

MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	Wireless Capsule Endoscopy Imaging and Wireless Motility Capsule for Examination of the Gastrointestinal (GI) Tract
Policy Number	6.01.27
Category	Technology Assessment
Original Effective Date	06/20/02
Committee Approval Date	01/16/03, 01/15/04, 12/16/04, 10/20/05, 09/21/06, 10/18/07, 11/20/08, 10/29/09, 12/16/10, 11/17/11, 10/18/12, 09/19/13, 08/21/14, 08/20/15, 07/21/16, 07/20/17, 07/19/18, 06/20/19, 08/20/20, 08/19/21, 08/18/22
Current Effective Date	08/18/22
Deleted Date	N/A
Archived Date	N/A
Archived Review Date	N/A
Product Disclaimer	<ul style="list-style-type: none"> • If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply. • If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit. • If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit. • If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit. • If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY STATEMENT

Based upon our criteria and assessment of the peer-reviewed literature:

- I. Wireless capsule endoscopy (CE) has been medically proven to be effective and, therefore, is considered **medically appropriate** for the evaluation of obscure gastrointestinal (GI) bleeding (OGIB), suspected to be of small bowel origin, when the patient has undergone conventional diagnostic work-up that has not revealed the source of bleeding. The conventional diagnostic work-up generally consists of colonoscopy, upper endoscopy, and, in some situations, a small bowel series (*see Policy Guidelines*). In the event of active bleeding during the work-up in the appropriate clinical setting, angiography and/or tagged red cell scanning and Meckel scanning (if patient is less than 60 years old) would also have been done. If these diagnostic procedures were performed within six months of the planned wireless endoscopy, repeat testing is at the discretion of the managing clinician.
- II. Wireless CE of the small bowel has been medically proven effective and, therefore, is considered **medically appropriate** for the initial diagnosis of patients with suspected Crohn's disease (CD), when conventional diagnostic work-up has failed to reveal any lesions consistent with the disease, and there still remains a strong clinical suspicion of CD. Findings in those patients with a high suspicion of Crohn's should include fever, weight loss, anemia, elevated white blood cell (WBC) count, and/or elevated laboratory markers of inflammation.
- III. Wireless CE of the small bowel has been medically proven effective and, therefore, is considered **medically appropriate** in patients with an established diagnosis of Crohn's disease, when there are unexpected change(s) in the course of the disease or response to treatment, suggesting that the initial diagnosis may be incorrect, and re-examination may be indicated. The presence of bowel strictures must be assessed prior to the CE.

Medical Policy: WIRELESS CAPSULE ENDOSCOPY IMAGING AND WIRELESS MOTILITY CAPSULE FOR EXAMINATION OF THE GASTROINTESTINAL (GI) TRACT

Policy Number: 6.01.27

Page: 2 of 10

- IV. Wireless CE has been medically proven to be effective and, therefore, is considered **medically appropriate** for surveillance of the small bowel, in patients with hereditary GI polyposis syndromes such as familial adenomatosis polyposis (FAP) or Peutz-Jeghers syndrome.
- V. Wireless CE has been medically proven to be effective and, therefore, is considered **medically appropriate** for the screening or surveillance of esophageal varices, in cirrhotic patients with significantly compromised liver function (i.e., Child-Pugh score of Class B or greater), where a standard upper endoscopy with sedation or anesthesia is contraindicated.
- VI. Wireless CE has not been medically proven to be effective and, therefore, is considered **investigational** for any other indication, including but not limited to:
 - A. Evaluating diseases of the esophagus other than as stated above;
 - B. Confirmation of lesions/pathology found by other diagnostic means;
 - C. As the initial procedure in the diagnosis of GI bleeding, where upper endoscopy or colonoscopy has not been performed;
 - D. For the diagnosis of irritable bowel syndrome;
 - E. For the diagnosis of diseases of the stomach;
 - F. For the diagnosis of any other diseases of the small bowel; or
 - G. For the diagnosis of diseases of the large intestine/colon.
- VII. Use of the patency capsule to verify adequate patency of the gastrointestinal tract prior to administration of the wireless capsule, in patients with known or suspected strictures, has not been medically proven to be effective and, therefore, is considered **investigational**.
- VIII. The use of the wireless motility capsule (e.g., SmartPill GI Monitoring System) has not been medically proven to be effective and, therefore, is considered **investigational** for the evaluation of suspected gastroparesis, constipation, or other gastrointestinal motility disorders.

