

<b>Title: Helicobacter Pylori Serology Testing</b>	<b>Division: Medical Management Department: Utilization Management</b>
<b>Approval Date: 6/8/2020</b>	<b>LOB: Medicaid, HARP, HIV-SNP CHP, Medicare, Ultracare, Essential Plan 3 &amp; 4</b>
<b>Effective Date: 6/8/2020</b>	<b>Policy Number: UM-MP256</b>
<b>Review Date: 1/28/22</b>	<b>Cross Reference Number:</b>
<b>Retired Date:</b>	<b>Page 1 of 5</b>

## 1. POLICY DESCRIPTION:

Helicobacter pylori (H. pylori) is a gram negative bacteria which causes chronic inflammation (infection) in the stomach and is associated with conditions such as peptic ulcer disease, chronic gastritis, gastric adenocarcinoma, and gastric mucosa associated lymphoid tissue (MALT) lymphoma.

Serologic evaluation of patients to determine the presence/absence of Helicobacter pylori (H. pylori) infection is no longer considered clinically useful. Alternative noninvasive testing methods (e.g., the urea breath test and stool antigen test) exist for detecting the presence of the bacteria and have demonstrated higher clinical utility, sensitivity, and specificity. Additionally, both the American College of Gastroenterology and the American Gastroenterology Association recommend either the breath or stool antigen tests as the preferred testing modalities for active H. pylori infection. Finally, several laboratories have dropped the serological test from their menus, and many insurance providers are no longer reimbursing patients for serologic testing.

## 2. RESPONSIBLE PARTIES:

Medical Management Administration, Utilization Management, Integrated Care Management, Pharmacy, Claim Department, Providers Contracting.

## 3. DEFINITIONS:

Helicobacter pylori (H. pylori) — gram-negative rod bacteria found in adults and children; associated with chronic active/persistent gastritis, peptic ulcer disease, gastric cancer and possibly gastric lymphoma.

Urea breath testing (UBT) – Laboratory-based using ELISA technology to detect immunoglobulin G (IgG) antibodies.

Fecal (stool) antigen – Detects the presence of H. pylori antigen in stool by enzyme immunoassay (Lab or office-based [rapid])

## 4. POLICY:

MetroPlus Health considers antibody H. Pylori (86677) to be non-covered. Non-invasive options for detection of active H. pylori infection include urea breath tests and stool antigen testing. See section 6 for covered codes and applicable diagnosis.

<b>Title: Helicobacter Pylori Serology Testing</b>	<b>Division: Medical Management</b> <b>Department: Utilization Management</b>
<b>Approval Date: 6/8/2020</b>	<b>LOB: Medicaid, HARP, HIV-SNP</b> <b>CHP, Medicare, Ultracare, Essential Plan 3 &amp; 4</b>
<b>Effective Date: 6/8/2020</b>	<b>Policy Number: UM-MP256</b>
<b>Review Date: 12/23/2020</b>	<b>Cross Reference Number:</b>
<b>Retired Date:</b>	<b>Page 2 of 5</b>

The stool antigen test is an immunoassay that detects the presence of *H. pylori* in a stool sample. The test is reported to have greater than 90% sensitivity and specificity for detection of active *H. pylori* infection, and its use has been FDA cleared for all ages. This test may be used for initial diagnostic purposes and for post-treatment testing. Urea breath tests, which take advantage of the bacteria's urease activity, may also be used to detect active *H. pylori* infection. The patient ingests a solution containing either 13C or 14C labeled urea, after a set amount of time, the patient's breath is collected and analyzed for the presence of 13C or 14C labeled CO<sub>2</sub>. If *H. pylori* is present it will have metabolized the labeled urea and labeled CO<sub>2</sub> will be detected, thus indicating infection with *H. pylori*. This test takes approximately 15-20 minutes (Crowe, 2018).

### Documentation Requirements:

The patient's medical record must contain documentation that fully supports the medical necessity for services included within this Medical Policy. (See "Limitations/Exclusions.") This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures.

