



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

Subject Wireless Gastrointestinal Motility Monitoring System (SmartPill®)

Effective Date 5/15/2011
Next Review Date 5/15/2012
Coverage Policy Number 0490

Table of Contents

Coverage Policy	1
General Background	1
Coding/Billing Information	4
References	5
Policy History	6

Hyperlink to Related Coverage Policies

- Capsule Endoscopy
- Gastric Pacing/Gastric Electrical Stimulation (GES)
- Wireless Esophageal pH Monitoring System (Bravo™)

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2011 CIGNA

Coverage Policy

CIGNA does not cover the use of a wireless gastrointestinal motility monitoring system (e.g., SmartPill®) for any indication because it is considered experimental, investigational or unproven.

General Background

Gastrointestinal (GI) motility is defined by the movements of the digestive system, and the transit of the contents within it. When nerves or muscles in any portion of the digestive tract do not function with their normal strength and coordination, a person develops symptoms related to motility problems. Tests of GI motility allow the assessment and identification of abnormal patterns and physiology. For each area of the GI tract, there are different GI motility tests that assess different functions and provide different types of information. Diagnostic testing typically begins with defining intestinal tract anatomy. The presence of structural problems are generally ruled out before proceeding to studies that evaluate GI tract functioning.

The SmartPill Gastrointestinal (GI) Monitoring System® (The SmartPill Corporation, Buffalo, NY) has been proposed as an alternative testing method for the diagnosis of gastric conditions and intestinal motility disorders such as gastroparesis and chronic constipation. The system records pH and pressure measurements from the entire length of the gastrointestinal tract for use by physicians to aid in the evaluation of gastrointestinal motility diseases and conditions. Sensors on board an ingestible capsule measure pH and pressure as the capsule travels the length of the GI tract. Measurements are transmitted from the capsule within the GI tract via radiofrequency signal to a patient worn receiver and subsequently downloaded for analysis and review. Next,

software performs data analyses providing the physician with a printable report containing regional gut transit times: gastric emptying or transit time (GET), small bowel transit time (SBTT), combined small and large bowel transit time (SLBTT), colonic transit time (CTT) and whole gut transit time (WGTT). The capsule is expelled naturally from the body.

U.S. Food and Drug Administration (FDA)

The SmartPill GI Monitoring System[®] was approved in 2006 by the U.S. by the Food and Drug Administration (FDA) under the 510(k) process. Indications for use state SmartPill is used in evaluating patients with suspected gastroparesis. In October 2009, the SmartPill was FDA-approved for the evaluation of colonic transit in patients with chronic constipation, to aid in differentiating slow and normal transit constipation. It is not indicated for pediatric patients.

Gastroparesis

Gastroparesis, or delayed emptying of the stomach contents into the small intestines, occurs when the vagus nerve is damaged; resulting in food moving slowly through or stopping in the digestive tract. The condition may be caused by diabetes, surgery, or certain medications; sometimes the cause is unknown. Once other causes have been ruled out, a gastric emptying scintigraphy (GES) is typically performed. GES is considered the standard for the measurement of gastric motility in clinical practice, because it provides a physiologic, noninvasive, and quantitative measurement of gastric emptying. While GES is currently considered the standard, published data regarding sensitivity, specificity and predictive values are limited. With GES, the presence of gastric retention > 90% at one hour, >60% at two hours and >10% at four hours on GES indicates delayed gastric emptying (Society of Nuclear Medicine, 2009; Abell, et al., 2008, Tougas, et al., 2000). Tougas et al. (2000) was a multinational, observational study that established these gastric emptying values based on data obtained using 123 healthy subjects and consistent meal and methodology. Diagnostic utility of GES can be negatively impacted by not following established, published meal preparation and imaging procedures. Other tests that may be performed include non-invasive isotope breath test and invasive antropyloroduodenal manometry. Both provide information on gastrointestinal functioning; however, neither can solely confirm a diagnosis of gastroparesis.