POLICY GUIDELINES

- I. Wireless CE must be performed under the supervision of a gastroenterologist with expertise in this technology.
- II. In the case of obscure gastrointestinal bleeding, (OGIB), because of low lesion detection rate, a small bowel follow-through or enteroclysis is not necessarily required prior to wireless CE. A small bowel follow-through may be beneficial in some cases, at the discretion of the clinician, prior to or after wireless CE, in the detection of small bowel lesions and in their anatomical localization.
- III. The Federal Employee Health Benefit Program (FEHBP/FEP) does not permit certain services approved by the U.S. Food and Drug Administration (FDA) to be denied as experimental/investigational, even though they may meet the contractual definition of experimental/investigational. Those services may be assessed only on the basis of their medical necessity, in accordance with FEHBP/FEP Clinical Review Guidelines.

DESCRIPTION

The American Gastroenterological Association defines OGIB as bleeding from the GI tract that persists or recurs without an obvious etiology, after esophagogastroduodenoscopy (EGD), colonoscopy, and radiologic evaluation of the small bowel, such as small-bowel follow-through or enteroclysis. OGIB can be categorized as obscure overt or obscure occult bleeding, based on the presence or absence of clinically evident bleeding. OGIB may present only with symptoms such as positive fecal occult blood test and/or persistent iron deficit anemia.

The small bowel is the most difficult portion of the bowel to examine. Because of its remoteness from the mouth and anus, and its relatively long length, conventional endoscopic techniques (gastroscopy, enteroscopy, and colonoscopy) are limited in their ability to provide a thorough examination of the small intestine. Conventional endoscopic techniques usually require intravenous sedation in an outpatient setting and can be uncomfortable for the patient.

Medical Policy: WIRELESS CAPSULE ENDOSCOPY IMAGING AND WIRELESS MOTILITY CAPSULE FOR EXAMINATION OF THE GASTROINTESTINAL (GI) TRACT

Policy Number: 6.01.27

Page: 3 of 10

Wireless Capsule Endoscopy

Wireless CE (e.g., PillCam SB or Capsule Endoscope System for small bowel use, PillCam ESO for esophageal use, and PillCam Colon) has been developed to provide imaging of the esophagus, entire small bowel, and colon. Wireless CE is a non-invasive diagnostic imaging device for use in the GI tract, especially the small bowel, which is not easily accessible to standard upper- and lower-endoscopic procedures. Wireless CE requires no preparation of the GI tract (other than fasting) and allows the patient to continue daily activities throughout the entire endoscopic examination. The capsule, approximately the size of a vitamin, is swallowed by the patient, propelled by peristalsis through the gastrointestinal tract, and naturally excreted. As the capsule is propelled through the GI tract, video pictures are transmitted to sensors attached to the patient's body and stored on a portable recorder strapped to the patient's waist. The stored video images are later downloaded to a computer, from which they may be viewed and processed. The average transit time from ingestion to evacuation is approximately 24 hours. The most recently approved Capsule Endoscope System has the ability to provide real time image viewing.

The capsule camera has been most frequently proposed as a technique to identify the source of obscure intestinal bleeding, where conventional diagnostic work-up has not provided a definitive diagnosis. Wireless CE has also been proposed as a diagnostic tool for other abnormalities of the small bowel, for abnormalities of the upper GI tract such as the esophagus, and as an alternative to colonoscopy.

The Given AGILE Patency System is an accessory to the PillCam video capsule. It is intended to verify adequate patency of the gastrointestinal tract, prior to administration of the PillCam video capsule, in patients with known or suspected strictures. Once the patient ingests the Given AGILE Patency capsule, it is propelled through the GI tract by normal peristalsis. If the AGILE Patency capsule is excreted structurally whole, then this indicates patency of the patient's GI tract, and a PillCam capsule can be administered.

Wireless Motility Capsule

The American Gastroenterological Association defines gastroparesis as delayed gastric emptying of the stomach, possibly due to issues with the stomach muscles, nerves, or brain and spinal cord nerves. Gastroparesis is not a mechanical block in the stomach. Symptoms of gastroparesis are often nonspecific and may mimic other gastrointestinal tract disorders. Gastroparesis can be caused by many conditions; most common causes include idiopathic, diabetic, or postsurgical. Gastric emptying scintigraphy is considered the reference standard for diagnosing gastroparesis.

Constipation is a chronic disorder involving infrequent bowel movements, a sensation of obstruction, and incomplete evacuation. Many medical conditions can cause constipation, including 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 radiopaque markers and colonic transit scintigraphy.

The ingestible pH and pressure-sensing capsule (SmartPill GI Monitoring System) measures pH, pressure, and temperature changes of the GI tract, to evaluate gastric emptying for the diagnosis of gastroparesis, as well as colonic transit times for the diagnosis of slow-transit constipation. During wireless GI motility monitoring, the individual swallows a small capsule (approximately the size of a multivitamin) that contains sensors to measure peristaltic pressure, pH, and temperature. As the capsule moves through the GI tract, radiofrequency signals are transmitted to a wireless data receiver, which is usually worn on the individual's belt. After excretion, the receiver is returned to the physician, who then downloads the data and analyzes the results.

