Medical Coverage Policy | Ingestible pH and Pressure Capsule

EFFECTIVE DATE: 12/01/2014
POLICY LAST UPDATED: 02/17/2015

OVERVIEW
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.

PRIOR AUTHORIZATION
Not Applicable

POLICY STATEMENT
BlueCHiP for Medicare and Commercial

Measurement of gastrointestinal transit times, including gastric emptying and colonic transit times, using an ingestible pH and pressure capsule is considered not medically necessary for the evaluation of suspected gastroparesis, constipation, or other gastrointestinal motility disorders as there is insufficient peer-reviewed literature that demonstrates that the procedure is effective.

MEDICAL CRITERIA
None

BACKGROUND
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 called gastric emptying scintigraphy. The patient ingests a radionuclide-labeled standard meal, and then images are 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, 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 radio-opaque markers and colonic transit scintigraphy. In the radio-opaque 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.

In 2006, an ingestible capsule (SmartPill® GI Monitoring System) was cleared for marketing by the U.S. Food and Drug Administration (FDA)via a 510(k) application, with the indication for use to evaluate delayed gastric emptying. Gastric emptying is signaled when the pH monitor in the capsule indicates a change in pH from the acidic environment of the stomach to the alkaline environment of the small intestine. While SmartPill does not measure 50% emptying time, it can be correlated with scintigraphically measured 50% emptying time. The capsule also measures pressure and temperature throughout its transit through the entire gastrointestinal tract, allowing calculations of total gastrointestinal tract transit time. In 2009, FDA expanded the use of the SmartPill to determine colonic transit time for the evaluation of chronic constipation and to differentiate between slow versus normal transit constipation. When colonic transit time cannot be determined, small and large bowel transit times combined can be used instead. The SmartPill is not for use in pediatric patients.

The ingestible pH and pressure capsule (ie, SmartPill®) measures pH, pressure, and temperature changes to signify passage of the capsule through portions of the gastrointestinal tract. For example, an increase of 2 or more pH units usually indicates gastric emptying, and a subsequent decrease of 1 or more pH units usually indicates passage to the ileocecal junction. This differs from esophageal pH monitoring for gastroesophageal reflux disease, which measures pH levels in various ways such as through catheters, impedance or a temporarily implanted device such as the Bravo. The ingestible pH and pressure capsule (ie, SmartPill®) also differs from the wireless capsule endoscopy (ie, PillCam™), which is a capsule swallowed by the patient that transmits video images wirelessly.

An ingestible pH and pressure-sensing capsule (SmartPill® GI Monitoring System) is proposed as a means of evaluating gastric emptying time and small bowel, colonic and whole-gut transit times. This technology is used to evaluate suspected gastrointestinal motility disorders such as gastroparesis, intestinal dysmotility, and constipation. Available studies provide some information regarding the comparison of SmartPill to other techniques for measuring gastric emptying and whole-gut transit times, but this evidence primarily consists of concordance with available tests. Since 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. This does not provide sufficient information to determine whether health outcomes are improved as a result of the information provided by the SmartPill**.** Because the impact of this technology on net health outcome is unknown, this technology is considered not medically necessary as there is insufficient peer-reviewed literature that demonstrates that the service is effective.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement for applicable diagnostic tests benefits/coverage.

CODING

BlueCHiP for Medicare and Commercial

The following CPT code is considered not medically necessary:

91112

RELATED POLICIES

Preauthorization via Web-Based Tool for Procedures

PUBLISHED

Provider Update	April 2015
Provider Update	Jan 2015

Provider Update	Apr 2013
Provider Update	March 2012
Provider Update	Feb 2010
Provider Update	Feb 2011
Provider Update	Jul 2009
Provider Update	Jun 2008

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