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Harmony Behavioral Health of Florida, Inc.

Harmony Health Plan of Illinois, Inc.

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Helicobacter Pylori Testing

Policy Number: HS-131

Original Effective Date: 9/17/2009

Revised Date(s): 9/24/2010; 9/1/2011

DISCLAIMER

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

BACKGROUND

H. pylori is a spiral-shaped, gram-negative bacterium found in the gastric mucosa or attached to the epithelial lining of the stomach. The organism weakens the protective mucous coating of the stomach and duodenum, allowing acid to get through to the sensitive lining beneath. Both the acid and the bacteria irritate the lining and cause the ulcer. *H. pylori* is able to survive in stomach acid because it secretes enzymes that neutralize the acid. Acute infection is commonly asymptomatic but may be associated with epigastric burning, abdominal distention or bloating, belching, nausea, flatulence, and/or halitosis. Almost all members infected with *H. pylori* who have had endoscopic biopsies are found to have histological gastritis. *H. pylori* infection can lead to ulceration of the gastric mucosa and duodenum and has been found to be strongly associated with the development of epithelial and lymphoid malignancies of the stomach. It has been classified by the International Agency for Research on Cancer as a group I carcinogen and a definite cause of gastric cancer in humans.

Associations have been made between *H. pylori* and both dyspepsia and gastroesophageal reflux disease (GERD). Dyspepsia is clinically defined as nausea, epigastric pain or discomfort experienced on more than seven days of a four-week period. Factors that affect the management of dyspepsia include the patient's age, routine use of NSAIDs, and presence of any alarm symptoms. Alarm symptoms are identified as melena, hematemesis, persistent vomiting, anemia, acute onset of total dysphagia or involuntary weight loss greater than 5%. The procedure of choice for evaluation of dyspepsia is endoscopy, especially when alarm symptoms are present. For patients with a documented history of PUD who present with dyspepsia in the absence of reflux or alarm symptoms, management should begin with testing for *H. pylori*, followed by eradication therapy if results are positive. It has not been proven that eradication of *H. pylori* improves symptoms in patients with non-ulcer dyspepsia.

According to the National Institute for Clinical Excellence (NICE) guidelines for the management of dyspepsia in adults, *H. pylori* can be initially detected using either a carbon-13 urea breath test (UBT), stool antigen test or laboratory-based serology where its performance has been locally validated. Initial therapeutic strategies for dyspepsia include empirical treatment with a proton pump inhibitor (PPI) or testing for and treating *H. pylori*. There is currently insufficient evidence to guide which should be offered first.

H. pylori infection can be confirmed by invasive or noninvasive methods. Invasive tests require upper esophagogastroduodenal (EGD) endoscopy, which is considered the reference method of diagnosis. During endoscopy, biopsy specimens of the stomach and duodenum are obtained, and the diagnosis of *H. pylori* can be made by urease testing, histology and/or culture. If possible, noninvasive testing is done before tissue testing.

Noninvasive methods include *H. pylori* stool antigen (HpSA), serology, and urea breath testing. HpSA testing is based on monoclonal antibody immunochromatography of stool samples. This testing method identifies active infection and can be used to detect eradication after treatment. A sensitivity and specificity range of 92–98% is reported in the literature for stool antigen testing.

In a UBT, the patient is given an oral preparation of either nonradioisotope carbon-13- (13C-) labeled urea, or radioactive isotope carbon-14- (14C-) labeled urea. In the presence of *H. pylori* infection, bacterial urease metabolizes the urea to produce labeled carbon dioxide (CO₂) and ammonia. The labeled carbon diffuses into the bloodstream and is excreted by the lungs. This labeled carbon can then be measured as CO₂ in the patient's expired breath to determine the presence of *H. pylori*. The 13C-labeled urea is detected by mass spectrometry and the 14C-labeled urea by liquid scintillation. UBT is indicated for the initial diagnosis of *H. pylori* infection and for follow-up of eradication therapy. The sensitivity and specificity of UBT ranges from 94–98%. False-negatives can result from acid suppression with PPIs; therefore, acid suppression treatment should be withheld for two weeks prior to testing. In addition, retesting for confirmation of eradication should be done at least four weeks after completion of therapy. ICSI guidelines state that UBT is the test of choice when post-treatment testing is needed. UBT is reliable in children over six years of age but needs further validation in younger children.