RATIONALE

Wireless Capsule Endoscopy

The Given Diagnostic Imaging System, PillCam SB, received initial Section 510(k) marketing clearance from the FDA on August 1, 2001. The FDA cleared the device for use along with, not as a replacement for, other endoscopic and radiologic evaluations of the small bowel. On July 2, 2003, the FDA approved the PillCam SB as a first-line tool in the detection of abnormalities of the small bowel, removing the adjunctive tool qualifier. On October 29, 2003, the FDA announced that it

Medical Policy: WIRELESS CAPSULE ENDOSCOPY IMAGING AND WIRELESS MOTILITY CAPSULE FOR EXAMINATION OF THE GASTROINTESTINAL (GI) TRACT

Policy Number: 6.01.27

Page: 4 of 10

had expanded its approved indications for the use of wireless CE, PillCam SB, to include visualization of the small bowel and detection of abnormalities in symptomatic children aged 10 to 18 years. This approval was based on data from a small trial where the wireless CE was able to diagnose or definitively exclude a bleeding source, small bowel polyps or Crohn's disease in 29 out of 30 children. In September 2009, the FDA expanded its approval of the PillCam SB for use in children aged two years and up.

The Olympus Capsule Endoscope System received Section 510(k) marketing clearance from the FDA in September 2007, as equivalent in intended use, method of operation, material, and design to the predicate device (PillCam SB). It is used for visualization of the small intestine mucosa. FDA approval was based upon a study of 51 patients with OGIB who swallowed both the PillCam SB and the Endocapsule, 40 minutes apart and in randomized order. The devices were similar, in terms of the detection of normal versus abnormal small intestine mucosa and in their diagnostic capability (Cave et al. 2008).

Studies have been published that compare the results of CE and push enteroscopy in patients with undiagnosed OGIB. Though the evidence is small, these studies report that CE provided additional diagnostic yield, leading to changes in patient management and improvement in health outcomes (Hartmann 2005, Pennazio 2004).

Although the current available evidence does not allow conclusions as to whether wireless CE is an effective alternative to conventional diagnostic tests in the workup of patients with suspected CD, the evidence does suggest the wireless CE can identify small bowel lesions suggestive of CD, when the conventional workup failed to do so in 43-71% of patients with suspected CD. These studies have also reported improved patient outcomes, after CD therapy was initiated based on wireless CE findings. For patients with an established diagnosis of Crohn's disease who remain symptomatic or develop new, unexpected symptoms, other methods are not available for visualizing the small bowel. Although the performance characteristics of the capsule for this indication is uncertain, it is likely to improve health outcomes by identifying some cases of these disorders and directing specific treatment. There are very limited studies of wireless CE as a diagnostic tool for other diseases of the small bowel (e.g., carcinoma, celiac sprue), and they have yet to provide sufficient data on the diagnostic yield and changes in patient management.

Small bowel capsule endoscopy (SBCE) can be used as a surveillance tool for small bowel polyps in patients with inherited polyposis syndromes. SBCE has been found to have a better diagnostic capability to reveal small bowel polyps, compared to barium follow-through, in patients with Peutz-Jeghers syndrome (Brown 2006, Iaquinto 2008).

The PillCam ESO (Given Imaging) was approved by the FDA in November 2004 as a non-invasive alternative to endoscopy, to diagnose and evaluate diseases of the esophagus. Direct imaging of the small bowel with an endoscope is limited, and, thus, wireless CE of the small bowel occupies a unique diagnostic niche. In contrast, esophageal endoscopy, which also offers the opportunity for biopsy, is a routinely performed procedure. Therefore, assessment of CE of the esophagus requires comparison of its diagnostic performance to the gold standard of conventional endoscopy. One proposed indication for the capsule camera is detection of Barrett's esophagus, considered a premalignant condition associated with gastroesophageal reflux disease (GERD). Conventional endoscopy is often recommended in patients with longstanding symptoms of GERD, or in those requiring pharmacologic therapy to control GERD symptoms, in order to rule out Barrett's esophagus. This is a high-volume indication for conventional upper endoscopy, given the high prevalence of GERD.

Capsule endoscopy offers a potential alternative to endoscopy; patients with a negative study could potentially forego conventional endoscopy. In this setting, the negative predictive value of CE is the key diagnostic parameter. Patients who are believed to have suggestive findings of Barrett's esophagus will require a confirmatory conventional endoscopy with biopsy.

