

**Policy: MP245**

**Section: Medical Benefit Policy**

**Subject: Helicobacter pylori Infection Testing**

### Applicable Lines of Business

<b>Commercial</b>	<b>X</b>	<b>CHIP</b>	<b>X</b>
<b>Medicare</b>	<b>X</b>	<b>ACA</b>	<b>X</b>
<b>Medicaid</b>	<b>X</b>		

**I. Policy:** Helicobacter pylori Infection Testing

**II. Purpose/Objective:**

To provide a policy of coverage regarding Helicobacter pylori Infection Testing

**III. Responsibility:**

- A. Medical Directors
- B. Medical Management

**IV. Required Definitions**

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

**V. Additional Definitions**

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**Medicaid Business Segment**

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an

illness, condition, injury or disability.

- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

#### **DESCRIPTION:**

It is thought that *Helicobacter pylori* (*H. pylori*) causes more than half of peptic ulcers worldwide. The bacterium causes peptic ulcers by damaging the mucous coating that protects the stomach and duodenum. Damage to the mucous coating allows stomach acid to get through to the lining beneath. Together, the stomach acid and *H. pylori* irritate the lining of the stomach or duodenum and cause an ulcer.

#### **INDICATIONS:**

Based on guidelines of the American Gastroenterological Association (2005) and the American College of Gastroenterology (2007), carbon isotope urea breath testing (<sup>13</sup>C or <sup>14</sup>C) or stool antigen testing is considered to be medically necessary in insured individuals who meet any of the following conditions:

- Active peptic ulcer disease (gastric or duodenal ulcer) or symptoms consistent with peptic ulcer disease
- Confirmed history of peptic ulcer disease and not previously treated for *H. pylori*
- Low-grade mucosa-associated lymphoid tissue (MALT) lymphoma
- Post resection of early gastric cancer
- Gastric intestinal metaplasia
- Evaluation of individuals with chronic immune thrombocytopenic purpura (ITP) and suspected *H. pylori* infection
- Insured individuals less than 55 years of age who have persistent dyspepsia without alarm symptoms
- To confirm eradication prior to cessation of treatment if recurrent or refractory peptic ulcer disease is present
- Pre-operative assessment prior to bariatric surgery

According to the AGA guidelines, individuals with alarm symptoms including, but not limited to: gastrointestinal bleeding, anemia, obstruction, perforation, anorexia, early satiety, or weight loss and new onset dyspepsia should undergo endoscopy. Biopsy specimens for *H. pylori* should be obtained at the time of endoscopy, and therapy to eradicate *H. pylori* should be offered to those who are infected to help reduce the risk of subsequent peptic ulcer disease and/or gastric malignancy.

#### **EXCLUSIONS:**

Testing for *H. pylori* is considered not medically necessary and **NOT COVERED** when used for the following:

- Screening of asymptomatic individuals;
- Serology-based testing is considered not medically necessary and is **NOT COVERED**. The ACG and AGA recommendations stress the need to eliminate the use of serology testing, and to test, treat, and retest to confirm eradication by utilizing active *H. pylori* infection testing. Serologic testing which does not test for active infection is no longer recommended for diagnosing, monitoring infection or confirming the eradication of *H. pylori* and should no longer be used.
- *H. pylori* detection, with or without antimicrobial resistance testing using molecular methods (such as PCR or next generation sequencing) for any indication and is considered **experimental, investigational or unproven** and therefore **NOT COVERED**.

#### **Medicaid Business Segment:**

Coverage may be allowed by exception. Serology should not be performed in areas of low *H. pylori* prevalence. If performed, positive results should be confirmed with a test for active infection prior to initiating eradication therapy.

- Genotyping to determine cytochrome p450 (CYP2C19) genetic polymorphisms is considered **experimental, investigational or unproven** for the purpose of managing the treatment of *H. pylori* infection. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this technology on health outcomes when compared to established tests or technologies.

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis

**Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.**

#### **CODING ASSOCIATED WITH: Helicobacter pylori testing**

***The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider***

**reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at [www.cms.gov](http://www.cms.gov) or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.**

43239 - Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; with biopsy, single or multiple  
78267 - Urea breath test, C-14 (isotopic); acquisition for analysis  
78268 - Urea breath test, C-14 (isotopic); analysis  
83009 - Helicobacter pylori, blood test analysis for urease activity, non-radioactive isotope (eg, C-13)  
83013 - Helicobacter pylori; breath test analysis for urease activity, non-radioactive isotope (eg, C-13)  
83014 - Helicobacter pylori; drug administration  
86677 - Antibody; Helicobacter pylori  
87338 - Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; Helicobacter pylori, stool  
87339 - Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; Helicobacter pylori  
0008U H. Pylori Detection and Antimicrobial Resistance in DNA, Biopsy  
Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL.

#### **LINE OF BUSINESS:**

**Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.**

#### **REFERENCES:**

Sapone A, Vaira Padol S, Yuan Y, Thabane M et al. The effect of CYP2C19 polymorphisms on H. pylori eradication rate in dual and triple first-line PPI therapies: a meta-analysis. Am J Gastroenterol 2006; 101(7):1467-75.