Constipation

Constipation is generally defined as having hard stools, infrequent stools (typically fewer than three per week), the need for excessive straining, a sense of incomplete bowel evacuation, and excessive time spent on the toilet or in unsuccessful defecation. Constipation is frequently multifactorial and can result from systemic or neurological disorders or medications. Constipation can be classified into three broad categories: normal-transit constipation, slow-transit constipation, and disorders of defecatory or rectal evacuation. The diagnosis of chronic constipation is based predominantly on clinical symptoms. Physiological testing is necessary only in patients with refractory symptoms who do not have a secondary cause of constipation or in whom a trial of a high-fiber diet and laxatives was not effective. The initial physiological test generally conducted is measurement of the colonic transit time (CTT), to distinguish slow-transit constipation from normal-transit constipation. If there is a defecatory disorder, measurement of the colonic transit time should be considered after the underlying pelvic-floor dysfunction has been corrected. CTT is normally less than 72 hours. It is measured by performing abdominal radiography 120 hours (5 days) after the patient has ingested radiopaque markers (ROM) in a gelatin capsule. Retention of more than 20% of the markers at 120 hours indicates prolonged transit. Although CTT is currently considered the standard, published data regarding sensitivity, specificity and predictive values are limited. Anorectal manometry, balloon-expulsion tests and defecography are additional diagnostic tests that may be ordered.

Literature Review

Published studies in the peer-reviewed scientific literature are observational or retrospectively conducted with small populations. Although well-established motility testing methods exist, studies are not designed to provide comparison of the accuracy—including sensitivity, specificity, positive and negative predictive values— of the SmartPill to conventional tests as the reference standard in same symptomatic patient population. As a result no strong conclusions can be made regarding the clinical utility of this technology.

Rao et al. (2010) retrospectively reported on 86 patients with gastrointestinal dysmotility. In this retrospective records analysis, subjects were included if they reported symptoms suggestive of GI dysmotility for at least six months and had normal upper endoscopy and/or colonoscopy, normal hematology and metabolic profiles, and normal abdominal ultrasound and computed tomography (CT) scan evaluations. On the basis of the

predominant symptom or symptom profile at the time of presentation, the patients underwent appropriate GI physiology testing such as nuclear scintigraphic gastric emptying test to determine upper gut motility dysfunction and radiopaque marker (ROM) colonic transit test to determine lower gut motility dysfunction. In addition, the SmartPill was administered to all of these patients to assess their GI transit. These tests were usually accomplished within 2 to 4 weeks of initial presentation. Upper gut function was assessed by gastric emptying test with technetium-labeled meal. Colonic function was assessed by ingestion of a single capsule containing 24 radiopaque markers. An abnormal scintigraphic gastric emptying time (GET) was defined as greater than 10% retention at 4 hours (delayed gastric emptying) or less than 20% retention at 1 hour (rapid gastric emptying). Retention of 6 or more radiopaque markers at 120 hours was defined as abnormal colonic transit. Although conventional studies were administered, reported results did not include statistical comparison with calculation of sensitivity, specificity or accuracy of the SmartPill. An additional study limitation is the retrospective design.

Camilleri et al. (2010) prospectively compared colon transit measurements gathered with the SmartPill and conventional quantitative ROM protocol, in 158 patients with symptomatic chronic constipation. ROM protocol includes 24 markers ingested each day for three successive days with abdominal radiographs on the fourth and seventh day to count the number of ROM remaining in the abdomen. The study was designed to demonstrate substantial equivalence, defined as diagnostic agreement >65% for patients who had normal or delayed ROM transit. There was no comparator, no conventional standard used as reference to calculate sensitivity, specificity or accuracy.