Eliakim et al. 2004 reported on an initial case series of 17 patients with suspected esophageal disorders. The negative predictive value for any esophageal disorder was 100%, while the positive predictive value was 92% (sensitivity 100%, specificity 80%). In a larger, multi-center study of 106 patients with either GERD or Barrett's esophagus, Eliakim et al. 2005 reported esophageal abnormalities in 66/106 patients, providing a sensitivity of 92% and specificity of 95%. In an abstract presentation at the 2004 Gastrointestinal Cancers Symposium of ASCO, Schnoll-Sussman et al. reported on the results of 53 consecutive patients who underwent both conventional and capsule camera endoscopy as part of an

Medical Policy: WIRELESS CAPSULE ENDOSCOPY IMAGING AND WIRELESS MOTILITY CAPSULE FOR EXAMINATION OF THE GASTROINTESTINAL (GI) TRACT

Policy Number: 6.01.27

Page: 5 of 10

evaluation for Barrett's esophagus. The sensitivity of the capsule camera in detecting Barrett-like changes was 67%, while the specificity was 75%. The positive predictive value was 35%, and the negative predictive value was 92%. The results of these relatively small studies are inadequate to permit scientific conclusions regarding the clinical role of esophageal CE. Studies (n = 73) have been published, comparing the Pill Cam ESO to upper endoscopy in patients with portal hypertension and esophageal varices (Eisen et al. 2006; Lapalus et al. 2006, and Penna et al. 2008). Based on the outcomes of these small studies, PillCam ESO may represent an accurate, non-invasive alternative to EGD for the detection of esophageal varices and portal hypertensive gastropathy. While further studies are required to validate these initial findings, the use of wireless CE for those patients with significantly compromised liver function, who cannot tolerate sedation or anesthesia, appears reasonable.

A tethered or string CE for esophageal use remains under investigation. Strings and a sling are attached to the CE to allow for multiple controlled passes across the esophagus, with the aim of improving transit time. The ability to completely retrieve the device eliminates the risk of capsule retention in susceptible patients and also offers an advantage over conventional wireless CE. A preliminary study of 40 patients with dysphagia (Gilani et al. 2007) found that tethered CE was safe and well-tolerated by patients. The overall agreement between tethered CE and traditional upper endoscopy was 92.7%. Larger studies are needed, to determine its efficacy/accuracy and to further define its role as an alternative to upper endoscopy.

Given Imaging received FDA Section 510(k) clearance (Class II) for the PillCam COLON 2 in February 2014. The clearance is intended for use in patients who had an incomplete traditional colonoscopy and still require a better review of the passageway. Given Imaging conducted an 884-patient, 16-site clinical trial that studied the accuracy and safety of PillCam COLON 2, compared to optical colonoscopy, in detecting adenomas 6 millimeters or larger. Results from this clinical trial demonstrated that the sensitivity for PillCam COLON was 88% and specificity was 82% in detecting adenomas at least 6 mm in size. The FDA based its clearance decision on an analysis of this clinical trial data, which used a more restrictive methodology for matching polyps. In this analysis, which was conducted on hyperplastic polyps and adenomas, the positive percent agreement for PillCam COLON and optical colonoscopy was 69%, and negative percent agreement was 81% for polyps at least 6 millimeters in size. The wireless capsule had not been adequately studied in the large intestine. The colon was not well-visualized due to stool obscuring the colonic mucosa. Adequate visualization of the colon was also hampered by the colon's larger diameter which made it possible for the capsule camera to miss suspicious areas. R Eliakim et al. (2006) conducted a prospective study to determine whether CE of the colon can provide similar detection rates of pathological colonic conditions, compared to conventional colonoscopy. Conventional colonoscopy detected more polyps compared to wireless CE: 70% were identified with the capsule and 16/20 (80%) were identified by conventional colonoscopy. In comparison with conventional colonoscopy, false-positive findings on PillCam Colon capsule examination were recorded in 15/45 cases (33%). Additional studies are needed, to evaluate the accuracy of PillCam Colon endoscopy in patient populations with different prevalence levels of colonic disease. A prospective study by Parodi et al. (2018) included 177 first-degree relatives of individuals with colorectal cancer and found, for lesions 6 mm or larger, a sensitivity of 91% (95% CI, 81% to 96%) and specificity of 88% (95% CI, 81% to 93%) for colon CE, using optical colonoscopy as the reference.