## 5. LIMITATIONS/ EXCLUSIONS:

Urea breath tests and stool antigen tests are the most widely used non-invasive tests for identifying *H. pylori* infection, as well as most accurate. In addition, they can be used to confirm cure. Serologic tests are a convenient but less accurate alternative and cannot be used to confirm cure.

CPT code 86677 is non covered for any diagnosis.

The correct use of an ICD-10-CM code listed below does not assure coverage of a service. The service must be reasonable and necessary in the specific case and must meet the criteria specified in this determination.

## 6. APPLICABLE PROCEDURE CODES:

Applicable procedure code(s) below covered only with the applicable diagnosis codes below and the following place of service (POS): 11, 12, 20, 22, 81.

CPT	Description
83013	H pylori breath test for urease activity, non-radioactive isotope
83014	H pylori drug administration & sample collection

**87338** Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step method; Helicobacter pylori, stool

<b>Title: Helicobacter Pylori Serology Testing</b>	<b>Division: Medical Management</b> <b>Department: Utilization Management</b>
<b>Approval Date: 6/8/2020</b>	<b>LOB: Medicaid, HARP, HIV-SNP</b> <b>CHP, Medicare, Ultracare, Essential Plan 3 &amp; 4</b>
<b>Effective Date: 6/8/2020</b>	<b>Policy Number: UM-MP256</b>
<b>Review Date: 12/23/2020</b>	<b>Cross Reference Number:</b>
<b>Retired Date:</b>	<b>Page 3 of 5</b>

### 7. APPLICABLE DIAGNOSIS CODES

Code	Description
B96.81	H pylori as the the cause of disease classified elsewhere
C16.0	Malignant neoplasm of cardia
C16.1	Malignant neoplasm of fundus of stomach
C16.2	Malignant neoplasm of pyloric antrum
C16.3	Malignant neoplasm of pyloric antrum
C16.4	Malignant neoplasm of pylorus
C16.5	Malignant neoplasm of lesser curvature of stomach
C16.6	Malignant neoplasm of greater curvature of stomach, unspecified
C16.8	Malignant neoplasm of overlappings sites of stomach
C16.9	Malignant neoplasm of stomach, unspecified
C83.30	Diffuse large B-cell lymphoma, unspecified site
C83.31	Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck
C83.32	Diffuse large B-cell lymphoma, intrathoracic lymph nodes
C83.33	Diffuse large B-cell lymphoma, intra-abdominal lymph nodes
C83.34	Diffuse large B-cell lymphoma, lymph nodes of axilla and upper limb
C83.35	Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C83.36	Diffuse large B-cell lymphoma, intrapelvic lymph nodes
C83.37	Diffuse large B-cell lymphoma, spleen
C83.38	Diffuse large B-cell lymphoma, lymph nodes of multiple sites
C83.39	Diffuse large B-cell lymphoma, extranodal and solid organ sites
C88.4	Extranodal marginal zone B-cell lymphoma of mucosa-associated lymphoid tissue [MALT-lymphoma]
E66.01	Morbid (severe) obesity due to excess calories
E66.09	Other obesity due to excess calories
E66.1	Drug-induced obesity
E66.2	Morbid (severe) obesity with alveolar hypoventilation
E66.3	Overweight