POSITION STATEMENT

The following methods **are considered medically necessary** for diagnosing Helicobacter pylori (H. pylori) infection:

- Endoscopic biopsy with urease testing, histology and/or culture
- H. pylori stool antigen (HpSA)
- Serology in individuals not previously treated for H. pylori infection
- Urea breath testing (criteria outlined below)

The H. pylori urea breath test **is considered medically necessary** in the following circumstances:

- Member with uncomplicated symptoms of peptic ulcer disease for whom antibiotic therapy is planned, if H. pylori breath test is positive, and no endoscopy is planned; **OR**,
- Members who have had an upper gastrointestinal endoscopy and in whom no helicobacter testing was performed; **OR**,
- Members who have non-specific dyspeptic symptoms with a positive H. pylori serum antibody test, and no endoscopy is planned; **OR**,
- An upper gastrointestinal contrast X-ray series has been done that shows a duodenal ulcer or significant gastritis and/or duodenitis, and no endoscopy is planned; **OR**,
- There are persistent or recurrent symptoms six weeks after treatment for a documented H. pylori infection, and no endoscopy is planned; **OR**,
- Anyone with complications from peptic ulcer disease after appropriate antibiotic/H3 antagonist treatment, to establish a bacterial cure.

The H. pylori breath test **is considered NOT medically necessary** in the following circumstances:

- Members who are being (V74.9) screened for H. pylori infection in the absence of documented upper gastrointestinal tract symptoms and/or pathology; **OR**,
- Members who have had an upper gastrointestinal endoscopy within the preceding six weeks and helicobacter testing was performed, or for whom an upper gastrointestinal endoscopy is planned who have not been treated for H. pylori; **OR**,
- Members who have non-specific dyspeptic symptoms with a negative H. pylori serum antibody test or a negative H. pylori stool antigen test; **OR**,
- Members who are asymptomatic after treatment of an H. pylori infection except in the situation of a history of a major complication of ulcer disease such as bleeding, perforation, penetration or multiple recurrences in which case an H. pylori breath test may be used to document eradication of the infection in lieu of a follow-up endoscopy.

CODING

Covered CPT ©* 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 (C-13)
83013	H pylori; breath test analysis for urease activity, non-radioactive isotope; C13
83014	H pylori; drug administration
86677	H pylori; antibody
87338	H pylori, stool ; EIA or ELISA

