

SUBJECT: WIRELESS CAPSULE ENDOSCOPY/ IMAGING FOR EXAMINATION OF THE GASTROINTESTINAL (GI) TRACT POLICY NUMBER: 6.01.27 CATEGORY: Technology Assessment	EFFECTIVE DATE: 06/20/02 REVISED 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
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- *If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.*
- *Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.*
- *Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.*

POLICY STATEMENT:

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

- I. Wireless capsule endoscopy has been medically proven to be effective and therefore **medically appropriate** for the evaluation of obscure gastrointestinal (GI) bleeding, 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 appropriate clinical setting (active bleeding during the work-up), 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 capsule endoscopy has been medically proven effective and therefore **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 WBC, and/or elevated sedimentation rate.
- III. Wireless capsule endoscopy has been medically proven to be effective and therefore **medically appropriate** for surveillance of the small bowel in patients with hereditary GI polyposis syndromes such as familial adenomatous polyposis (FAP) or Peutz-Jeghers syndrome.
- IV. Wireless capsule endoscopy has been medically proven to be effective and therefore **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.
- V. Wireless capsule endoscopy has not been medically proven to be effective and is considered **investigational** for any other indication, including but not limited to:
 - A. evaluating diseases of the esophagus other than 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 have not been performed;
 - D. for the diagnosis of irritable bowel syndrome;
 - E. any other diseases of the small bowel; or
 - F. diseases of the large intestine/colon.
- VI. 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 effective and is considered **investigational**.

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POLICY GUIDELINES:

- I. Wireless capsule endoscopy must be performed under the supervision of a gastroenterologist or a general surgeon with expertise in this technology.
- II. In the case of obscure GI bleeding, because of low lesion detection rate, a small bowel follow- through or enteroclysis is not necessarily required prior to wireless capsule endoscopy. A small bowel follow-through may be beneficial in some cases at the discretion of the clinician prior to, or after wireless capsule endoscopy in the detection of small bowel lesions and in their anatomical localization.
- III. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

The American Gastroenterological Association defines obscure GI bleeding (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 into obscure overt and obscure occult bleeding based on the presence or absence of clinically evident bleeding. Obscure occult bleeding may only present 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, along with the relatively long length of the small intestine, conventional endoscopic techniques (gastroscopy, enteroscopy and colonoscopy) are limited in providing 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.

Wireless capsule endoscopy (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. The wireless capsule endoscopy is a non-invasive diagnostic imaging device for use in the gastrointestinal (GI) tract, especially the small bowel which is not easily accessible to standard upper and lower endoscopic procedures. Wireless capsule endoscopy requires no preparation of the GI tract (other than fasting) and allows the patient to continue their daily activities throughout the entire endoscopic examination. The capsule, approximately the size of a vitamin, is swallowed by the patient, and 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 capsule endoscopy 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 and 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 GI tract of the patient, and a PillCam capsule can be administered.

RATIONALE:

The Given Diagnostic Imaging System, PillCam™ SB received initial 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

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abnormalities of the small bowel, removing the adjunctive tool qualifier. On October 29, 2003 the FDA announced that it had expanded approved indications for the use of wireless capsule endoscopy, PillCam™ SB to include visualization of the small bowel and the detection of abnormalities in symptomatic children age 10 to 18 years. This approval was based on data from a small trial where the wireless capsule endoscopy 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 approved the use of the PillCam SB to include use in children from the age of 2 years and up.

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

Studies have been published that compare the results of capsule endoscopy and push enteroscopy in patients with undiagnosed, obscure GI bleeding. Though the evidence is small, these studies report that capsule endoscopy provided additional diagnostic yield in 25-50% of the cases and this information led to changes in patient management and improvement in health outcomes.

Though the current available evidence does not allow conclusions as to whether wireless capsule endoscopy is an effective alternative to conventional diagnostic tests in the workup of patients with suspected CD, the evidence does suggest the wireless capsule endoscopy 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 capsule endoscopy findings. There are very limited studies of wireless capsule endoscopy as a diagnostic tool for other diseases of the small bowel (e.g., irritable bowel disease, 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 capsule endoscopy 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 capsule endoscopy 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; those patients with a negative study could potentially forego conventional endoscopy. In this setting, the negative predictive value of capsule endoscopy is the key diagnostic parameter. Patients who are found to have suggestive findings of Barrett's esophagus will require a confirmatory conventional endoscopy with biopsy.

At the present time, there is minimal published literature regarding the diagnostic performance of the wireless esophageal capsule endoscopy. 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 multicenter study of 106 patients with either GERD or Barrett's, 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

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of an evaluation for Barrett's esophagus. The sensitivity of the capsule camera in detected 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 capsule endoscopy. New 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 noninvasive 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 capsule endoscopy for those patients with significantly compromised liver function who can not tolerate sedation or anesthesia, appears reasonable.

A tethered or string capsule endoscopy for esophageal use is currently 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 also offers an advantage over conventional WCE. A preliminary study of 40 patients with dysphagia (Gilani, et al. 2007) found that tethered capsule endoscopy was safe and well tolerated by patients. The overall agreement between tethered capsule endoscopy 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 FDA510(k) clearance (Class II) for the PillCam® COLON 2 in February 2014. The clearance is intended for 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 studying 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 millimeters in size.¹ The FDA based its clearance decision on an analysis of this clinical trial data that 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 has not been adequately studied in the large intestine. The colon is not well visualized due to stool obscuring the colonic mucosa. Adequate visualization of the colon is also hampered by the colon's larger diameter making it possible for the capsule camera to miss suspicious areas. R Eliakim, et al. (2006) conducted a prospective study to determine if capsule endoscopy of the colon can provide similar detection rates of pathological colonic conditions compared to conventional colonoscopy. Conventional colonoscopy detected more polyps compared to WCE: 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.

The Agile patency capsule did receive FDA approval in May 2006 as "an accessory to the Pill Cam video capsule and 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 but 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 CT or SBFT. They stated that the start of dissolution at 40 hours after ingestion is 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 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

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capsule. Conventional evaluations remain the gold standard for ruling out any known or suspected gastrointestinal obstruction, strictures, and fistulas prior to CE.

CODES: Number Description

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.

<u>CPT:</u>	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
	0355T (E/I)	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), colon, with interpretation and report

This medical policy does not address the ingestible pH and pressure capsule (e.g., SmartPill® GI Monitoring System) billed with CPT code 91112. This technology has been proposed as a means of evaluating gastric emptying for the diagnosis of gastroparesis and colonic transit times for the diagnosis of slow-transit constipation.

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HCPCS: No codes

ICD9: Multiple codes

ICD10: Multiple codes

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*key article

KEY WORDS:

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

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a Local Coverage Determination (LCD) and related article for endoscopy by capsule. Please refer to the following LCD websites for Medicare Members:

http://apps.ngsmedicare.com/lcd/LCD_L25468.htm

http://apps.ngsmedicare.com/sia/ARTICLE_A48399.htm