<b>E66.8</b>	Other obesity
<b>E66.9</b>	Obesity, unspecified
<b>K25.0</b>	Acute gastric ulcer with hemorrhage
<b>K25.1</b>	Acute gastric ulcer with perforation
<b>K25.2</b>	Acute gastric ulcer with both hemorrhage and perforation
<b>K25.3</b>	Acute gastric ulcer without hemorrhage or perforation
<b>K25.4</b>	Chronic or unspecified gastric ulcer with hemorrhage
<b>K25.5</b>	Chronic or unspecified gastric ulcer with perforation
<b>K25.6</b>	Chronic or unspecified gastric ulcer with both hemorrhage and perforation
<b>K25.7</b>	Chronic gastric ulcer without hemorrhage or perforation
<b>K25.9</b>	Gastric ulcer, unspecified as acute or chronic, without hemorrhage or
<b>K26.0</b>	Acute duodenal ulcer with hemorrhage
<b>K26.1</b>	Acute duodenal ulcer with perforation
<b>K26.2</b>	Acute duodenal ulcer with both hemorrhage and perforation
<b>K26.3</b>	Acute duodenal ulcer without hemorrhage or perforation
<b>K26.4</b>	Chronic or unspecified duodenal ulcer with hemorrhage
<b>K26.5</b>	Chronic or unspecified duodenal ulcer with perforation
<b>K26.6</b>	Chronic or unspecified duodenal ulcer with both hemorrhage and
<b>K26.9</b>	Duodenal ulcer, unspecified as acute or chronic, without hemorrhage or
<b>K26.7</b>	Chronic duodenal ulcer without hemorrhage or perforation
<b>K27.0</b>	Acute peptic ulcer, site unspecified, with hemorrhage
<b>K27.1</b>	Acute peptic ulcer, site unspecified, with perforation
<b>K27.2</b>	Acute peptic ulcer, site unspecified, with both hemorrhage and perforation
<b>K27.3</b>	Acute peptic ulcer, site unspecified, without hemorrhage or perforation
<b>K27.4</b>	Chronic or unspecified peptic ulcer, site unspecified, with both hemorrhage
<b>K27.5</b>	Chronic or unspecified peptic ulcer, site unspecified, with hemorrhage
<b>K27.6</b>	Chronic or unspecified peptic ulcer, site unspecified, with perforation
<b>K27.7</b>	Chronic peptic ulcer, site unspecified, without hemorrhage or perforation
<b>K27.9</b>	Peptic ulcer, site unspecified, unspecified as acute or chronic, without
<b>K28.0</b>	Acute gastrojejunal ulcer with hemorrhage
<b>K28.1</b>	Acute gastrojejunal ulcer with perforation
<b>K28.2</b>	Acute gastrojejunal ulcer with both hemorrhage and perforation
<b>K28.3</b>	Acute gastrojejunal ulcer without hemorrhage or perforation
<b>K28.4</b>	Chronic or unspecified gastrojejunal ulcer with hemorrhage
<b>K28.5</b>	Chronic or unspecified gastrojejunal ulcer with perforation
<b>K28.6</b>	Chronic or unspecified gastrojejunal ulcer with both hemorrhage and
<b>K28.7</b>	Chronic gastrojejunal ulcer without hemorrhage or perforation
<b>K28.9</b>	Gastrojejunal ulcer, unspecified as acute or chronic, without hemorrhage or
<b>K29.00</b>	Acute gastritis without bleeding
<b>K29.01</b>	Acute gastritis with bleeding
<b>K29.20</b>	Alcoholic gastritis without bleeding
<b>K29.21</b>	Alcoholic gastritis with bleeding
<b>K29.30</b>	Chronic superficial gastritis without bleeding
<b>K29.31</b>	Chronic superficial gastritis with bleeding
<b>K29.40</b>	Chronic atrophic gastritis without bleeding

<b>K29.41</b>	Chronic atrophic gastritis with bleeding
<b>K29.50</b>	Unspecified chronic gastritis without bleeding
<b>K29.51</b>	Unspecified chronic gastritis with bleeding
<b>K29.60</b>	Other gastritis without bleeding
<b>K29.61</b>	Other gastritis with bleeding
<b>K29.70</b>	Gastritis, unspecified, without bleeding
<b>K29.71</b>	Gastritis, unspecified, with bleeding
<b>K29.80</b>	Duodenitis without bleeding
<b>K29.81</b>	Duodenitis with bleeding
<b>K29.90</b>	Gastroduodenitis, unspecified, without bleeding
<b>K29.91</b>	Gastroduodenitis, unspecified, with bleeding
<b>K30</b>	Functional dyspepsia
<b>K31.89</b>	Other diseases of stomach and duodenum
<b>R10.13</b>	Epigastric pain
<b>Z87.11</b>	Personal history of peptic ulcer disease

