

LCD for Helicobacter Pylori Testing (L30163)

Contractor Information

Contractor Name

Wisconsin Physicians Service Insurance Corporation

Contractor Number

00951, 00952, 00953, 00954, 52280, 05101, 05201, 05301, 05401, 05102, 05202, 05302, 05402

Contractor Type

Carrier – MAC – FI

LCD Information

LCD ID Number

L30163

LCD Title

Helicobacter Pylori Testing

Contractor's Determination Number

PATH-026

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CMS National Coverage Policy

Social Security Act

Title XVII of the *Social Security Act*, section 1862 (a)(1)(A). This section allows coverage and payment for only those services that are considered to be medically reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member.

Title XVII of the *Social Security Act*, section 1862 (a)(1)(D).

Title XVII of the *Social Security Act*, section 1862 (a)(7). This section excludes routine physical examinations.

Title XVII of the *Social Security Act*, section 1833(e).

CMS Publication

CMS Publication, *Medicare Benefit Policy Manual*, 100-02.

CMS Publication, *Medicare Claims Processing Manual*, 100-04.

CMS Publication Medicare national Coverage Determinations Manual, 100-03.

Correct Coding Initiative, *Medicare Contractor beneficiary and Provider Communications Manual*, Publication 100-09, Chapter 5.

Oversight Region

Region V

Original Determination Effective Date

For services performed on or after 10/16/2009

Original Determination Ending Date**Revision Effective Date**

For services performed on or after 02/01/2010

Revision Ending Date**Indications and Limitations of Coverage and/or Medical Necessity**

Indications and Limitations of Coverage and/or Medical Necessity

Helicobacter pylori (H. pylori) is a gram-negative rod bacteria that is uniquely adapted to survive in the highly acidic gastric environment. H. pylori infection of the stomach and duodenum has been causally linked to the development of chronic active gastritis, peptic ulcer disease, gastric cancer, and probably some forms of gastric lymphoma. However, an association between H. pylori infection and non-ulcerative dyspepsia has not been established.

H. pylorus is a chronic infection, which increases in prevalence with age. Only 15%-30% of infected individuals develop peptic ulcers. Eradication of the infection results in resolution of the gastritis and a marked decrease in the recurrence rate of peptic ulcers. Gastric cancer develops in only 1% of patients with H. pylori-induced chronic atrophic gastritis. The pathogenesis of H. pylori-related peptic ulcers is not yet well understood. No theory explains why duodenal ulcers develop in some infected individuals; gastric ulcers develop in others, and most experience no ulcers at all.

According to the American College of Gastroenterology, the established indications for diagnosis and treatment of H. pylori are:

- Active peptic ulcer disease (gastric or duodenal ulcer)
- Confirmed history of peptic ulcer disease (not previously treated for H. pylori infection)
- Gastric MALT lymphoma (low grade)
- After endoscopic resection of early gastric cancer
- Uninvestigated dyspepsia (depending upon H. pylori prevalence)
- o Test and treat strategy, especially for those under 55 who have no alarm features.

Alarm features identified by the College of Gastroenterology are:

- Bleeding
- Anemia
- Early satiety
- Unexplained weight loss

- Progressive dysphagia
- Odynophagia
- Recurrent vomiting
- Family history of GI cancer
- Previous esophagogastric malignancy

It is not necessary to perform H. pylori testing in the following situations:

1. In the absence of documented gastritis or duodenal pathology (i.e. Patients who have had a normal upper GI endoscopy within the preceding six weeks).
2. Patients for whom an upper GI endoscopy is planned either for initial diagnosis or follow-up.
3. Patients who are asymptomatic after treatment of H. pylori infection, unless there is a documented family history of gastric cancer or it is necessary to resume NSAIDs or ulcerogenic medications.
4. Patients with dyspepsia requiring endoscopy and biopsy or to monitor response to therapy.
5. Patients with new onset, uncomplicated dyspeptic symptoms.

Types of Tests:

Testing for H. pylori can be divided into invasive specimen collection (biopsy and/or culture), non-invasive specimen collection (gram stain, rapid urease testing, serologic tests, breath tests) and assay for stool antigens (HpSA). The choice of specific testing depends on the clinical presentation of the patient and whether or not the patient requires endoscopy for evaluation. When medically necessary, more than one test may be needed to achieve the best diagnostic accuracy.