Rao et al. (2009) conducted a non-randomized, controlled trial, including 78 constipated and 87 healthy subjects who ingested ROMs and the SmartPill simultaneously. Regional and CTT in constipated and healthy subjects measured by the SmartPill were compared to regional and CTT measure by ROM, although ROM was not utilized as the reference standard. Comparison was addressed through estimation, hypothesis testing and Spearman correlation. The diagnostic utility of the SmartPill for identifying subjects with constipation symptoms was examined through construction of a receiver operating characteristic (ROC) curve; the area under the curve (AUC) was taken as an overall measure of diagnostic accuracy. Similarly, the utility of the ROM test was examined through construction of a ROC curve for the number of ROMs remaining on day 5. It should be noted that one or more SmartPill transit parameters could not be identified in 12 subjects because of a software malfunction. Cecal arrival time was not recognizable in five other subjects. Thus, data from 148 subjects (67 constipated and 81 healthy) were available for analysis of transit time. Two subjects failed to obtain radiographs on day 2/day 5 and ten other subjects had radiographs on day 4 rather than day 5. Thus, ROM data were available in 153 subjects (67 constipated and 86 healthy). The diagnostic accuracy of the SmartPill CTT to predict constipation from ROC was 0.73. These were comparable with those of day 5 ROM (ROC, 0.71). This study did not utilize ROM CTT as the reference standard and was not blinded.

Hasler et al. (2009) prospectively studied regional differences in colon pressure using SmartPill. A total of 53 healthy and 36 constipated subjects (12 of which had constipation-predominant irritable bowel syndrome) ingested the SmartPill. Hasler et al. quantified transit and contractile activity (e.g., the colon exhibits differential regional motor activity both in healthy individuals and most but not all patients with constipation with greater activity in the distal colon compared with more proximal regions). This study was an observational, with no comparator.

Kuo et al. (2008) prospectively evaluated 125 subjects (77 healthy and 48 known gastroparetic subjects). Kuo et al. compared the gastric emptying time measured by the SmartPill (in minutes) with GES results (% of the meal retained). The reference standard utilized for the SmartPill was the clinically ideal sensitivity and specificity of gastric emptying time measured by the SmartPill. The reference standard utilized for GES was sensitivity and specificity for GES % of meal retained based on established cut-offs from literature. Using those values as standard reference, the diagnostic accuracy from the receiver operating characteristic (ROC) curve between gastroparetics and healthy subjects was SmartPill = 0.83, GES four hour = 0.82 and GES two hour = 0.79. Confirmation of capsule elimination by either retrieval or x-ray was conducted. This study was not blinded, did not included a population of patients with suspected gastroparesis, and did not evaluate the accuracy of SmartPill in diagnosing gastroparesis in a symptomatic population using the same day and same patients' GES results as the standard reference.

Sarosiek et al. (2010) conducted an analysis of a subset of the patients from the study above (Kuo, et al., 2008), reviewing data from 100 subjects (66 healthy controls; 34 gastroparetic patients). Sarosiek et al. reported regional transit times measured by the SmartPill in healthy controls and gastroparetics, with no comparison to

standard transit time testing methods. Kloetzer et al. (2010) reported antroduodenal pressure profiles measured by the SmartPill in healthy controls (n=71) and gastroparetics (n=42), with no comparison to standard motility testing methods. These studies are small retrospective studies, not designed to provide comparison to conventional, well-established motility testing methods.

Professional Societies/Organizations

American Neurogastroenterology and Motility Society (ANMS)/ Society of Nuclear Medicine (SNM): The ANMS/SNM Consensus Recommendations for Gastric Emptying Scintigraphy states that GES is the standard for the measurement of gastric motility in clinical practice (Abell, et al., 2008). The SNM Procedure Guideline for Adult Solid Meal Gastric Emptying Study (2009) states that radionuclide studies of gastric emptying and motility are the most comprehensive and physiologic studies available for studying gastric motor function. The study is noninvasive, uses a physiologic meal (solids with/without liquids), and is quantitative. Serial testing can determine the effectiveness of therapy. The SNM states that the standard measurement of gastric emptying is based on the percentage of gastric retention at specific times after meal ingestion (e.g., at 2, 3, and 4 hours).

