Medical Coverage Policy

Genetic Testing for Helicobacter pylori Treatment

☐ Device/Equipment  ☐ Drug  ☐ Medical  ☐ Surgery  ☒ Test  ☐ Other

Effective Date: 1/1/2012  Policy Last Updated: 03/06/2012

☐ Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.

☒ Prospective review is not required.

Description:

Helicobacter pylori (H. pylori) are a bacterium associated with a range of gastrointestinal (GI) disorders, such as peptic ulcer disease, chronic gastritis, and gastric malignancy. Eradication of H. pylori has been proven beneficial for a number of indications.

Currently, multiple regimens are available for treating H. pylori infection. These include proton pump inhibitors (PPIs), as well as similar medication(s), to suppress acid production in combination with antibiotic treatment, consisting of one or more agents such as amoxicillin, clarithromycin, or metronidazole. These first-line regimens generally achieve eradication rates in the 70–90% range. Differences in eradication rates are dependent on the regimen used and the population being treated. Treatment failures are most often attributed to antibiotic resistance or poor patient compliance. Resistance to clarithromycin is an important factor associated with treatment failure, with high rates of treatment failure for standard first-line regimens in patients infected with clarithromycin-resistant strains of H. pylori. A 2002 survey from the U.S. estimated that 13% of H. pylori strains are resistant to clarithromycin and that the rate of resistance was rising in comparison to earlier studies.

Genetic factors may influence the success of H. pylori treatment through effects on proton pump inhibitors (PPI) metabolism. Individuals with polymorphisms in the CYP2C19 gene, a component of the cytochrome p450 (CYP450) system, metabolize PPIs more slowly than normal. Genetic variation in the CYP450 enzyme system is one of the most extensively studied in the field of pharmacogenomics. This family of enzymes is found in the liver and is important for metabolizing and eliminating a large number of pharmacologic agents. Differences in PPI metabolism lead to variability in gastric acid suppression, with associated variability in gastric pH and potential impact on the efficacy of H. pylori treatment. Observational research suggests that patients who are on extensive metabolizers of PPIs have lower eradication rates following standard treatment for H. pylori, compared with poor metabolizers.

Pharmacogenomics is the study of how an individual's genetic inheritance affects the body's response to drugs. It may be possible to predict therapeutic failures or severe adverse drug reactions in individual patients by testing for important DNA polymorphisms (genotyping) in
genes related to the metabolic pathway (pharmacokinetics) or signal transduction pathway (pharmacodynamics) of the drug. Potentially, test results could be used to optimize drug choice and/or dose for more effective therapy, avoid serious adverse effects, and decrease medical costs.

It has been proposed that a pharmacogenomics-based treatment regimen individualized by CYP2C19 status may improve the success rate of treatment for H. pylori. If CYP2C19 status is known prior to treatment, adjustments can be made in the selection of PPI and/or the dosing schedule to achieve optimal acid suppression in all patients. Improved eradication rates for H. pylori could lead to improved health outcomes by reducing the need for retreatment following treatment failure, reducing recurrences of H. pylori-associated disorders and reducing the morbidity and mortality associated with disease recurrence.

While the single available randomized, controlled trial reports an increased rate of H. pylori eradication in the pharmacogenomics strategy compared with a standard approach, this study does not provide definitive evidence that use of a pharmacogenomics-based treatment regimen improves health outcomes. Therefore, the scientific evidence does not permit conclusions on whether the use of a pharmacogenomics-based treatment regimen for H. pylori improves eradication rates.

Medical Criteria:
Not applicable.

Policy:
Genotyping to determine cytochrome p450 (CYP2C19) genetic polymorphisms is considered not medically necessary for the purpose of managing the treatment of H. pylori infection as the scientific evidence does not permit conclusions on whether the use of a pharmacogenomics-based treatment regimen for H. pylori improves eradication rates.

Coverage:
Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement, or Benefit Booklet, for applicable “Services Not Medically Necessary.”

Codes:
81225 (new code 1/1/12)

Also known as:
Roche AmpliChip Cytochrome P450® Genotyping test
CYP450
CYP2C19 gene

Related Policies:
Genetic Testing and Counseling
add CYP 450

Published:
Provider Update, Dec 2011
Provider Update, May 2012

References:


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