The FDA approved the Agile patency capsule in May 2006 as "an accessory to the Pill Cam video capsule," noting that it "is intended to verify adequate patency of the gastrointestinal tract prior to administration of the Pill Cam video capsule in patients with known or suspected strictures." Delvaux et al. (2005) evaluated the usefulness of this system in 22 patients with suspected intestinal stenosis who were also undergoing CE. The authors stated that the current technical development of the patency capsule limits its use in clinical practice, as it did not detect stenoses undiagnosed by computed tomography (CT) or small bowel follow-through. They also stated that the start of dissolution at 40 hours after ingestion was too slow to prevent episodes of intestinal occlusion. The authors noted that patients with Crohn's disease are most likely to be at risk of blockage of progression of the capsule and should benefit from a CT investigation before CE. They noted that a careful interview eliciting the patient's medical history and symptoms remains the most useful indicator with regard to suspicion of an intestinal stenosis. Signorelli et al. (2006) evaluated 32 patients. The 26 patients who excreted the patency capsule intact, without experiencing abdominal pain, were deemed eligible for the CE procedure, which was performed uneventfully in the 25 who agreed to undergo the examination. The authors stated that the patency capsule "is

Medical Policy: WIRELESS CAPSULE ENDOSCOPY IMAGING AND WIRELESS MOTILITY CAPSULE FOR EXAMINATION OF THE GASTROINTESTINAL (GI) TRACT

Policy Number: 6.01.27

Page: 6 of 10

an effective method for the assessment of small bowel patency before CE. However, the real incidence of complications such as the development of severe abdominal pain and small bowel obstruction needs to be ascertained before the patency test can be recommended as the standard method to evaluate patients at risk of developing capsule retention.” There is a lack of data defining the safety and role of the patency capsule. Conventional evaluations remain the gold standard for ruling out any known or suspected gastrointestinal obstruction, strictures, and fistulas, prior to CE.

Wireless Motility Capsule

In 2006, the ingestible capsule (SmartPill GI Monitoring System) was FDA-cleared through the Section 510(k) process for the 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 means passage to the ileocecal junction. The capsule also measures pressure and temperature during its transit through the entire GI tract, allowing calculations of total GI tract transit time. In 2009, the FDA 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. The SmartPill is not for use in pediatric patients.

The American Gastroenterological Association’s 2013 guidelines on gastroparesis diagnosis and treatment indicated that WCE testing requires validation before it can be considered as an alternative to scintigraphy for diagnosing gastroparesis. There is a lack of data defining the safety and role of the SmartPill. Standard tests used in the evaluation of constipation include ingestion of radiopaque markers and colonic transit scintigraphy.

In a systematic review by Stein et al. (2013) that was conducted for the Agency for Healthcare Research and Quality (AHRQ), the strength of evidence in available studies on the ingestible capsule for assessing colonic transit times was found to be low overall. No studies were identified that compared the SmartPill to colonic scintigraphy. Accuracy of the ingestible capsule in diagnosing slow-transit constipation was similar to tests using radiopaque markers. A moderate correlation between colonic transit times with the ingestible capsule and tests with radiopaque markers was shown in five studies (range, 0.69-0.71). The overall strength of evidence favoring the ingestible capsule was low. There was a moderate correlation on transit data and device agreement between the ingestible capsule and gastric emptying scintigraphy in five studies.

The American College of Gastroenterology’s clinical guideline on “Management of gastroparesis” (Camilleri et al. 2013) noted, “Alternative approaches for assessment of gastric emptying include wireless capsule motility testing and ¹³C breath testing using octanoate or spirulina incorporated into a solid meal; they require further validation before they can be considered as alternates to scintigraphy for the diagnosis of gastroparesis” (conditional recommendation, moderate level of evidence).

Surjanhata et al. (2018) performed a retrospective, multi-center clinical trial of 190 participants, to evaluate colonic wake response using the WMC. Colonic wake response is a relative increase in colonic motility upon awakening as colonic manometry studies have demonstrated reduced wake response in slow transit subjects. WMC motility parameters of contraction frequency (Ct) and area under the contraction curve (AUC) were analyzed in 20-minute windows one hour before and after awakening for all study participants. The participants were evaluated at the study center at 48 hours post ingestion and then returned the data receiver and diary at 120 hours post ingestion. Recorded WMC events were correlated with the participants’ diary entries and pH tracings to quantify transit times of gastric emptying, small bowel transit, and colonic transit. At baseline prior to awakening, there was no significant difference in the mean contraction frequency (Ct) between the study participants ($p > 0.15$). At 20, 40, and 60 minutes after awakening, e4 (STC) subjects had significantly lower mean Ct when compared to H ($p < 0.001$) and NTC ($p < 0.01$). Linear regression demonstrated that outlet obstruction was not associated with a decreased wake response ($\beta = 3.94$, $CI -3.12-1.00$, $P = 0.27$). Blunted wake response sensitivity was 84% and specificity was 32% for chronic constipation at the Ct threshold of 64 at 20-min post-wake. The authors concluded that WMC technology can be utilized to identify an impaired wake response in subjects with STC and not normal transit constipation (NTC) which may support previous studies of neuronal dysfunction as an etiology of STC and potential for pharmacologic intervention.

