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
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
(ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
(iii) The service or benefit 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 (13C or 14C) 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
- 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.

FOR 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.

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 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 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


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 supersede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:


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


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

**Devised:** 02/2011

**Revised:**

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