Tests available for the diagnosis of H. pylori infection differ with respect to sensitivity, specificity, invasiveness, cost and the additional information that they provide. The appropriate choice of testing is dependent on the clinical presentation of the patient.

Invasive Specimen Collection (i.e. endoscopy or surgery): Biopsy with culture is optimal for the detection of active infection. Esophagogastroduodenoscopy (EGD) is used to obtain specimens of gastric mucosa. If endoscopy is indicated for the clinical evaluation of the patient, collection of biopsy specimens for histologic examination, urease activity and/or culture may be considered. They are most frequently performed when endoscopy or open surgery is needed to define the presence and/or extent of upper gastrointestinal pathology. Negative tests may require follow-up testing of specimens collected by non-invasive techniques, like urea breath test or stool antigen test.

Biopsy samples: slides with or without special stains for microorganisms require an evaluation by a pathologist.

1. Rapid urease testing (CLO test, HP fast, HUT test). These are an agar test with a special pH indicator. When this test is positive for the presence of H. pylori, further histologic evaluation may not be needed. Urease testing of antral biopsies is likely to provide the best sensitivity and specificity of any single test, but performance depends on a number of factors such as sampling error, number of biopsies tested, presence of blood, medications, test technique, etc and may decrease the sensitivity of the urease tissue testing.
2. Histology is optimal for diagnosing H. pylori.
3. Culture is the least sensitive of the invasive methods and may not be recommended for initial evaluation, but should be considered in patients with refractory or recurrent infection. It is primarily a research tool to test for drug sensitivity. It is useful in the presence of antibiotic allergies or when drug resistance is a factor.
4. Histopathologic examination of endoscopically collected tissue is frequently performed using stains not specific for H. pylori, however the pathologic changes and presence of bacteria with characteristic morphology provide an accurate diagnosis. Histopathologic examination may be improved with special stains, like Giemsa or specific immunologic reagents. Gastric biopsy with organism staining is not regulated by this policy, therefore CPT codes 88305 for biopsy, 88312 for organism staining, and 88342 for immunohistochemistry (including tissue immunoperoxidase), each antibody are not addressed in this policy.

Non-Invasive Specimen Collection (blood, breath, stool, etc): These tests do not require endoscopy.

1. Serology, qualitative and semi-qualitative (86318 and 86677).

a. Quantitative: [Enzyme linked immunoabsorbent assays (ELISA).] This test is performed on serum in the laboratory.

b. Qualitative or semi-qualitative: This is an immunoassay test available in kit form that can be performed in the office setting.

The urea breath test or stool test is recommended for initial testing for *H. pylori* because they are non-invasive, accurate and cost-effective. Although the serological test for *H. pylori* antigen is non-invasive and cost-effective, it is not recommended for initial as well as eradication testing according to the American College of Gastroenterology (2007). Patient history and presenting complaints would determine if these tests and/or endoscopy would be performed. Serological testing may be appropriate for the patient with non-specific dyspeptic symptoms in order to rule in or out *H. Pylori* infection. This test is not appropriate to determine treatment outcome because the test is limited to the detection of antibodies and therefore cannot accurately detect active infection because high levels of antibodies persist for months after treatment. Serology is not used for follow-up testing or to determine cure.

2. Breath testing for *H. pylori* is considered to be a reliable proxy for active infection. Urea breath testing is considered a reliable form of non-invasive testing for initial diagnosis, confirmation of negative invasive testing, or test of cure, if indicated and medically reasonable and necessary. C-13 codes: 83013 and 83014 and C-14 codes: 78267 and 78268 are codes for administration of isotopes and analysis for qualitative breath tests using isotopes that can be used for pre-treatment assessment. There are currently two FDA approved tests available. The urea breath test is based on the ability of the *H. pylori* to breakdown urea, a chemical made up of nitrogen and carbon. Urease enzyme is not present in human cells; therefore the presence of urease in the stomach is evidence that bacteria are present. The person to be tested swallows a dose of urea labeled with C-13 or C-14. If gastric urease is present, urea is split to form carbon dioxide and nitrogen. The C-14 or C-13 labeled carbon dioxide is absorbed into the blood and exhaled in the breath. The breath is sampled at intervals for measurement of C-13 or C-14 carbon dioxide.

a. Urea-labeled with C-14 contains a radioactive isotope. Because of its radioactivity, C-14 is not recommended for use in children or during pregnancy or in women of childbearing years.

b. Urea-labeled with C-13 utilizes a stable non-radioactive isotope, available in kit form. It requires the use of an isotope-radio mass spectrometer.

