALT) lymphoma, or

- v. a history of endoscopic resection of early gastric cancer (EGC), or
 - vi. in patients with gastric intestinal metaplasia (GIM), or
 - vii. patients with uninvestigated dyspepsia who are under the age of 60 years and without alarm features, or
 - viii. Patients initiating chronic treatment with a non-steroidal anti-inflammatory drug (NSAID), or
 - ix. Patients with unexplained iron deficiency anemia, or
 - x. In the evaluation of a patient with chronic immune thrombocytopenic purpura (ITP) and suspected *H. pylori* infection.
 - xi. In patients with family history of gastric cancer
 - xii. In patients who are first-generation immigrants from high prevalence areas
- b. Re-evaluation to measure success of eradication of *H. pylori* infection, at least 4 weeks post-treatment.
- i. Any patient with an *H. pylori*-associated ulcer.
 - ii. As part of the follow-up of patients with persistent symptoms of dyspepsia following appropriate antibiotic treatment for *H. pylori*.
 - iii. In patients with Gastric MALT Lymphoma.
In individuals who have undergone resection of early gastric cancer.
2. Urea Breath testing OR stool antigen testing for *H. pylori* infection **may be reimbursable** for pediatric patients (<18y) in the following situations:
- a. In the evaluation of a patient with chronic immune thrombocytopenic purpura (ITP) and suspected *H. pylori* infection.
 - b. Re-evaluation to measure success of eradication of *H. pylori* infection, at least 4 weeks post-treatment.
3. Biopsy-based endoscopic histology test and either Rapid Urease Test or culture with susceptibility testing **may be reimbursable** in pediatric patients (<18y) for the diagnosis of *H. pylori* infection in following situations:
- a. Children with gastric or duodenal ulcers.
 - b. Children with refractory iron deficiency anemia (IDA) in which other causes have been ruled out.
4. Biopsy-based endoscopic histology test and Rapid Urease Test or culture with susceptibility testing **may be reimbursable** in adult patients (>18 y) undergoing endoscopic examination or in those with alarm symptoms for the diagnosis of *H. pylori* infection
5. Urea Breath testing OR stool antigen testing for *H. pylori* infection **is not reimbursable** for asymptomatic pediatric (<18y) and asymptomatic adult (>18y) patients in all other situations and adult patients with typical symptoms of gastroesophageal reflux disease (GERD) who do not have a history of peptic ulcer disease (PUD)
6. Serologic testing for *H. pylori* infection **is not reimbursable** in adult and pediatric patients as it does not distinguish between currently active infection with past exposure and an infection that has been cured.
7. Biopsy-based endoscopic histology test and Rapid Urease Test or culture with susceptibility testing **is not reimbursable** in pediatric patients (<18y) for the diagnosis of *H. pylori* infection in following situations:
- a. Children with functional abdominal pain
 - b. As part of initial investigation in children with iron deficiency anemia
 - c. When investigating causes of short stature

8. Testing with the Urea Breath test and/or stool antigen and/or biopsy-based testing **is not reimbursable** in patients with recent use of antibiotics, proton pump inhibitors (PPIs) or bismuth.
9. Concurrent testing with the Urea Breath test and/or stool antigen testing and/or biopsy-based testing **is not reimbursable** as simultaneous use of both methods does not improve clinical understanding.
10. The use of nucleic acid testing for *H. pylori*, including polymerase chain reaction (PCR), 16S rRNA, 23S rRNA, and next-generation sequencing (NGS) of *H. pylori*, **is not reimbursable** as it is not practical for routine diagnosis.

Procedure Codes

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

References:

- 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. doi:10.1053/j.gastro.2015.07.040
- ASCP. (2016). Do not request serology for *H. pylori*. Use the stool antigen or breath tests instead. Retrieved from <http://www.choosingwisely.org/clinician-lists/american-society-clinical-pathology-serology-for-h-pylori/>
- Bhatt, D. L., Scheiman, J., Abraham, N. S., Antman, E. M., Chan, F. K., Furberg, C. D., . . . 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. doi: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. doi:10.1038/ajg.2016.563
- Dechant, F. X., Dechant, R., Kandulski, A., Selgrad, M., Weber, F., Reischl, U., . . . 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. doi:10.1159/000497810
- El-Serag, H. B., Kao, J. Y., Kanwal, F., Gilger, M., LoVecchio, F., Moss, S. F., . . . 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. doi:https://doi.org/10.1016/j.cgh.2018.03.013
- FDA. (2002). 510k summary. Retrieved from https://www.accessdata.fda.gov/cdrh_docs/pdf/K014225.pdf
- FDA. (2012). SUMMARY OF SAFETY AND EFFECTIVENESS Retrieved from https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100025B.pdf

FDA. (2020). PyloPlus UBT System. Retrieved from <https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm?db=pma&id=409747>

FDA. (2021). Devices@FDA. Retrieved from https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm?start_search=1&q=cHlsb3Jp&approval_date_from=&approval_date_to=&sort=approvaldatedesc&pagenum=10

Ferwana, M., Abdulmajeed, I., Alhajiahmed, A., Madani, W., Firwana, B., Hasan, R., . . . Knawy, B. (2015). Accuracy of urea breath test in Helicobacter pylori infection: meta-analysis. *World J Gastroenterol*, 21(4), 1305-1314. doi: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. doi:10.1111/j.1572-0241.2006.00668.x