D, Trespidi S et al. The clinical role of cytochrome P450 genotypes in Helicobacter pylori management. Am J Gastroenterol 2003; 98(5):1010-5.

Padol S, Yuan Y, Thabane M et al. The effect of CYP2C19 polymorphisms on H. pylori eradication rate in dual and triple first-line PPI therapies: a meta-analysis. Am J Gastroenterol 2006; 101(7):1467-75.

Sheu BS, Fock KM. CYP2C19 genotypes and Helicobacter pylori eradication. J Gastroenterol Hepatol 2008; 23(8 Pt 1):1163

Klotz U. Impact of CYP2C19 polymorphisms on the clinical action of proton pump inhibitors (PPIs). Eur J Clin Pharmacol 2009; 65(1):1-2.

Vakil N. How to test for Helicobacter pylori in 2005. Cleveland Clinic Journal of Medicine 2005;72(Suppl 2): S8-S13.

Blue Cross Blue Shield Technology Evaluation Center (TEC) Assessments 2008, "Pharmacogenomics-based Treatment of Helicobacter pylori Infection."

Chey WD, Wong BC; Practice Parameters Committee of the American College of Gastroenterology. American College of Gastroenterology guideline on the management of Helicobacter pylori infection. Am J Gastroenterol. 2007 Aug;102(8):1808-25. Epub 2007 Jun 29.

Chey WD, Leontiadis GI, Howden CW, et al. ACG clinical guideline: Treatment of helicobacter pylori infection. Am J Gastroenterol. 2017 Feb; 112(2):212-239.

Talley NJ, Vakil NB, Moayyedi P. American Gastroenterological Association technical review on the evaluation of dyspepsia. Gastroenterology. 2005a Nov;129(5):1756-80.

Talley NJ; American Gastroenterological Association. American Gastroenterological Association medical position statement: evaluation of dyspepsia. Gastroenterology. 2005 Nov;129(5):1753-5.

Talley NJ, Vakil N; Practice Parameters Committee of the American College of Gastroenterology. Guidelines for the management of dyspepsia. Am J Gastroenterol. 2005b Oct;100(10):2324-37.

National Cancer Institute. Helicobacter Pylori and Cancer. Reviewed on November 16, 2011.  
<http://www.cancer.gov/cancertopics/factsheet/Risk/h-pylori-cancer>

UpToDate. May 2022 <https://www.uptodate.com/contents/indications-and-diagnostic-tests-for-helicobacter-pylori-infection-in-adults>

Gurusamy K, Yaghoobi M, Davidson BR Non-invasive diagnostic tests for Helicobacter pylori infection. The Cochrane database of Systematic Reviews Feb. 2016

Moayyedi PM, Lacy BE, Andrews CN, et al. ACG and CAG clinical guideline: Management of dyspepsia. Am J Gastroenterol. 2017; 112(7):987.

Mocanu V, Dang JT, Switzer N, et al. The effect of helicobacter pylori on postoperative outcomes in patients undergoing bariatric surgery: a systematic review and meta-analysis. Obes Surg. 2018 Feb; 28(2):567-573

Khadangi F, Yassi M, Kerachian MA. Review: Diagnostic accuracy of PCR-based detection tests for Helicobacter Pylori in stool samples. Helicobacter. 2017;22(6).

Singh, V., Mishra, S., Rao, G. R., Jain, A. K., Dixit, V. K., Gulati, A. K., et al Evaluation of nested PCR in detection of Helicobacter pylori targeting a highly conserved gene: HSP60. Helicobacter, 2008; 13(1), 30-34

Pohl, D., Keller, P. M., Bordier, V., & Wagner, K. Review of current diagnostic methods and advances in Helicobacter pylori diagnostics in the era of next generation sequencing. World J Gastroenterol, 2019;25(32), 4629-4660

Gupta, S., Li, D., El Serag, H. B., et al. AGA Clinical Practice Guidelines on Management of Gastric Intestinal Metaplasia. Gastroenterology, 2020 158(3), 693-702.

Kato, S., Shimizu, T., Toyoda, S., Gold, et al. The updated JSPGHAN guidelines for the management of Helicobacter pylori infection in childhood. Pediatr Int, 2020;62(12), 1315-1331

Katelaris, P., Hunt, R., Bazzoli, F., et al. Helicobacter pylori. World Gastroenterology Organization Global Guidelines. 2021

This policy will be revised as necessary and reviewed no less than annually.

**Devised:** 02/2011

**Revised:** 01/22 (add exclusion PCR NGS testing) ; 1/24 (add indications to align with vendor)

**Reviewed:** 2/12, 2/13, 2/14, 2/15, 2/16, 1/17, 1/18, 1/19, 1/20, 1/21, 1/23

### **CMS UM Oversight Committee Approval: 12/23**

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.