Medical Policy: WIRELESS CAPSULE ENDOSCOPY IMAGING AND WIRELESS MOTILITY CAPSULE FOR EXAMINATION OF THE GASTROINTESTINAL (GI) TRACT

Policy Number: 6.01.27

Page: 7 of 10

Two large, prospective, multicenter trials (Lee et al., 2019 and Hasler et al., 2019) compared WMC testing with gastric emptying scintigraphy (GES) in patients with gastroparesis symptoms. Both studies found that WMC detected delayed gastric emptying more often than GES, due to WMC's capability of profiling the entire gastrointestinal tract in patients. However, the studies were limited by practice standards, participant population, and lack of correlation of physiological results with symptoms and/or management outcomes. Additional clinical studies are needed, to further investigate and compare GES versus WMC testing in patients with gastroparesis symptoms.

The available published evidence demonstrates that the diagnostic accuracy of the SmartPill is not well-defined. The current test (gastric emptying scintigraphy) is an imperfect standard, which creates difficulty in defining the sensitivity and specificity of the SmartPill. There is moderate correlation between the SmartPill and scintigraphy. For constipation, studies showed moderate correlation between the SmartPill and other methods of assessing colonic transit times and should be interpreted cautiously.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- ***CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.***
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*

CPT Codes

Code	Description
91110	Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus through ileum, with interpretation and report
91111	Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus with interpretation and report
91112 (E/I)	Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report
91113 (E/I)	Gastrointestinal tract imaging, intraluminal colon (<i>Effective 01/01/22</i>)
0651T (E/I)	Magnetically controlled capsule endoscopy, esophagus through stomach, including intraprocedural positioning of capsule, with interpretation and report.

Copyright © 2022 American Medical Association, Chicago, IL

HCPCS Codes

Code	Description
No codes	

ICD10 Codes

Code	Description
Multiple codes	

REFERENCES

- *Albert JG, et al. Impact of capsule endoscopy on outcome in mid-intestinal bleeding: a multicentre cohort study in 285 patients. Eur J Gastroenterol Hepatol 2008 Oct;20(10):971-7.
- *Amano Y, et al. Gastric screening examination using PillCam ESO 2: a pilot study. Dig Liver Dis 2011 Jul;43(7):580-1.
- *Atlas DS, et al. Capsule endoscopy in nonresponsive celiac disease. Gastrointest Endosc 2011 Dec;74(6):1315-22.

Medical Policy: WIRELESS CAPSULE ENDOSCOPY IMAGING AND WIRELESS MOTILITY CAPSULE FOR EXAMINATION OF THE GASTROINTESTINAL (GI) TRACT

Policy Number: 6.01.27

Page: 8 of 10

*Bailey AA, et al. Diagnosis and outcome of small bowel tumors found by capsule endoscopy: a three-center Australian experience. Am J Gastroenterol 2006 Oct;101(10):2237-43.

Baltes P, et al. PillCamColon2 after incomplete colonoscopy - a prospective multicenter study. World J Gastroenterol 2018 Aug 21;24(31):3556-3566.

*Banerjee R, et al. Safety and efficacy of the M2A patency capsule for diagnosis of critical intestinal patency: results of a prospective trial. J Gastroenterol Hepatol 2007 Dec;22(12):2060-63.

*Bhardwaj A, et al. A meta-analysis of the diagnostic accuracy of esophageal capsule endoscopy for Barrett's esophagus in patients with gastroesophageal reflux disease. Am J Gastroenterol 2009 Jun;104(6):1533-9.

*Bourreille A, et al. Role of small-bowel endoscopy in the management of patients with inflammatory bowel disease: an international OMED-ECCO consensus. Endoscopy 2009;41:618-37.

Brito HP, et al. Video capsule endoscopy vs double-balloon enteroscopy in the diagnosis of small bowel bleeding: a systematic review and meta-analysis. World J Gastrointest Endosc 2018 Dec 16;10(12):400-421.

Bruining DH, et al. BLINK study group. Panenteric capsule endoscopy versus ileocolonoscopy plus magnetic resonance enterography in Crohn's disease: a multicentre, prospective study. BMJ Open Gastroenterol 2020 Jun;7(1):e000365.

*Camilleri M, et al. Clinical guideline: management of gastroparesis. Am J Gastroenterol 2013 Jan;108(1):18-38.

*Casciani E, et al. MR enterography versus capsule endoscopy in paediatric patients with suspected Crohn's disease. Eur Radiol 2011 Apr;21(4):823-31.

*Cave D, et al. A Multicenter randomized comparison of the endocapsule and the PillCam SB. Gastrointest Endosc 2008; Sep;68(3):487-94.

*De Franchis R, et al. Esophageal capsule endoscopy (PillCam ESO) is comparable to traditional endoscopy for detection of esophageal varices- an international multicenter trial. Gastrointest Endosc 2007;65(5):AB107.