Breath tests can detect the continued presence of *H-pylori* after treatment, (which is not the case with serology, where the presence of antibodies can exist for long periods of time).

Urea Breath Tests (UBTs) are indicated in patients who:

1. Continue to have symptoms of dyspepsia after completing a treatment regimen which includes appropriate antibiotics and no endoscopy is planned.
2. Have symptoms that continue four weeks after the treatment regimen has been completed.
3. Patients that have a history of hemorrhage, or outlet obstruction from peptic ulcer disease.
4. Patients with a history of ulcer on chronic NSAID or on anticoagulant therapy.

Breath tests are not considered medically necessary in the following situations:

1. Patients who are being screened for *H. pylori* infection in the absence of documented upper gastrointestinal tract symptoms and/or pathology.
2. Patients who have had upper gastrointestinal endoscopy within the preceding six weeks or for whom an upper gastrointestinal endoscopy is planned.
3. Patients who have non-specific dyspeptic symptoms with a negative *H. Pylori* serum antibody test.
4. Patients who are asymptomatic after treatment of an *H. pylori* infection (either proven or suspected). 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. If a follow-up breath test is used to document eradication of *H. pylori* in the asymptomatic patient, it is expected that the medical record documentation should verify the history of the previous complication.

Assay for Stool Antigen Microwell Based Enzyme Immunoassay (Premier Platinum HpSATM (87338)). This is a qualitative/semi quantitative test that detects H pylori antigens in human stool. The test is performed in the laboratory setting. Test results can aid in the diagnosis of H pylori as well as response to therapy. The stool test is appropriate for the patient with non-specific dyspeptic symptoms. In contrast to the serum antibody test, the stool antigen test returns to normal (negative) after successful treatment, and may determine treatment outcome.

Indications for stool antigen testing include:

- a. The initial detection of H pylori
- b. Follow-up of patients, who continue to have symptoms after completing a treatment regimen that includes appropriate antibiotics, i.e. symptoms continue four weeks after the treatment regimen has been completed.

Follow-up Testing: For patients who have been treated for a definitive diagnosis of H pylori infection, clinical follow-up for the ulcer/gastritis is indicated and may require continued antisecretory treatment. The American College of Gastroenterology (2005 & 2007) specifically recommends the assay for stool antigen and the urea breath tests for confirmation of eradication of the bacteria. The ease of test and relatively low costs make the assay for stool antigen an attractive alternative to the breath tests and endoscopy. However, it is not necessary in all cases to determine if the H. pylori organism is eradicated. The overall cure rate with current antibiotic treatment protocols is 90%. Those in whom recurrent ulcer symptoms develop during the first 2 years after treatment should be re-evaluated by endoscopy, breath test, or by enzyme immunoassay. In summary, the guidelines from the American College of Gastroenterology and American Gastroenterology Association (2005) suggest the use of accurate tests, such as the stool test, over other available tests (specifically serology) for the initial diagnosis and confirmation of eradication of H. Pylori.

The serological test for H. pylori is not recommended for eradication testing according to the American College of Gastroenterology (2007) because high levels of antibodies persist for months after successful or unsuccessful treatment.

Confirmation of successful H pylori cure may be necessary:

- In Patients with an H. pylori-associated ulcer
- Individuals with persistent dyspeptic symptoms despite the test-and –treat strategy
- Those with H. pylori-associated MALT lymphoma
- Individuals who have undergone resection of early gastric cancer

Refractory Conditions: A refractory duodenal ulcer is defined as one that is unhealed after eight weeks of antisecretory therapy. The therapeutic response of gastric ulcers is slower and is considered refractory if still present after twelve weeks of therapy. It is essential that the urease tests, breath tests or enzyme immunoassay are performed no sooner than one month, and preferably longer, after discontinuing agents capable of suppressing H. pylori (e.g. Bismuth, Omeprazole, antibiotics).