American Gastroenterological Association (AGA): The AGA Medical Position Statement ‘Diagnosis and Treatment of Gastroparesis’ (Parkman, et al., 2004) also states that GES of a radiolabeled solid meal is the best accepted method to test for delayed gastric emptying. The AGA Medical Position Statement ‘Guidelines on Constipation’ (Locke, et al., 2000) supports the use of special tests such as CTT, anorectal manometry, balloon-expulsion tests or defecography in refractory patients. Neither guideline addresses the use of SmartPill.

American Society of Colon and Rectal Surgeons (ASCRS): The ASCRS practice parameter for the evaluation and management of constipation notes that anorectal physiology and colon transit time investigations may help to identify the underlying etiology and improve the outcome in patients with refractory constipation. “The measurement of colon transit time using radio-opaque markers in patients with suspected slow-transit constipation is inexpensive, simple, and safe” (Ternent, et al., 2007).

North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHN): The NASPGHN recommendations on evaluation and treatment of constipation in infants and children (2006) notes that an evaluation of colonic transit time with radiopaque markers may be helpful in children with a history of infrequent bowel movements who have no objective findings of constipation.

Summary

Evidence in the published, peer-reviewed scientific literature is insufficient to establish the accuracy or clinical utility of the SmartPill Gastrointestinal Monitoring System[®] for any indication. Large population well-designed comparative trials are needed, comparing SmartPill with established gastrointestinal motility diagnostic tools.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Experimental/Investigational/Unproven/Not Covered:

CPT* Codes	Description
0242T	Gastrointestinal tract transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report (Effective January 1, 2011)

ICD-9-CM Diagnosis Codes	Description
536.3	Gastroparesis
564.00 – 564.09	Constipation
	All other codes

*Current Procedural Terminology (CPT[®]) © 2010 American Medical Association: Chicago, IL.

References

1. Abell TL, Camilleri M, Donohoe K, Hasler WL, Lin HC, et al. American Neurogastroenterology and Motility Society and the Society of Nuclear Medicine. 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*. 2008 Mar;36(1):44-54. Epub 2008 Feb 20.
2. Camilleri M, Thorne NK, Ringel Y, Hasler WL, Kuo B, Esfandyari T, et al. Wireless pH-motility capsule for colonic transit: prospective comparison with radiopaque markers in chronic constipation. *Neurogastroenterol Motil*. 2010 Aug;22(8):874-82, e233. Epub 2010 May 11.
3. Constipation Guideline Committee of the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition. Evaluation and treatment of constipation in infants and children: recommendations of the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition. *J Pediatr Gastroenterol Nutr*. 2006 Sep;43(3):e1-13.
4. Hasler WL, Saad RJ, Rao SS, Wilding GE, Parkman HP, Koch KL, et al. Heightened colon motor activity measured by a wireless capsule in patients with constipation: relation to colon transit and IBS. *Am J Physiol Gastrointest Liver Physiol*. 2009 Dec;297(6):G1107-14. Epub 2009 Oct 1.
5. Kloetzer L, Chey WD, McCallum RW, Koch KL, Wo JM, Sitrin M, et al. Motility of the antroduodenum in healthy and gastroparetics characterized by wireless motility capsule. *Neurogastroenterol Motil*. 2010 Jan 29. [Epub ahead of print]
6. Kuo B, McCallum RW, Koch KL, Sitrin MD, Wo JM, Chey WD, et al. Comparison of gastric emptying of a nondigestible capsule to a radio-labelled meal in healthy and gastroparetic subjects. *Aliment Pharmacol Ther*. 2008 Jan 15;27(2):186-96. Epub 2007 Oct 28.
7. Lembo A, Camilleri M. Chronic constipation. *N Engl J Med*. 2003 Oct 2;349(14):1360-8.
8. Locke GR 3rd, Pemberton JH, Phillips SF. American Gastroenterological Association Medical Position Statement: guidelines on constipation. *Gastroenterology*. 2000 Dec;119(6):1761-6. Accessed April 2011. Available at URL address: <http://www.gastro.org/practice/medical-position-statements>
9. Parkman HP, Hasler WL, Fisher RS; American Gastroenterological Association. American Gastroenterological Association medical position statement: diagnosis and treatment of gastroparesis. *Gastroenterology*. 2004 Nov;127(5):1589-91. Accessed April 2011. Available at URL address: <http://www.gastro.org/practice/medical-position-statements>
10. Rao SS, Kuo B, McCallum RW, Chey WD, DiBaise JK, Hasler WL, et al. Investigation of colonic and whole-gut transit with wireless motility capsule and radiopaque markers in constipation. *Clin Gastroenterol Hepatol*. 2009 May;7(5):537-44.
11. Rao SS, Mysore K, Attaluri A, Valestin J. Diagnostic Utility of Wireless Motility Capsule in Gastrointestinal Dysmotility. *J Clin Gastroenterol*. 2010 Dec 3. [Epub ahead of print]
12. Sarosiek I, Selover KH, Katz LA, Semler JR, Wilding GE, Lackner JM, et al. The assessment of regional gut transit times in healthy controls and patients with gastroparesis using wireless motility technology. *Aliment Pharmacol Ther*. 2010 Jan 15;31(2):313-22. Epub 2009 Oct 8.
13. SmartPill GI Monitoring System. The SmartPill Corporation. Accessed March 2011. Available at URL address: http://www.smartpillcorp.com/index.cfm?pagepath=Professionals/Peer_Reviewed_Articles&id=17823

