Medical Policy
Ingestible pH and Pressure Capsule

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Policy Number: 045
BCBSA Reference Number: 2.01.81
NCD/LCD: N/A

Related Policies
• Esophageal pH Monitoring, #069
• Wireless Capsule Endoscopy as a Diagnostic Technique in Disorders of the Small Bowel, Esophagus, and Colon, #185

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

Measurement of gastrointestinal transit times, including gastric emptying and colonic transit times, using an ingestible pH and pressure capsule is considered INVESTIGATIONAL for the evaluation of suspected gastroparesis, constipation, or other gastrointestinal motility disorders.

Prior Authorization Information
Pre-service approval is required for all inpatient services for all products. See below for situations where prior authorization may be required or may not be required for outpatient services.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.
N/A indicates that this service is primarily performed in an inpatient setting.

<table>
<thead>
<tr>
<th>Outpatient</th>
<th></th>
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<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
<td>This is not a covered service.</td>
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<tr>
<td>Commercial PPO and Indemnity</td>
<td>This is not a covered service.</td>
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<tr>
<td>Medicare HMO BlueSM</td>
<td>This is not a covered service.</td>
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<tr>
<td>Medicare PPO BlueSM</td>
<td>This is not a covered service.</td>
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CPT Codes / HCPCS Codes
The following codes are included below for informational purposes. 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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<tr>
<td>91112</td>
<td>Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report</td>
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Diagnosis Codes
Investigational for all diagnoses.

Description
Gastroparesis is a chronic disorder characterized by delayed gastric emptying in the absence of mechanical obstruction. Symptoms of gastroparesis are often nonspecific and may mimic other gastrointestinal tract disorders. It can be caused by many conditions; most commonly it is idiopathic, diabetic, or postsurgical.

The test considered the reference standard for gastroparesis is gastric emptying scintigraphy. The patient ingests a radionuclide-labeled standard meal and subsequent imaging is performed at 0, 1, 2, and 4 hours postprandially, to measure how much of the meal has passed beyond the stomach. A typical threshold to indicate abnormal gastric emptying is more than 10% of the meal remaining at 4 hours after ingestion.

Constipation is a chronic disorder involving infrequent bowel movements, a sensation of obstruction, and incomplete evacuation. Many medical conditions can cause constipation, such as mechanical obstruction, metabolic conditions, myopathies, and neuropathies. Diagnostic testing for constipation can aid in distinguishing between 2 categories of disorders, slow-transit constipation and pelvic floor dysfunction.

Standard tests used in the evaluation of constipation include ingestion of radiopaque markers and colonic transit scintigraphy. In the radiopaque markers test, small markers are ingested over 1 or several days, and abdominal radiographs are performed at 4 and/or 7 days. The number of remaining markers correlates with the colonic transit time. In colonic transit scintigraphy, a radio-labeled meal is ingested, followed by scintigraphic imaging at several time intervals. The location of the scintigraphic signals correlates with colonic transit times.

Summary
An ingestible pH and pressure-sensing capsule (SmartPill® GI Monitoring System) measures pH, pressure, and temperature changes to signify passage of the capsule through portions of the gastrointestinal tract. It is proposed as a means of evaluating gastric emptying for diagnosis of gastroparesis, and colonic transit times for the diagnosis of slow-transit constipation.

The evidence for the ingestible pH and pressure capsule in patients who are suspected of having disorders of gastric emptying or slow-transit constipation includes studies of test characteristics and case series of patients who have undergone the test. Relevant outcomes are test accuracy and validity, other performance measures, symptoms, functional outcomes, and health status measures. Available studies provide some information regarding the comparison of the SmartPill ingestible pH and pressure-sensing 
capsule to other techniques for measuring gastric emptying and colonic transit times, but this evidence primarily consists of concordance with available tests. Because the available tests, such as nuclear scintigraphy, are imperfect criterion standards, it is not possible to determine the true sensitivity and specificity of SmartPill. The results of the concordance studies reveal a moderate correlation with alternative tests but provide only limited further information on the true accuracy of the test in clinical care. Evaluation of cases with discordant results would be of particular value, and ideally, these studies should be linked to therapeutic decisions and to meaningful clinical outcomes. The evidence to date on clinical utility of testing is lacking, consisting of a small number of retrospective studies. It is not possible to determine whether there is net improvement in health outcomes using SmartPill versus standard diagnostic tests. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy History

<table>
<thead>
<tr>
<th>Date</th>
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<tbody>
<tr>
<td>1/2016</td>
<td>New references added from BCBSA National medical policy.</td>
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<td>5/2015</td>
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</tr>
<tr>
<td>5/2013</td>
<td>New references from BCBSA National medical policy.</td>
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<tr>
<td>11/11-4/12</td>
<td>Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.</td>
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<tr>
<td>4/12/2011</td>
<td>New policy transferring current ongoing non-coverage information from document 400.</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