Screening services are not covered under Medicare.

Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

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Revenue codes only apply to providers who bill these services to the fiscal intermediary or MAC Part A. Revenue codes do not apply to physicians, other professionals and suppliers who bill these services to the carrier or MAC Part B.

Please note that not all Revenue Codes apply to every type of bill code. Providers are encouraged to refer to the FISS revenue code file for allowable bill types. Similarly, not all Revenue Codes apply to each CPT/HCPCS code. Providers are encouraged to refer to the FISS HCPCS file for allowable Revenue Codes.

030X	Laboratory-general classification
031X	Laboratory pathological-general classification

CPT/HCPCS Codes

Waived tests under CLIA:

Regulations require a facility to be appropriately certified for each test performed. To ensure that Medicare only pays for laboratory tests categorized as waived complexity under CLIA in facilities with a CLIA certificate of waiver, laboratory claims are currently edited at the CLIA certificate level (Medicare Claims Processing Manual, 100-04, Chapter 16, Section.

Note:
In addition to the above list, CPT codes that are not definitionally specific for H. pylori testing, but are used for the tests in this policy, are subject to the indications and limitations of this policy.

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 ENZYME IMMUNOASSAY TECHNIQUE, QUALITATIVE OR SEMIQUANTITATIVE, MULTIPLE-STEP METHOD; HELICOBACTER PYLORI, STOOL
87339	INFECTIOUS AGENT ANTIGEN DETECTION BY ENZYME IMMUNOASSAY TECHNIQUE, QUALITATIVE OR SEMIQUANTITATIVE, MULTIPLE-STEP METHOD; HELICOBACTER PYLORI

ICD-9 Codes that Support Medical Necessity

Note: ICD-9 codes must be coded to the highest level of specificity.

(CPT Codes 78267, 78268, 83009, 83013, 83014, 86677, 87338, 87339)

041.86	HELICOBACTER PYLORI [H. PYLORI]
151.0 - 151.9	MALIGNANT NEOPLASM OF CARDIA - MALIGNANT NEOPLASM OF STOMACH UNSPECIFIED SITE
200.30 - 200.38	MARGINAL ZONE LYMPHOMA, UNSPECIFIED SITE, EXTRANODAL AND SOLID ORGAN SITES - MARGINAL ZONE LYMPHOMA, LYMPH NODES OF MULTIPLE SITES
202.80	OTHER MALIGNANT LYMPHOMAS UNSPECIFIED SITE
531.00 - 531.91	ACUTE GASTRIC ULCER WITH HEMORRHAGE WITHOUT OBSTRUCTION - GASTRIC ULCER UNSPECIFIED AS ACUTE OR CHRONIC WITHOUT HEMORRHAGE OR PERFORATION WITH OBSTRUCTION
532.00 - 532.91	ACUTE DUODENAL ULCER WITH HEMORRHAGE WITHOUT OBSTRUCTION - DUODENAL ULCER UNSPECIFIED AS ACUTE OR CHRONIC WITHOUT HEMORRHAGE OR PERFORATION WITH OBSTRUCTION
533.00 - 533.91	ACUTE PEPTIC ULCER OF UNSPECIFIED SITE WITH HEMORRHAGE WITHOUT OBSTRUCTION - PEPTIC ULCER OF UNSPECIFIED SITE UNSPECIFIED AS ACUTE OR CHRONIC WITHOUT HEMORRHAGE OR PERFORATION WITH OBSTRUCTION
534.00 - 534.91	ACUTE GASTROJEJUNAL ULCER WITH HEMORRHAGE WITHOUT OBSTRUCTION - GASTROJEJUNAL ULCER UNSPECIFIED AS ACUTE OR CHRONIC WITHOUT HEMORRHAGE OR PERFORATION WITH OBSTRUCTION
535.00 - 535.11	ACUTE GASTRITIS (WITHOUT HEMORRHAGE) - ATROPHIC GASTRITIS WITH HEMORRHAGE

