

MEDICAL POLICY



MEDICAL POLICY DETAILS	
Medical Policy Title	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, 08/20/15, 07/21/16, 07/20/17, 07/19/18, 06/20/19
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 product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit. • If a Medicare 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.

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 of the small bowel 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 of the small bowel has been medically proven effective and therefore **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 needs to be assessed prior to the capsule endoscopy.
- IV. 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.
- V. 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.
- VI. 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;

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

Policy Number: 6.01.27

Page: 2 of 9

- 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.

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 effective and is considered **investigational**.

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.

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

Policy Number: 6.01.27

Page: 3 of 9

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 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 and this information led to changes in patient management and improvement in health outcomes (Hartmann 2005, Pennazio 2004).

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. For patients with an established diagnosis of Crohn 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 capsule endoscopy 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 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

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

Policy Number: 6.01.27

Page: 4 of 9

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.

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 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. 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 a specificity of 88% (95% CI, 81% to 93%) for colon capsule endoscopy using optical colonoscopy as the reference.

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

Policy Number: 6.01.27

Page: 5 of 9

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

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

Copyright © 2019 American Medical Association, Chicago, IL

HCPCS Codes

Code	Description
No codes	

ICD10 Codes

Code	Description
Multiple codes	

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

Policy Number: 6.01.27

Page: 6 of 9

REFERENCES

Al-Bawardy B, et al. Retained capsule endoscopy in a large tertiary care academic practice and radiologic predictors of retention. Inflamm Bowel Dis 2015 Sep;21(9):2158-64.

*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.

ASGE Standards of Practice Committee, et al. The role of endoscopy in the management of suspected small-bowel bleeding. Gastrointest Endosc 2017 Jan;85(1):22-31.

*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.

BlueCross BlueShield Association. Wireless capsule endoscopy as a diagnostic technique in disorders of the small bowel, esophagus, and colon. Medical Policy Reference Manual Medical Policy #6.01.33. 2018 Nov 08.

*BlueCross BlueShield Association Technology Evaluation Center (TEC). Wireless capsule endoscopy. 2003 Feb;17(21).

*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.

Boal Carvalho P, et al. Pillcam COLON 2 in Crohn's disease: a new concept of pan-enteric mucosal healing assessment. World J Gastroenterol 2015 Jun 21;21(23):7233-41.

*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.

*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.

Choi M, et al. Effectiveness of capsule endoscopy compared with other diagnostic modalities in patients with small bowel Crohn's disease: a meta-analysis. Gut Liver 2017 Jan 15;11(1):62-72.

Colli A, et al. Capsule endoscopy for the diagnosis of oesophageal varices in people with chronic liver disease or portal vein thrombosis. Cochrane Database Syst Rev 2014 Oct 1;10:CD008760.

Curdia Goncalves T, et al. Small bowel capsule endoscopy in obscure gastrointestinal bleeding: normalcy is not reassuring. Eur J Gastroenterol Hepatol 2014 Aug;26(8):927-32.

Dabos KJ, et al. Small bowel capsule endoscopy and portal hypertensive enteropathy in cirrhotic patients: results from a tertiary referral center. Ann Hepatol 2016 May-June;15(3):394-401.

*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.

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

Policy Number: 6.01.27

Page: 7 of 9

*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.

D'Haens G, et al. Safety and feasibility of using the second-generation Pillcam Colon Capsule to assess active colonic Crohn's disease. Clin Gastroenterol Hepatol 2015 Aug;31(8):1480-6.

*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] accessed 5/2/19.

*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.

Gerson LB, et al. ACG clinical guideline: Diagnosis and management of small bowel bleeding. Am J Gastroenterol 2015 Sep;110(9):1265-87.

*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.

Hall BJ, et al. A prospective 12-week mucosal healing assessment of small bowel Crohn's disease as detected by capsule endoscopy. Eur J Gastroenterol Hepatol 2014 Nov;26(11):1253-9.

*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.

He B, et al. Obscure gastrointestinal bleeding: diagnostic performance of 64-section multiphase CT enterography and CT angiography compared with capsule endoscopy. Br J Radiol 2014 Nov;87(1043):20140229.

Igawa A, et al. Evaluation for the clinical efficacy of colon capsule endoscopy in the detection of laterally spreading tumors. Digestion 2017;95(1):43-48.

Jeon SR, et al. Portal hypertensive enteropathy diagnosed by capsule endoscopy in cirrhotic patients: a nationwide multicenter study. Dig Dis Sci 2014 May;59(5):1036-41.

