

Protocol

Ingestible pH and Pressure Capsule

(20181)

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| Medical Benefit | Effective Date: 10/01/12 | Next Review Date: 07/15 |
| Preauthorization | No | Review Dates: 09/10, 07/11, 07/12, 07/13, 07/14 |

*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is not required but is recommended if, despite this Protocol position, you feel this service is medically necessary.** Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Description

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.

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 zero, one, two, and four 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 four 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 two 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 one or several days, and abdominal radiographs are performed at four and/or seven 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 (i.e., SmartPill®) measures pH, pressure, and temperature changes to signify passage of the capsule through portions of the gastrointestinal tract. For example, an increase of two or more pH units usually indicates gastric emptying, and a subsequent decrease of one 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 (i.e., SmartPill®) also differs from the wireless capsule endoscopy (i.e., PillCam™), which is a capsule swallowed by the patient that transmits video images wirelessly.

Related Protocols

Esophageal pH Monitoring

Wireless Capsule Endoscopy as a Diagnostic Technique in Disorders of the Small Bowel, Esophagus, and Colon

Policy (Formerly Corporate Medical Guideline)

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.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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12. Camilleri M, Bharucha AE, di Lorenzo C et al. American Neurogastroenterology and Motility Society consensus statement on intraluminal measurement of gastrointestinal and colonic motility in clinical practice. *Neurogastroenterol Motil* 2008; 20(12):1269-82.
13. Rao SS, Camilleri M, Hasler WL et al. Evaluation of gastrointestinal transit in clinical practice: position paper of the American and European Neurogastroenterology and Motility Societies. *Neurogastroenterol Motil* 2011; 23(1):8-23.
14. Camilleri M, Parkman HP, Shafi MA et al. Clinical guideline: management of gastroparesis. *Am J Gastroenterol* 2013; 108(1):18-37; quiz 38.