Medical Policy
Genetic Testing for Helicobacter Pylori Treatment

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Policy Number: 288
BCBSA Reference Number: 2.04.50A
NCD/LCD: Local Coverage Determination (LCD): Molecular Pathology Procedures (L35000)

Related Policies
None

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Genetic testing to determine cytochrome p450 (CYP2C19) genetic polymorphisms for the purpose of managing the treatment of H. pylori infection is INVESTIGATIONAL.

Medicare HMO BlueSM and Medicare PPO BlueSM Members

Medical necessity criteria and coding guidance for Medicare Advantage members living in Massachusetts can be found through the link below.

Local Coverage Determination (LCD): Molecular Pathology Procedures (L35000)

For medical necessity criteria and coding guidance for Medicare Advantage members living outside of Massachusetts, please see the Centers for Medicare and Medicaid Services website for information regarding your specific jurisdiction at https://www.cms.gov.

Prior Authorization Information
Inpatient
- For services described in this policy, precertification/preauthorization IS REQUIRED for all products if the procedure is performed inpatient.

Outpatient
- For services described in this policy, see below for products where prior authorization might be required if the procedure is performed outpatient.

<table>
<thead>
<tr>
<th>Commercial Managed Care (HMO and POS)</th>
<th>Outpatient</th>
</tr>
</thead>
<tbody>
<tr>
<td>This is not a covered service.</td>
<td></td>
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Commercial PPO and Indemnity

<table>
<thead>
<tr>
<th></th>
<th>This is not a covered service.</th>
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<tbody>
<tr>
<td>Medicare HMO Blue℠</td>
<td>Prior authorization is not required.</td>
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<tr>
<td>Medicare PPO Blue℠</td>
<td>Prior authorization is not required.</td>
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**CPT Codes / HCPCS Codes / ICD Codes**

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

**CPT Codes**

<table>
<thead>
<tr>
<th>CPT codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>81225</td>
<td>CYP2C19 (cytochrome P450, family 2, subfamily C, polypeptide 19) (eg, drug metabolism), gene analysis, common variants (e.g., *2, *3, *4, *8, *17)</td>
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**ICD-10 Diagnosis Codes**

<table>
<thead>
<tr>
<th>ICD-10-CM Diagnosis codes:</th>
<th>Code Description</th>
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<tr>
<td>B96.81</td>
<td>Helicobacter pylori [H. pylori] as the cause of diseases classified elsewhere</td>
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**Description**

Helicobacter pylori (H. pylori) is a bacterium associated with a range of gastrointestinal 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) to suppress acid production in combination with antibiotic treatment.

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 extensive metabolizers of PPIs have lower eradication rates following standard treatment for H. pylori, compared with poor metabolizers.

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.

Examples of commercially available genetic tests for H. pylori treatment include the AmpliChip Cytochrome P450® Genotyping test from Roche. All genetic tests for H. pylori treatment are considered investigational regardless of the commercial name, the manufacturer or FDA approval status.

**Summary**

The scientific evidence does not permit conclusions on whether the use of a pharmacogenomics-based treatment regimen for H. pylori improves eradication rates. In general, eradication rates of H. pylori vary by CYP2C19 status. In the single randomized controlled trial comparing a pharmacogenomics-based treatment regimen with a standard regimen, eradication rates after first-line treatment were higher for the pharmacogenomics group compared with the standard treatment group. However, because of numerous variations in treatment protocol within the pharmacogenomics group, it is not possible to determine whether the improvement resulted from the tailored PPI dosages according to CYP2C19 genetic status or due to other variations in the treatment protocol unrelated to CYP2C19 status. The use of a PPI that is less susceptible to CYP2C19 status, such as rabeprazole, has been associated with higher eradication
rates compared to other PPIs. Additional trials are needed, including alternative treatment regimens, before conclusions can be made on whether a pharmacogenomics-based treatment regimen improves *H. pylori* eradication rates compared to a standard treatment regimen. Therefore, the use of genetic testing for *Helicobacter pylori* treatment is considered investigational.

**Policy History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tr>
<td>7/2015</td>
<td>Local Coverage Determination (LCD): Molecular Pathology Procedures (L34506) added.</td>
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<tr>
<td>6/2014</td>
<td>Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.</td>
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**Information Pertaining to All Blue Cross Blue Shield Medical Policies**

Click on any of the following terms to access the relevant information:

- Medical Policy Terms of Use
- Managed Care Guidelines
- Indemnity/PPO Guidelines
- Clinical Exception Process
- Medical Technology Assessment Guidelines

**References**