*Delvaux M, et al. Esophageal capsule endoscopy in patients with suspected esophageal disease: double blinded comparison with esophagogastroduodenoscopy and assessment of interobserver variability. Endoscopy 2008 Jan;40(1):16-22.

*Dionisio PM, et al. Capsule endoscopy has a significant higher diagnostic yield in patients with suspected and established small-bowel Crohn's disease: a met-analysis. Am J Gastroenterol 2010 Jun;105(6):1240-8.

*Eliakim R, et al. Evaluation of the Pill Cam Colon capsule in the detection of colonic pathology: results of the first multicenter, prospective, comparative study. Endoscopy 2006 Oct;38(10):963-70.

*Eliakim R, et al. Prospective multicenter performance evaluation of the second-generation colon capsule compared with colonoscopy. Endoscopy 2009 Dec;41(12):1026-31.

*El-Matary W, et al. Diagnostic characteristics of given video capsule endoscopy in diagnosis of celiac disease: A meta-analysis. J Laparoendosc Adv Surg Tech A 2009 Apr 30 [Epub ahead of print].

Food and Drug Administration. PillCam® COLON 2 Capsule Endoscopy System. [\[http://www.accessdata.fda.gov/cdrh_docs/pdf12/K123666.pdf\]](http://www.accessdata.fda.gov/cdrh_docs/pdf12/K123666.pdf) accessed 7/14/22.

*Fritscher-Ravens A, et al. The feasibility of wireless capsule endoscopy in detecting small intestinal pathology in children under the age of 8 years: a multicentre European study. Gut 2009 Nov;58(11):1467-72.

*Galmiche JP, et al. Screening for esophagitis and Barrett's esophagus with wireless esophageal capsule endoscopy: a multicenter prospective trial in patients with reflux symptoms. Am J Gastroenterol 2008 Mar;103(3):538-45.

González-Suárez B, et al. Colon capsule endoscopy versus CT colonography in FIT-positive colorectal cancer screening subjects: a prospective randomised trial-the VICOCA study. BMC Med 2020 Sep 18;18(1):255.

Medical Policy: WIRELESS CAPSULE ENDOSCOPY IMAGING AND WIRELESS MOTILITY CAPSULE FOR EXAMINATION OF THE GASTROINTESTINAL (GI) TRACT

Policy Number: 6.01.27

Page: 9 of 10

*Gostout C. Capsule endoscopy clinical update: American Society for Gastrointestinal Endoscopy. 2002 Oct;10(2):1-4.

Grigg-Gutierrez N, et al. Diagnostic yield of video capsule endoscopy for small bowel bleeding: eight consecutive years of experience at the VA Caribbean Healthcare System. P R Health Sci J 2016 June;35(2):93-96.

*Gupta A, et al. A prospective study of MT enterography versus capsule endoscopy for the surveillance of adult patients with Peutz-Jeghers syndrome. AJR Am J Roentgenol 2010 Jul;195(1):108-16.

*Guturu P, et al. Capsule endoscopy with PillCAM ESO for detecting esophageal varices: a meta-analysis. Minerva Gastroenterol Dietol 2011 Mar;57(1):1-11.

*Hartmann D, et al. A prospective two-center study comparing wireless capsule endoscopy with intraoperative enteroscopy in patients with obscure GI bleeding. Gastrointest Endosc Jun 2005;61(7):826-832.

*Hasler WL, et al. Influence of gastric emptying and gut transit testing on clinical management decisions in suspected gastroparesis. Clinical and Translational Gastroenterology 2019;10:e00084.

*Lai LH, et al. Long-term follow-up of patients with obscure gastrointestinal bleeding after negative capsule endoscopy. Am J Gastroenterol 2006 Jun;101(6):1224-8.

*Laine L, et al. Does capsule endoscopy improve outcomes in obscure gastrointestinal bleeding? Randomized trial versus dedicated small bowel radiography. Gastroenterol 2010 May;138(5):1673-80.

*Lee AA, et al. Validation of diagnostic and performance characteristics of the wireless motility capsule in patients with suspected gastroparesis. Clinical Gastroenterology and Hepatology 2019;17:1770–1779.

Lichtenstein GL, et al. ACG practice guidelines. Management of Crohn's disease in adults. Am J Gastroenterol 2018; 113:481–517 [<https://acgcdn.gi.org/wp-content/uploads/2018/04/ACG-Crohns-Guideline-Summary.pdf>]. accessed 07/14/22.

*Lin OS, et al. Blinded comparison of esophageal capsule endoscopy versus conventional endoscopy for a diagnosis of Barrett's esophagus in patients with chronic gastroesophageal reflux. Gastrointest Endosc 2007 Apr;65(4):577-83.

*Long MD, et al. Impact of capsule endoscopy on management of inflammatory bowel disease: a single tertiary care center experience. Inflamm Bowel Dis 2011 Sep;17(9):1855-62.