Gupta, S., Li, D., El Serag, H. B., Davitkov, P., Altayar, O., Sultan, S., . . . Mustafa, R. A. (2020). AGA Clinical Practice Guidelines on Management of Gastric Intestinal Metaplasia. *Gastroenterology*, 158(3), 693-702. doi:10.1053/j.gastro.2019.12.003

Jensen, P., Feldman, Mark. (2019). Acute and chronic gastritis due to Helicobacter pylori. Retrieved from https://www.uptodate.com/contents/acute-and-chronic-gastritis-due-to-helicobacter-pylori?search=H.%20Pylori%20symptoms&source=search_result&selectedTitle=2~150&usage_type=default&display_rank=2

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. doi: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.

L. Jones, N., Koletzko, S., Goodman, K., Bontems, P., Cadranel, S., Casswall, T., . . . Rowland, M. (2017). *Joint ESPGHAN/NASPGHAN guidelines for the management of Helicobacter pylori in children and adolescents (update 2016)* (Vol. 64).

Lamont, J. T. (2020). Indications and diagnostic tests for Helicobacter pylori infection - UpToDate. Retrieved from https://www.uptodate.com/contents/indications-and-diagnostic-tests-for-helicobacter-pylori-infection?search=helio bacter%20pylori%20testing&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1. Retrieved 1/12/21

Liou, J.-M., Malfertheiner, P., Lee, Y.-C., Sheu, B.-S., Sugano, K., Cheng, H.-C., . . . El-Omar, E. M. (2020). Screening and eradication of Helicobacter pylori for gastric cancer prevention: the Taipei global consensus. *Gut*, 69(12), 2093-2112. doi:10.1136/gutjnl-2020-322368

Longstreth, G., Lacy, Brian. (2017). Approach to the adult with dyspepsia. Retrieved from <https://www.uptodate.com/contents/approach-to-the-adult-with->

dyspepsia?search=H.%20Pylori%20symptoms&source=search_result&selectedTitle=3~150&usage_type=default&display_rank=3

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.

Malfertheiner, P., Megraud, F., Morain, C. A., Atherton, J., Axon, A. T. R., Bazzoli, F., . . . Kuipers, E. J. (2012). Management of *Helicobacter pylori* infection—the Maastricht IV/ Florence Consensus Report. *Gut*, *61*(5), 646. doi:10.1136/gutjnl-2012-302084

Malfertheiner, P., Megraud, F., Morain, C. A., Gisbert, J. P., Kuipers, E. J., Axon, A. T., . . . El-Omar, E. M. (2017). Management of *Helicobacter pylori* infection—the Maastricht V/Florence Consensus Report. *Gut*, *66*(1), 6. doi:10.1136/gutjnl-2016-312288

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. doi:10.1038/ajg.2017.154

Neunert, C., Terrell, D. R., Arnold, D. M., Buchanan, G., Cines, D. B., Cooper, N., . . . Vesely, S. K. (2019). American Society of Hematology 2019 guidelines for immune thrombocytopenia. *Blood Advances*, *3*(23), 3829-3866. doi: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). doi:10.1128/jcm.01834-18

NICE. (2015). Dyspepsia and gastro-oesophageal reflux disease in adults. Retrieved from <https://www.nice.org.uk/guidance/qs96/resources/dyspepsia-and-gastrooesophageal-reflux-disease-in-adults-investigation-and-management-2098972399813>. from National Institute for Health and Care Excellence (UK) Copyright (c) National Institute for Health and Care Excellence, 2015.

NICE. (2019). Gastro-oesophageal reflux disease and dyspepsia in adults: investigation and management. Retrieved from <https://www.nice.org.uk/guidance/cg184>. from National Institute for Health and Care Excellence (UK) Copyright (c) National Institute for Health and Care Excellence, 2014.

NICE. (2020). *Helicobacter pylori* testing and eradication in adults Retrieved from file:///C:/Users/AHCS8330/Downloads/dyspepsia-and-gastro-oesophageal-reflux-disease-helicobacter-pylori-testing-and-eradication-in-adults.pdf

Opekun, A. R., Zierold, C., Rode, A., Blocki, F. A., Fiorini, G., Saracino, I. M., . . . Sutton, F. M. (2020). Clinical Performance of the Automated LIAISON® Meridian H. pylori SA Stool Antigen Test. *Biomed Res Int*, *2020*, 7189519. doi: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. doi: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. doi: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. doi:10.1007/s11606-013-2630-y

Singh, V., Mishra, S., Rao, G. R., Jain, A. K., Dixit, V. K., Gulati, A. K., . . . Nath, G. (2008). Evaluation of nested PCR in detection of Helicobacter pylori targeting a highly conserved gene: HSP60. *Helicobacter*, 13(1), 30-34. doi: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. doi:10.1053/j.gastro.2005.09.019

Wang, T., Li, X., Zhang, Q., Ge, B., Zhang, J., Yu, L., . . . Xiong, H. (2019). Relationship between Helicobacter pylori infection and osteoporosis: a systematic review and meta-analysis. *BMJ Open*, 9(6), e027356. doi: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. doi: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. doi:10.1111/hel.12576

Policy Update History:

5/1/2022	New policy
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