535.21	GASTRIC MUCOSAL HYPERTROPHY WITH HEMORRHAGE
535.40 - 535.41	OTHER SPECIFIED GASTRITIS (WITHOUT HEMORRHAGE) - OTHER SPECIFIED GASTRITIS WITH HEMORRHAGE
535.50 - 535.51	UNSPECIFIED GASTRITIS AND GASTRODUODENITIS (WITHOUT HEMORRHAGE) - UNSPECIFIED GASTRITIS AND GASTRODUODENITIS WITH HEMORRHAGE
535.60 - 535.61	DUODENITIS (WITHOUT HEMORRHAGE) - DUODENITIS WITH HEMORRHAGE
536.8	DYSPEPSIA AND OTHER SPECIFIED DISORDERS OF FUNCTION OF STOMACH
558.9	OTHER AND UNSPECIFIED NONINFECTIOUS GASTROENTERITIS AND COLITIS
789.01 - 789.02	ABDOMINAL PAIN RIGHT UPPER QUADRANT - ABDOMINAL PAIN LEFT UPPER QUADRANT
789.06 - 789.07	ABDOMINAL PAIN EPIGASTRIC - ABDOMINAL PAIN GENERALIZED

Diagnoses that Support Medical Necessity

ICD-9 Codes that DO NOT Support Medical Necessity

ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation

Diagnoses that DO NOT Support Medical Necessity

General Information

Documentation Requirements

Documentation supporting the medical necessity of this item, such as ICD-9 codes, must be submitted with each claim. Claims submitted without such evidence will be denied as being not medically necessary.

Appendices

Utilization Guidelines

H. pylori testing should not be repeated any sooner than eight weeks from the previous H. pylori testing.

Procedure codes may be subject to National Correct Coding Initiative (NCCI) edits or OPPS packaging edits. Refer to NCCI and OPPS requirements prior to billing Medicare.

For services requiring a referring/ordering physician, the name and NPI of the referring/ordering physician must be printed on the claim.

The diagnosis code(s) must best describe the patient's condition for which the service was performed.

09/01/2009: Policy published for beginning of Notice period, policy sent to professional organizations for review and comment; see advisory Committee meeting notes for dates, published in September 2009 WPS Communique' and in eNews Listserv for provider notification.

Sources of Information and Basis for Decision

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Other Medicare Carrier Policies; Ohio, Texas, New York, Oklahoma.

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Wisconsin Physicians Service CAC; February 1998, March 1999 for carrier states and Wisconsin Physicians Service carrier policies L16837, L16836, L16835, L16834.

Advisory Committee Meeting Notes

Advisory Committee Meeting Notes

Illinois 05/13/2009

Michigan 06/06/2009

Minnesota 05/21/2009

Wisconsin 05/15/2009

J5 MAC 06/04/2009

Jurisdictional Open Meeting 04/15/2009

Start Date of Comment Period

06/04/2009

End Date of Comment Period

07/20/2009

Start Date of Notice Period

09/01/2009

Revision History Number

x

Revision History Explanation

11/19/2009: Policy revision based on LCD reconsideration request, narrative revision to the “Indications and Limitations” section of policy, this revision does not change coverage or claims processing, effective date of narrative change is 02/01/2009. Added revenue code 031X for CPT codes 78267-78268 with effective date for claims processing of 09/16/2009. Providers notified via WPS policy update webpage January 2010 and In the March 2010 Communique’.

09/01/2009: Policy published for beginning of Notice period, policy sent to professional organizations for review and comment; see advisory Committee meeting notes for dates, published in September 2009 WPS Communique’ and in eNews Listserv for provider notification.

Reason for Change

Last Reviewed On Date

11/18/2009

Related Documents

This LCD has no Related Documents.

LCD Attachments

[Coding and Billing 02/01/2010 \(PDF - 35,962 bytes\)](#)

All Versions

Updated on 12/11/2009 with effective dates 02/01/2010 - N/A

Updated on 08/14/2009 with effective dates 10/16/2009 - 01/31/2010