87339 H pylori; EIA or ELISA

ICD-9-CM Procedure Codes - No applicable codes

HCPCS Level II ©Codes - No applicable codes

Covered ICD-9 Diagnosis Codes

041.86 Helicobacter Pylori [H. PYLORI]
530.81 Esophageal Reflux
531.00 Acute Gastric Ulcer with hemorrhage without obstruction
531.01 Acute Gastric Ulcer with hemorrhage with obstruction
531.10 Acute Gastric Ulcer with perforation without obstruction
531.11 Acute Gastric Ulcer with perforation with obstruction
531.20 Acute Gastric Ulcer with hemorrhage and perforation without obstruction
531.21 Acute Gastric Ulcer with hemorrhage and perforation with obstruction
531.30 Acute Gastric Ulcer without hemorrhage or perforation without obstruction
531.31 Acute Gastric Ulcer without hemorrhage or perforation with obstruction
531.40 Chronic or unspecified Gastric Ulcer with hemorrhage without obstruction
531.41 Chronic or unspecified Gastric Ulcer with hemorrhage with obstruction
531.50 Chronic or unspecified Gastric Ulcer with perforation without obstruction
531.51 Chronic or unspecified Gastric Ulcer with perforation with obstruction
531.60 Chronic or unspecified Gastric Ulcer with hemorrhage and perforation without obstruction
531.61 Chronic or unspecified Gastric Ulcer with hemorrhage and perforation with obstruction
531.70 Chronic Gastric Ulcer without hemorrhage or perforation without obstruction
531.71 Chronic Gastric Ulcer without hemorrhage or perforation with obstruction
531.90 Gastric Ulcer unspecified as acute or chronic without hemorrhage or perforation without obstruction
531.91 Gastric Ulcer unspecified as acute or chronic without hemorrhage or perforation with obstruction
532.00 Acute Duodenal Ulcer with hemorrhage without obstruction
532.01 Acute Duodenal Ulcer with hemorrhage with obstruction
532.10 Acute Duodenal Ulcer with perforation without obstruction
532.11 Acute Duodenal Ulcer with perforation with obstruction
532.20 Acute Duodenal Ulcer with hemorrhage and perforation without obstruction
532.21 Acute Duodenal Ulcer with hemorrhage and perforation with obstruction
532.30 Acute Duodenal Ulcer without hemorrhage or perforation without obstruction
532.31 Acute Duodenal Ulcer without hemorrhage or perforation with obstruction
532.40 Chronic or unspecified Duodenal Ulcer with hemorrhage without obstruction
532.41 Chronic or unspecified Duodenal Ulcer with hemorrhage with obstruction
532.50 Chronic or unspecified Duodenal Ulcer with perforation without obstruction
532.51 Chronic or unspecified Duodenal Ulcer with perforation with obstruction
532.60 Chronic or unspecified Duodenal Ulcer with hemorrhage and perforation without obstruction
532.61 Chronic or unspecified Duodenal Ulcer with hemorrhage and perforation with obstruction

Covered ICD-9 Diagnosis Codes continued

532.70 Chronic Duodenal Ulcer without hemorrhage or perforation without obstruction
532.71 Chronic Duodenal Ulcer without hemorrhage or perforation with obstruction
532.90 Duodenal Ulcer unspecified as acute or chronic without hemorrhage or perforation without obstruction
532.91 Duodenal Ulcer unspecified as acute or chronic without hemorrhage or perforation with obstruction
533.00 Acute Peptic Ulcer of unspecified site with hemorrhage without obstruction
533.01 Acute Peptic Ulcer of unspecified site with hemorrhage with obstruction