*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.

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

Policy Number: 6.01.27

Page: 8 of 9

- *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.
- Leighton JA, et al. Capsule endoscopy is superior to small-bowel follow-through and equivalent to ileocolonoscopy in suspected Crohn's disease. Clin Gastroenterol Hepatol 2014 Apr;12(4):609-15.
- Lichtenstein GL, et al. ACG practice guidelines. Management of Crohn's disease in adults. Am J Gastroenterol 2018; 113:481–517 [<http://gi.org/wp-content/uploads/2018/04/ajg201827.pdf>]. accessed 5/2/19.
- *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 2018 Jun 20 [Epub ahead of print].
- *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.
- Oliva S, et al. Colon capsule endoscopy compared with other modalities in the evaluation of pediatric Crohn's disease of the small bowel and colon. Gastrointest Endosc 2016 May;83(5):975-983.
- *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.
- *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.
- Rahman M, et al. Comparison of the diagnostic yield and outcomes between standard 8 h capsule endoscopy and the new 12 h capsule endoscopy for investigating small bowel pathology. World J Gastroenterol 2015 May 14;21(18):5542-7.
- Rahman I, et al. Magnetic-assisted capsule endoscopy in the upper GI tract by using a novel navigation system (with video). Gastrointest Endosc 2016 May;83(5):889-895.
- *Raju GS, et al. American Gastroenterological Association (AGA) Institute technical review on obscure gastrointestinal bleeding. Gastroenterol 2007 Nov;133(5):1697-717.
- Rex DK, et al. Accuracy of capsule colonoscopy in detecting colorectal polyps in a screening population. Gastroenterology 2015 May;148(5):948-57.

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

Policy Number: 6.01.27

Page: 9 of 9

*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.

Rondonotti E, et al. Small-bowel capsule endoscopy and device-assisted enteroscopy for diagnosis and treatment of small-bowel disorders: European Society of Gastrointestinal Endoscopy (ESGE) Technical Review. Endoscopy 2018 Apr;50(4):423-446.

Sacher-Huvelin S, et al. Screening of esophageal varices by esophageal capsule endoscopy: results of a French multicenter prospective study. Endoscopy 2015 Jun;47(6):486-92.

San Juan-Acosta M, et al. Colon capsule endoscopy is a safe and useful tool to assess disease parameters in patients with ulcerative colitis. Eur J Gastroenterol Hepatol 2014 Aug;26(8):894-901.

Seiji K, et al. Safety and efficacy of small bowel examination by capsule endoscopy for patients before liver transplantation. Biomed Res Int 2017;2017:8193821.

*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.

Spada C, et al. Colon capsule versus CT colonography in patients with incomplete colonoscopy: a prospective, comparative trial. Gut 2015 Feb;64(2):272-81.

Sung JJ, et al. Use of capsule endoscopy in the emergency department as a triage of patients with GI bleeding. Gastrointest Endosc 2016 Dec;84(6):907-913.

Urquhart P, et al. Capsule endoscopy versus magnetic resonance enterography for the detection of small bowel polyps in Peutz-Jeghers syndrome. Fam Cancer 2014 Jun;13(2):249-55.

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

Xue M, et al. Small-bowel capsule endoscopy in patients with unexplained chronic abdominal pain: a systematic review. Gastrointest Endosc 2014 Jul 8 [Epub ahead of print].

Yang L, et al. Increased diagnostic yield of capsule endoscopy in patients with chronic abdominal pain. PLoS One 2014 Jan;9(1):e87396.

Zevit N, et al. Wireless capsule endoscopy of the small intestine in children. J Pediatr Gastroenterol Nutr 2015 Jun;60(6):696-701.

*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

Based on our review, capsule endoscopy is not addressed in National or Regional Medicare coverage determinations or policies. However, there is a local Medicare coverage determination (LCD) addressing category III codes (e.g., 0355T). Please refer to the following LCD website for Medicare Members:

[https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33392&ver=95&CntrctrSelected=298*1&Cntrctr=298&name=National+Government+Services%2c+Inc.+\(13201%2c+A+and+B+and+HHH+MAC%2c+J+K\)&s=All&DocType=Active&bc=AggAAAQBAAA&](https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33392&ver=95&CntrctrSelected=298*1&Cntrctr=298&name=National+Government+Services%2c+Inc.+(13201%2c+A+and+B+and+HHH+MAC%2c+J+K)&s=All&DocType=Active&bc=AggAAAQBAAA&)