*Lu Y, et al. Meta-analysis of capsule endoscopy in patients diagnosed or suspected with esophageal varices. World J Gastroenterol 2009 Mar 14;15(10):1254-8.

*Marmo R, et al. Capsule endoscopy versus enteroclysis in the detection of small-bowel involvement in Crohn's disease: a prospective trial. Clin Gastroenterol Hepatol 2005 Aug;3(8):772-6.

Marya NB, et al. A randomized controlled trial comparing efficacy of early video capsule endoscopy with standard of care in the approach to non-hematemesis gastrointestinal bleeding (with videos). Gastrointest Endosc 2019 Jan;89(1):33-43.e4.

*Mergener K, et al. Literature review and recommendations for clinical application of small-bowel capsule endoscopy, based on a panel discussion by international experts. Consensus statements for small-bowel capsule endoscopy, 2006/2007. Endoscopy 2007 Oct;39(10):895-909.

*Milano A, et al. A prospective evaluation of iron deficiency anemia in the GI endoscopy setting: role of standard endoscopy, videocapsule endoscopy, and CT-enteroclysis. Gastrointest Endosc 2011 May;73(5):1002-8.

Nemeth A, et al. Video capsule endoscopy in pediatric patients with Crohn's disease: a single-center experience of 180 procedures. Therap Adv Gastroenterol 2018 Mar 4;11:1756284818758929.

*Parodi A, et al. Colon capsule endoscopy to screen for colorectal neoplasia in those with family histories of colorectal cancer. Gastrointest Endosc 2018 Mar;87(3):695-704.

*Pennazio M, et al. Outcome of patients with obscure gastrointestinal bleeding after capsule endoscopy: report of 100 consecutive cases. Gastroenterology Mar 2004;126(3):643-653.

Medical Policy: WIRELESS CAPSULE ENDOSCOPY IMAGING AND WIRELESS MOTILITY CAPSULE FOR EXAMINATION OF THE GASTROINTESTINAL (GI) TRACT

Policy Number: 6.01.27

Page: 10 of 10

*Postgate A, et al. Feasibility of video capsule endoscopy in the management of children with Peutz-Jeghers syndrome: a blinded comparison with barium enterography for the detection of small bowel polyps. J Pediatr Gastroenterol Nutr 2009 Oct;49(4):417-23.

*Raju GS, et al. American Gastroenterological Association (AGA) Institute technical review on obscure gastrointestinal bleeding. Gastroenterol 2007 Nov;133(5):1697-717.

*Rokkas T, et al. A meta-analysis evaluating the accuracy of colon capsule endoscopy in detecting colon polyps. Gastrointest Endosc 2010 Apr;71(4):792-8.

*Sharma P, et al. The diagnostic accuracy of esophageal capsule endoscopy in patients with gastroesophageal reflux disease and Barrett's esophagus: a blinded, prospective study. Am J Gastroenterol 2008 Mar;103(3):525-32.

Singh K, et al. Diagnostic yield of capsule endoscopy for small bowel arteriovenous malformations in patients with hereditary hemorrhagic telangiectasia: a systematic review and meta-analysis. Endosc Int Open 2019 Feb;7(2):E282-E289.

*Stein E, et al. Wireless motility capsule versus other diagnostic technologies for evaluating gastroparesis and constipation: A comparative effectiveness review. 2013 May; AHRQ Publication No. 13-EHC060-EF.

*Surjanhata B, et al. Colonic motor response to wakening is blunted in slow transit constipation as detected by wireless motility capsule. Clinical and Translational Gastroenterology (2018) 9:144.

Valdivia PC et al. Indications, detection, completion and retention rates of capsule endoscopy in two decades of use: a systematic review and meta-analysis. Diagnostics 2022 Apr;12(5):1105.

*Van Gossum A, et al. Capsule endoscopy versus colonoscopy for the detection of polyps and cancer. NEJM 2009 Jul 16;361(3):264-70.

Zammit SC & Sidhu R. Capsule endoscopy – Recent developments and future directions. Expert Review of Gastroenterology & Hepatology 2021 Vol 15;2: 127-137.

*Key Article

KEY WORDS

AGILE patency capsule, Capsule Endoscope System, Given capsule camera, PillCam SB, PillCam ESO, PillCam Colon, SmartPill.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based on our review, wireless capsule endoscopy and wireless motility capsule are not addressed in National Medicare coverage determinations or policies.

There is currently a Local Coverage Determination (LCD) for colon capsule endoscopy. Please refer to the following LCD website for Medicare Members:

Colon Capsule Endoscopy (CCE):<http://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38571&ver=8&lcdStatus=all&sortBy=title&bc=6> (effective 2/15/22)