- 533.10** Acute Peptic Ulcer of unspecified site with perforation without obstruction
- 533.11** Acute Peptic Ulcer of unspecified site with perforation with obstruction
- 533.20** Acute Peptic Ulcer of unspecified site with hemorrhage and perforation without obstruction
- 533.21** Acute Peptic Ulcer of unspecified site with hemorrhage and perforation with obstruction
- 533.30** Acute Peptic Ulcer of unspecified site without hemorrhage and perforation without obstruction
- 533.31** Acute Peptic Ulcer of unspecified site without hemorrhage and perforation with obstruction
- 533.40** Chronic or unspecified Peptic Ulcer of unspecified site with hemorrhage without obstruction
- 533.41** Chronic or unspecified Peptic Ulcer of unspecified site with hemorrhage with obstruction
- 533.50** Chronic or unspecified Peptic Ulcer of unspecified site with perforation without obstruction
- 533.51** Chronic or unspecified Peptic Ulcer of unspecified site with perforation with obstruction
- 533.60** Chronic or unspecified Peptic Ulcer of unspecified site with hemorrhage & perforation without obstruction
- 533.61** Chronic or unspecified Peptic Ulcer of unspecified site with hemorrhage and perforation with obstruction
- 533.70** Chronic Peptic Ulcer of unspecified site without hemorrhage or perforation without obstruction
- 533.71** Chronic Peptic Ulcer of unspecified site without hemorrhage or perforation with obstruction
- 533.90** Peptic Ulcer of unspecified site unspecified as acute or chronic without hemorrhage or perforation without obstruction
- 533.91** Peptic Ulcer of unspecified site unspecified as acute or chronic without hemorrhage or perforation with obstruction
- 534.00** Acute Gastrojejunal Ulcer with hemorrhage without obstruction.
- 534.01** Acute Gastrojejunal Ulcer with hemorrhage with obstruction
- 534.10** Acute Gastrojejunal Ulcer with perforation without obstruction
- 534.11** Acute Gastrojejunal Ulcer with perforation with obstruction
- 534.20** Acute Gastrojejunal Ulcer with hemorrhage and perforation without obstruction
- 534.21** Acute Gastrojejunal Ulcer with hemorrhage and perforation with obstruction
- 534.30** Acute Gastrojejunal Ulcer without hemorrhage or perforation without obstruction
- 534.31** Acute Gastrojejunal Ulcer without hemorrhage or perforation with obstruction
- 534.40** Chronic or unspecified Gastrojejunal Ulcer with hemorrhage without obstruction
- 534.41** Chronic or unspecified Gastrojejunal Ulcer with hemorrhage with obstruction
- 534.50** Chronic or unspecified Gastrojejunal Ulcer with perforation without obstruction
- 534.51** Chronic or unspecified Gastrojejunal Ulcer with perforation with obstruction
- 534.60** Chronic or unspecified Gastrojejunal Ulcer with hemorrhage and perforation without obstruction
- 534.61** Chronic or unspecified Gastrojejunal Ulcer with hemorrhage and perforation with obstruction
- 534.70** Chronic Gastrojejunal Ulcer without hemorrhage or perforation without obstruction
- 534.71** Chronic Gastrojejunal Ulcer without hemorrhage or perforation with obstruction
- 534.90** Gastrojejunal Ulcer unspecified as acute or chronic without hemorrhage or perforation without obstruction
- 534.91** Gastrojejunal Ulcer unspecified as acute or chronic without hemorrhage or perforation with obstruction
- 535.00** Acute Gastritis without hemorrhage
- 535.01** Acute Gastritis with hemorrhage
- 535.10** Atrophic Gastritis without hemorrhage
- 535.11** Atrophic Gastritis with hemorrhage
- 535.20** Gastric Mucosal Hypertrophy without hemorrhage
- 535.21** Gastric Mucosal Hypertrophy with hemorrhage
- 535.30** Alcoholic Gastritis without hemorrhage
- 535.31** Alcoholic Gastritis with hemorrhage
- 535.40** Other specified Gastritis without hemorrhage
- 535.41** Other specified Gastritis with hemorrhage
- 535.50** Unspecified Gastritis and Gastroduodenitis without hemorrhage
- 535.51** Unspecified Gastritis and Gastroduodenitis with hemorrhage
- 535.60** Duodenitis without hemorrhage
- 535.61** Duodenitis with hemorrhage

- 536.2** Persistent vomiting
- 536.8** Dyspepsia and other specified disorders of function of stomach
- 537.89** Other specified disorders of stomach and duodenum
- 538** Gastrointestinal mucositis – ulcerative
- 787.01** Nausea with vomiting
- 787.03** Vomiting Alone

Covered ICD-9 Diagnosis Codes continued

- 787.1** Heartburn
- 787.3** Flatulence eructation and gas pain
- 789.01** Abdominal pain right upper quadrant
- 789.02** Abdominal pain left upper quadrant
- 789.06** Abdominal pain epigastric
- 793.4** Nonspecific Abnormal Findings on radiological and other examination of the gastrointestinal tract

NON-COVERED ICD-9-CM DIAGNOSIS CODE

- V74.9** Special Screen Examination for Bacterial and Spirochetal disease

*Current Procedural Terminology (CPT®) ©2011 American Medical Association: Chicago, IL.

REFERENCES**Peer Reviewed**

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Government Agencies, Professional and Medical Organizations

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HISTORY AND REVISIONS

Date	Action
12/1/2011	• New template design approved by MPC.
9/1/2011	• Approved by MPC.