

Medical Policy: Non-Invasive Helicobacter Pylori Testing (Commercial)



POLICY NUMBER	EFFECTIVE DATE	APPROVED BY
MG.MM.LA.16aC	02/11/2022	MPC (Medical Policy Committee)

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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.

Non-invasive Testing Modalities (those that do not require endoscopy)

Urea breath testing (UBT)	Identifies the presence of <i>H. pylori</i> infection by way of the organism's urease activity. In the presence of <i>H. pylori</i> , the ingestion of urea, labeled with either the nonradioactive isotope ¹³ C or the radioactive isotope ¹⁴ C, results in production of labeled CO ₂ , which can be quantitated in expired breath
Serology (antibody)	Laboratory-based using ELISA technology to detect immunoglobulin G (IgG) antibodies. (See Limitations/Exclusions)
Fecal antigen	Detects the presence of <i>H. pylori</i> antigen in stool by enzyme immunoassay (Lab or office-based [rapid])

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Guideline

Members are eligible for coverage of non-invasive *H. pylori* testing for both the initial work-up (to confirm suspicion of infection), as well as the post-treatment follow up (to confirm eradication of infection).

The UBT (¹³C or ¹⁴C) and fecal antigen (HpSA[®]) tests are considered medically necessary for members who are < 55 years of age without alarm features (bleeding, anemia, early satiety, unexplained weight loss, progressive dysphagia, odynophagia, recurrent vomiting, family history of gastrointestinal cancer, previous esophagogastric malignancy) when any of the following are applicable (list not all-inclusive):

1. Active gastric/duodenal ulcer disease (regardless of nonsteroidal inflammatory [NSAID] medication use)
2. History of complicated or uncomplicated peptic ulcer disease (not previously treated for *H. pylori*)
3. Presence of low grade gastric mucosa-associated lymphoid tissue (MALT)
4. Post endoscopic resection of early gastric cancer
5. Uninvestigated dyspepsia (depending upon *H. pylori* prevalence)¹

Post-treatment confirmation testing for *H. pylori* eradication is considered medically necessary

Limitations/Exclusions

1. Serological antibody testing (CPT 86677) does not test for active *H. pylori* infection and is therefore, not considered medically necessary for diagnosis or post treatment follow up.
2. Concurrent UBT–HpSA[®] testing is redundant and therefore not considered medically necessary.
3. Confirmation testing to insure infection-eradication is not considered medically necessary when performed < (4) four weeks post treatment and after PPI therapy has been withheld for 1-2 weeks.
4. *H. pylori* testing is not considered medically necessary for any of the following:
 - a. Screening without intent to treat infection
 - b. Member to undergo endoscopy
5. Genotyping to determine cytochrome p450 (CYP2C19) genetic polymorphisms is not considered medically necessary for *H. pylori* management, as there is insufficient evidence to permit the conclusion that pharmacogenomics-based treatment improves eradication rates.

¹The American College of Gastroenterology (ACG) endorses the test-and-treat strategy for *H. pylori* as a proven management strategy for persons with uninvestigated dyspepsia less than 55 years of age (without "alarm features").

Invasive testing through endoscopy is recommended for persons with alarm features or those 55 or over.

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Applicable Procedure Codes

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
87338	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzymelinked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step method; Helicobacter pylori, stool
87339	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzymelinked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step method; Helicobacter pylori

Applicable ICD-10 Diagnosis Codes

B96.81	Helicobacter pylori [H. pylori] as the cause of diseases classified elsewhere
C16.0	Malignant neoplasm of cardia
C16.1	Malignant neoplasm of fundus of stomach
C16.2	Malignant neoplasm of body of stomach
C16.3	Malignant neoplasm of pyloric antrum
C16.4	Malignant neoplasm of pylorus
C16.5	Malignant neoplasm of lesser curvature of stomach, unspecified
C16.6	Malignant neoplasm of greater curvature of stomach, unspecified
C16.8	Malignant neoplasm of overlapping sites of stomach
C16.9	Malignant neoplasm of stomach, unspecified
C83.83	Other non-follicular lymphoma, intra-abdominal lymph nodes
C83.86	Other non-follicular lymphoma, intrapelvic lymph nodes
C83.87	Other non-follicular lymphoma, spleen
C83.88	Other non-follicular lymphoma, lymph nodes of multiple sites
C83.89	Other non-follicular lymphoma, extranodal and solid organ sites
D00.2	Carcinoma in situ of stomach
D13.1	Benign neoplasm of stomach
K25.0	Acute gastric ulcer with hemorrhage
K25.1	Acute gastric ulcer with perforation
K25.2	Acute gastric ulcer with both hemorrhage and perforation
K25.3	Acute gastric ulcer without hemorrhage or perforation
K25.4	Chronic or unspecified gastric ulcer with hemorrhage
K25.5	Chronic or unspecified gastric ulcer with perforation
K25.6	Chronic or unspecified gastric ulcer with both hemorrhage and perforation
K25.7	Chronic gastric ulcer without hemorrhage or perforation
K25.9	Gastric ulcer, unspecified as acute or chronic, without hemorrhage or perforation
K26.0	Acute duodenal ulcer with hemorrhage

