Protocol

Ingestible pH and Pressure Capsule

(20181)

Medical Benefit		**Effective Date**: 10/01/12	**Next Review Date**: 07/21
Preauthorization	No	**Review Dates**: 09/10, 07/11, 07/12, 07/13, 07/14, 07/15, 07/16, 07/17, 07/18, 07/19, 07/20	

This protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. 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.

RELATED PROTOCOL

Wireless Capsule Endoscopy to Diagnose Disorders of the Small Bowel, Esophagus, and Colon

Populations	Interventions	Comparators	Outcomes
Individuals: • With suspected disorders of gastric emptying	Interventions of interest are: • Diagnostic testing with an ingestible pH and pressure capsule	Comparators of interest are: • Standard tests of gastric emptying (e.g., scinti-graphy)	Relevant outcomes include: • Test accuracy • Test validity • Other test performance measures • Symptoms • Functional outcomes • Health status measures
Individuals: • With suspected slow-transit constipation	Interventions of interest are: • Diagnostic testing with an ingestible pH and pressure capsule	Comparators of interest are: • Standard tests for slow-transit constipation (e.g., scintigraphy)	Relevant outcomes include: • Test accuracy • Test validity • Other test performance measures • Symptoms • Functional outcomes • Health status measures

DESCRIPTION

An ingestible pH and pressure-sensing capsule (SmartPill GI Monitoring System) measures pH, pressure, and temperature changes to signify the 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.

SUMMARY OF EVIDENCE

For individuals who have suspected disorders of gastric emptying or suspected slow-transit constipation who receive diagnostic testing with an ingestible pH and pressure capsule, the evidence includes studies of test characteristics and case series of patients who have undergone the test. Relevant outcomes are test validity, other performance measures, symptoms, functional outcomes, and health status measures. The available studies have provided some comparative data on the SmartPill ingestible pH plus pressure-sensing capsule and other techniques for measuring gastric emptying. This evidence primarily consists of assessments of concordance with available tests. Because the available tests (e.g., gastric emptying scintigraphy) are imperfect criterion standards, it is not possible to determine the true sensitivity and specificity of SmartPill. The results of the concordance studies have revealed a moderate correlation with alternative tests, but have provided only limited additional data 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 the 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 vs. standard diagnostic tests. The evidence is insufficient to determine the effects of the technology on health outcomes.

POLICY

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.

BACKGROUND

GASTROPARESIS AND CONSTIPATION

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.

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 two categories of disorders, slow-transit constipation and pelvic floor dysfunction.

Diagnosis

Gastric emptying scintigraphy is considered the reference standard for diagnosing gastroparesis. The patient ingests a radionuclide-labeled standard meal and subsequent imaging is 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.

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 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.

REGULATORY STATUS

In 2006, an ingestible capsule (SmartPill® GI Monitoring System; Given Imaging) was cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process, for evaluation of 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. 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 a passage to the ileocecal junction. 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 during its transit through the entire gastrointestinal tract, allowing calculations of total gastrointestinal tract transit time. In 2009, the Food and Drug Administration expanded the use of the SmartPill® to determine colonic transit time for the evaluation of chronic constipation and to differentiate between slow- and 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.

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

1. Abell TL, Camilleri M, Donohoe K, et al. Consensus recommendations for gastric emptying scintigraphy: a joint report of the American Neurogastroenterology and Motility Society and the Society of Nuclear Medicine. J Nucl Med Technol. Mar 2008;36(1):44-54. PMID 18287197.
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3. Tougas G, Eaker EY, Abell TL, et al. Assessment of gastric emptying using a low fat meal: establishment of international control values. Am J Gastroenterol. Jun 2000;95(6):1456-1462. PMID 10894578.
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5. Green AD, Belkind-Gerson J, Surjanhata BC, et al. Wireless motility capsule test in children with upper gastrointestinal symptoms. J Pediatr. Jun 2013;162(6):1181-1187. PMID 23290514.
6. Kuo B, Maneerattanaporn M, Lee AA, et al. Generalized transit delay on wireless motility capsule testing in patients with clinical suspicion of gastroparesis, small intestinal dysmotility, or slow transit constipation. Dig Dis Sci. Oct 2011;56(10):2928-2938. PMID 21625964.
7. Rao SS, Mysore K, Attaluri A, et al. Diagnostic utility of wireless motility capsule in gastrointestinal dysmotility. J Clin Gastroenterol. Sep 2011;45(8):684-690. PMID 21135705.

8. 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. Jan 2011;23(1):8-23. PMID 21138500.
9. Camilleri M, Parkman HP, Shafi MA, et al. Clinical guideline: management of gastroparesis. Am J Gastroenterol. Jan 2013;108(1):18-37; quiz 38. PMID 23147521.