### 8. REFERENCES:

American Society for Clinical Pathology. American Board of Internal Medicine's (ABIM) Foundation Choosing Wisely® Initiative. Do not request serology for H. pylori. Use the stool antigen or breath tests instead. 2016 Sep. Accessed April 14, 2020. Available at URL address: <http://www.choosingwisely.org/clinician-lists/american-society-clinical-pathology-serology-for-h-pylori/>

Best LMJ, Takwoingi Y, Siddique S, Selladurai A, Gandhi A, Low B, Yaghoobi M, Gurusamy KS. Noninvasive diagnostic tests for Helicobacter pylori infection. Cochrane Database of Systematic Reviews 2018, Issue 3. Art. No.: CD012080.

Miftahussurur M, Yamaoka Y. Diagnostic Methods of Helicobacter pylori Infection for Epidemiological Studies: Critical Importance of Indirect Test Validation. Biomed Res Int. 2016;2016:4819423. Doi: 10.1155/2016/4819423. Epub 2016 Jan 19. PMID: 26904678; PMCID: PMC4745376.

Chey WD, Leontiadis GI, Howden CW, Moss SF. ACG Clinical Guideline: Treatment of Helicobacter pylori Infection. Am J Gastroenterol. 2017 Feb;112(2):212-239.

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.

Vakil N, Fendrick AM. How to test for Helicobacter pylori in 2005. Cleve Clin J Med. 2005 May;72 Suppl 2:S8-13; discussion S14-21.

<https://medlineplus.gov/lab-tests/helicobacter-pylori-h-pylori-tests/>

<b>Title: Helicobacter Pylori Serology Testing</b>	<b>Division: Medical Management Department: Utilization Management</b>
<b>Approval Date: 6/8/2020</b>	<b>LOB: Medicaid, HARP, HIV-SNP CHP, Medicare, Ultracare, Essential Plan 3 &amp; 4</b>
<b>Effective Date: 6/8/2020</b>	<b>Policy Number: UM-MP256</b>
<b>Review Date: 12/23/2020</b>	<b>Cross Reference Number:</b>
<b>Retired Date:</b>	<b>Page 6 of 5</b>

### REVISION LOG:

REVISIONS	DATE
Creation date	04/14/20
Update coverage limitation by LOB and Place of Service	12/23/20
Revised with changes	1/29/21
Annual Review	1/28/22

Approved:

Date:

Approved:

Date:

---

**Glendon Henry, MD**  
Senior Medical Director

---

**Sanjiv Shah, MD**  
Chief Medical Officer

<b>Title: Helicobacter Pylori Serology Testing</b>	<b>Division: Medical Management</b>
<b>Approval Date: 6/8/2020</b>	<b>Department: Utilization Management</b>
<b>Effective Date: 6/8/2020</b>	<b>LOB: Medicaid, HARP, HIV-SNP</b>
<b>Review Date: 12/23/2020</b>	<b>CHP, Medicare, Ultracare, Essential Plan 3 &amp; 4</b>
<b>Retired Date:</b>	<b>Policy Number: UM-MP256</b>
	<b>Cross Reference Number:</b>
	<b>Page 7 of 5</b>

### **Medical Guideline Disclaimer:**

Property of Metro Plus Health Plan. All rights reserved. The treating physician or primary care provider must submit MetroPlus Health Plan clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, MetroPlus Health Plan will not be able to properly review the request for prior authorization. The clinical review criteria expressed in this policy reflects how MetroPlus Health Plan determines whether certain services or supplies are medically necessary. MetroPlus Health Plan established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). MetroPlus Health Plan expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by MetroPlus Health Plan, as some programs exclude coverage for services or supplies that MetroPlus Health Plan considers medically necessary. If there is a discrepancy between this guidelines and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and website links are accurate at time of publication. MetroPlus Health Plan has adopted the herein policy in providing management, administrative and other services to our members, related to health benefit plans offered by our organization.