14. Society Of Nuclear Medicine (SNM). Procedure Guideline for Adult Solid Meal Gastric Emptying Study. Version 3.0. Approved February 8, 2009. Accessed April 2011. Available at URL address: <http://www.snm.org/index.cfm?PageID=772>
15. Ternent CA, Bastawrous AL, Morin NA, Ellis CN, Standards Practice Task Force of The American Society of Colon and Rectal Surgeons, et al. Practice parameters for the evaluation and management of constipation. Dis Colon Rectum. 2007 Dec;50(12):2013-22.
16. Tougas G, Eaker EY, Abell TL, Abrahamsson H, Boivin M, Chen J, et al. Assessment of gastric emptying using a low fat meal: establishment of international control values. Am J Gastroenterol. 2000 Jun;95(6):1456-62.
17. U.S. Food and Drug Administration. SmartPill GI Monitoring System. 510(k) Summary. Accessed March 2011. Available at URL address: http://www.accessdata.fda.gov/cdrh_docs/pdf5/K053547.pdf and www.accessdata.fda.gov/cdrh_docs/pdf9/K092342.pdf

Policy History

<u>Pre-Merger Organizations</u>	<u>Last Review Date</u>	<u>Policy Number</u>	<u>Title</u>
Great-West Healthcare	7/18/2007	07.354.01	SmartPill Gastrointestinal (GI) Monitoring System

“CIGNA”, “CIGNA HealthCare” and the “Tree of Life” logo are registered service marks of CIGNA Intellectual Property, Inc., licensed for use by CIGNA Corporation and its operating subsidiaries. All products and services are provided by such operating subsidiaries and not by CIGNA Corporation. Such operating subsidiaries include Connecticut General Life Insurance Company, CIGNA Health and Life Insurance Company, CIGNA Behavioral Health, Inc., CIGNA Health Management, Inc., and HMO or service company subsidiaries of CIGNA Health Corporation and CIGNA Dental Health, Inc. In Arizona, HMO plans are offered by CIGNA HealthCare of Arizona, Inc. In California, HMO plans are offered by CIGNA HealthCare of California, Inc. In Connecticut, HMO plans are offered by CIGNA HealthCare of Connecticut, Inc. In North Carolina, HMO plans are offered by CIGNA HealthCare of North Carolina, Inc. In Virginia, HMO plans are offered by CIGNA HealthCare Mid-Atlantic, Inc. All other medical plans in these states are insured or administered by Connecticut General Life Insurance Company or CIGNA Health and Life Insurance Company.