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K26.1	Acute duodenal ulcer with perforation
K26.2	Acute duodenal ulcer with both hemorrhage and perforation
K26.3	Acute duodenal ulcer without hemorrhage or perforation
K26.4	Chronic or unspecified duodenal ulcer with hemorrhage
K26.5	Chronic or unspecified duodenal ulcer with perforation
K26.6	Chronic or unspecified duodenal ulcer with both hemorrhage and perforation
K26.7	Chronic duodenal ulcer without hemorrhage or perforation
K26.9	Duodenal ulcer, unspecified as acute or chronic, without hemorrhage or perforation
K27.0	Acute peptic ulcer, site unspecified, with hemorrhage
K27.2	Acute peptic ulcer, site unspecified, with both hemorrhage and perforation
K27.3	Acute peptic ulcer, site unspecified, without hemorrhage or perforation
K27.4	Chronic or unspecified peptic ulcer, site unspecified, with hemorrhage
K27.5	Chronic or unspecified peptic ulcer, site unspecified, with perforation
K27.6	Chronic or unspecified peptic ulcer, site unspecified, with both hemorrhage and perforation
K27.7	Chronic peptic ulcer, site unspecified, without hemorrhage or perforation
K27.9	Peptic ulcer, site unspecified, unspecified as acute or chronic, without hemorrhage or perforation
K28.0	Acute gastrojejunal ulcer with hemorrhage
K28.1	Acute gastrojejunal ulcer with perforation
K28.2	Acute gastrojejunal ulcer with both hemorrhage and perforation
K28.3	Acute gastrojejunal ulcer without hemorrhage or perforation
K28.4	Chronic or unspecified gastrojejunal ulcer with hemorrhage
K28.5	Chronic or unspecified gastrojejunal ulcer with perforation
K28.6	Chronic or unspecified gastrojejunal ulcer with both hemorrhage and perforation
K28.7	Chronic gastrojejunal ulcer without hemorrhage or perforation
K28.9	Gastrojejunal ulcer, unspecified as acute or chronic, without hemorrhage or perforation
K29.21	Alcoholic gastritis with bleeding
K29.30	Chronic superficial gastritis without bleeding
K29.31	Chronic superficial gastritis with bleeding
K29.40	Chronic atrophic gastritis without bleeding
K29.41	Chronic atrophic gastritis with bleeding
K29.50	Unspecified chronic gastritis without bleeding
K29.51	Unspecified chronic gastritis with bleeding
K29.60	Other gastritis without bleeding
K29.61	Other gastritis with bleeding
K29.70	Gastritis, unspecified, without bleeding
K29.71	Gastritis, unspecified, with bleeding
K29.90	Gastroduodenitis, unspecified, without bleeding
K29.91	Gastroduodenitis, unspecified, with bleeding
K30	Functional dyspepsia

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References

American College of Gastroenterology. Guideline on the Management of Helicobacter pylori Infection. Jan. 2017. <http://gi.org/wp-content/uploads/2018/04/ACG-H.-pylori-Guideline-Summary.pdf>. Accessed February 16, 2022.

Raman G, Trikalinos TA, Zintzaras E, et al. Reviews of selected pharmacogenetic tests for non-cancer and cancer conditions. Technology Assessment Report. Prepared by the Tufts Evidence-based Practice Center for the Agency for Healthcare Research and Quality (AHRQ). Contract No. 290-02-0022. Rockville, MD: AHRQ; November 12, 2008. <http://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id61TA.pdf>. Accessed February 16, 2022.

Specialty Matched Clinical Peer Review.

Revision history

DATE	REVISION
02/12/2021	Connecticare has adopted the clinical criteria of its parent corporation, EmblemHealth.