Operations Bulletin 04-11

Date: June 1, 2011

To: Participating Family Practice, Internal Medicine, and Gastroenterology Providers

Re: **Helicobacter pylori (*H. pylori*)**

As a leader in quality driven health outcomes, Geisinger Health Plan[1] has developed the following reimbursement and clinical guidelines for Helicobacter pylori (H. pylori), effective July 1, 2011.

Helicobacter pylori (*H. pylori*) is known to be a causative agent linked to the development of dyspeptic symptoms, peptic ulcer disease and gastric malignancy. A new perspective on the comparative utility of diagnostic testing for *H. pylori* infection has emerged over the past 5 years. Guidelines from the American College of Gastroenterology (AGC) and the American Gastroenterological Association (AGA) recommend a strategy of "test, treat, retest and confirm eradication" rather than empirical proton-pump inhibitor (PPI) therapy.

What has changed?
The Health Plan encourages the use of the following AGC and AGA guidelines in the evaluation and management of dyspepsia and peptic ulcer disease:

- Eliminate the use of serology testing. Serology testing will not be reimbursed as of July 1, 2011.
- Test, treat, and retest symptomatic patients.
- Confirm eradication utilizing active *H. pylori* testing.
- Testing for active *H. pylori* infection should be done prior to prescribing PPI's.

Why should I test for "active" *H. pylori* infection?
H. pylori is a class I carcinogen and has been linked as a causative agent in peptic ulcer disease, gastric carcinoma and MALT lymphoma.

Why is serology testing discouraged?
Studies indicate that approximately half of the patients with a positive *H. pylori* serology test do not have active infection. Serologic testing is no longer recommended because:

- It does not test for active infection. Serology tests for the antibody not the antigen. Antibody levels remain elevated for months to years after successful treatment, so serology testing cannot confirm eradication.
- It has poor predictive value which leads to increased and often inappropriate antibiotic use.
- It leads to increased patient anxiety over the implications of a positive test.
- Sensitivity is 85% and specificity is 79%.

What test is recommended?
Stool antigen testing (CPT code 87338) is cleared by the FDA for use in initial diagnosis, therapeutic monitoring, and retesting for confirmation of eradication. Stool testing is also cleared by the FDA for pediatric use. Stool antigen testing does not require any special patient preparation such as fasting, time off work, and temporary cessation of symptom relieving meds such as PPI's, H2 blockers, antimicrobials

[1] Geisinger Health Plan, Geisinger Indemnity Insurance Company and Geisinger Quality Options, shall be collectively referred to herein as "Health Plan".

and bismuth. Stool antigen testing is being recommended as the **preferred** active infection test of choice. Sensitivity is 96.1% and specificity is 95.7% for diagnostic purposes.

Urea breath testing (CPT codes 83013, 83014) is also cleared by the FDA for the initial diagnosis and to confirm eradication. Urea breath testing is not cleared by the FDA for use in patients under the age of 18 years. Special equipment is required, patients must make an appointment, fast for 24 hours, and the patient is required to be off symptom relieving meds for 2 weeks prior to testing. Sensitivity is 95.2% and specificity is 89.7% for diagnostic purposes

What are the recommendations for appropriate test use?
The ACG and AGA guidelines offer clear guidance on appropriate patient care for management of patients with peptic ulcer disease or dyspepsia and for *H. pylori* testing:

- For patients over age 55, endoscopy should be utilized.
- Patients under age 55 without alarm symptoms such as; family history of upper-GI malignancy, unintended weight loss, GI bleeding or iron deficiency anemia, progressive trouble swallowing, pain with swallowing, persistent vomiting, palpable mass or lymphadenopathy, and jaundice, should utilize active infection testing (stool antigen or urea breath testing).
- Serology should **NOT** be used. **Effective July 1, 2011, serology testing will no longer be reimbursable.**

Information contained in this Operations Bulletin is effective July 1, 2011 for all Health Plan product lines and amends the Participating Provider Guide.

For assistance, please contact your Provider Relations Representative at (800) 876-5357.

References:

- American Gastroenterological Association (AGA). American Gastroenterological Association Medical Position Statement: Evaluation of Dyspepsia. Gastroenterol. 2005;129:1753-1755.
- American Gastroenterological Association (AGA). American Gastroenterological Association Technical Review on the Evaluation of Dyspepsia. Gastroenterol. 2005;129:1756-1780.
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- Vakil N, Fendrick AM. How to Test for *Helicobacter pylori* in 2005. Cleve Clin J Med 2005;72 Suppl 2:S8-S21.
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