



# CIGNA MEDICAL COVERAGE POLICY

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Subject **Capsule Endoscopy**

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## Hyperlink to Related Coverage Policies

Serological Testing for Inflammatory Bowel Disease (ANCA/pANCA/ASCA)

### INSTRUCTIONS FOR USE

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

## Coverage Policy

CIGNA covers capsule endoscopy (i.e., Pillcam<sup>®</sup>, Endo Capsule) as medically necessary in adults and children two years of age or older, when standard endoscopic and imaging evaluations are inconclusive and the individual has **ONE** of the following:

- obscure source of gastrointestinal bleeding
- suspected Crohn's disease
- suspected small bowel tumor
- celiac disease

CIGNA does not cover capsule endoscopy for any other indication, including, but not limited to, suspected esophageal or colonic pathology, because it is considered experimental, investigational or unproven.

CIGNA does not cover the patency capsule because it is considered experimental, investigational or unproven.

## General Background

Wireless capsule endoscopy (WCE), or capsule endoscopy, is a noninvasive procedure in which an ingestible, multivitamin-sized capsule containing a miniaturized video camera, light, transmitter, and batteries, is

swallowed. A video recording is taken as it moves through the gastrointestinal (GI) tract. The capsule was originally developed to reach inaccessible areas that standard endoscopic examination cannot reach due to significant length and distance from accessible orifices. Proponents currently support its use to view the entire gastrointestinal tract, esophagus to colon, for multiple conditions.

Two companies currently market a video capsule: Pillcam<sup>®</sup> (Given<sup>®</sup> Imaging, Ltd., Yoqneam, Israel); and the Olympus Capsule Endoscope System with Endo Capsule (Olympus Medical Systems Corporation, Tokyo, Japan). Both include the capsule that is swallowed, the data recorder (worn around patient's waist) and a computer workstation (with software and viewer/monitor). The European Society of Gastrointestinal Endoscopy (ESGE) states that the PillCam employs complementary metal oxide silicon (COMS) technology, while the Olympus capsule utilizes technology based on a charge-coupled device (CCD) (Rey, et al., 2006).

The Given AGILE<sup>™</sup> Patency System is an optional accessory to the PillCam video capsule and is intended to validate patency of the GI tract. The main capsule body contains a small inner radiofrequency identification (RFID) tag. The tag retransmits a radiofrequency signal once it is excited by an appropriate radiofrequency signal from the Patency Scanner. Following ingestion, detection of a radiofrequency signal by the Patency Scanner means that the capsule is still retained in the GI tract. Once the patient ingests the 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. The capsule is designed to dissolve starting 30 hours following ingestion, during a period of approximately 12 hours.

### **Indications and Contraindications**

The most common indication for capsule endoscopy is the evaluation of obscure gastrointestinal bleeding (OGIB) after negative upper endoscopy (esophagogastroduodenoscopy [EGD]), push enteroscopy, colonoscopy, and small bowel radiography. Other proposed indications for capsule endoscopy include suspected Crohn's disease, diagnosing GI tumors or nonsteroidal anti-inflammatory drug (NSAID)-induced small bowel damage, abdominal pain, surveillance of polyposis syndromes, monitoring mucosal healing after various treatments (e.g., for Crohn's), assessing the extent of disease (e.g., Crohn's, celiac) and monitoring/surveillance of upper or lower GI damage (e.g., esophagitis, Barrett's, polyps) and most recently, as a replacement for colonoscopy. Some limitations to capsule endoscopy include: the device has no therapeutic capabilities; it cannot insufflate air to distend the bowel to enhance mucosal visualization; there is risk of impaction in a region of stricture; and it is difficult to discern the exact anatomic location of visualized lesions. Contraindications include: known or suspected obstruction or stricture; cardiac pacemakers; implanted defibrillators; implanted electromechanical devices; pregnancy; Zenker's diverticulum; intestinal pseudo-obstruction and motility disorders.

### **U.S. Food and Drug Administration (FDA)**

The FDA has classified Ingestible Telemetric Gastrointestinal Capsule Imaging System as class II devices; Product codes NEZ (System, Imaging, Gastrointestinal, Wireless, Capsule) and NSI (System, Imaging, Esophageal, Wireless, Capsule).

**Small Bowel:** In 2001, the PillCam<sup>®</sup> Small Bowel (SB) Capsule received clearance from the FDA for use as an adjunctive method of evaluating small bowel abnormalities in persons with unexplained or recurrent GI bleeding who have undergone conventional endoscopy and/or other diagnostic procedures that failed to locate the source of bleeding. It is intended "for visualization of the small bowel mucosa". It was originally approved as a tool in the detection of abnormalities of the small bowel in adults. In July 2003, the FDA approved the capsule endoscopy system as a first-line method for detecting small bowel abnormalities. It is contraindicated in persons with: a cardiac pacemaker or other implanted electromagnetic devices, an intestinal blockage; a significantly narrowed small bowel; an abnormal connection between the bowel and another organ, or in people with swallowing disorders. In October 2003, the FDA approved the system for use in pediatric patients ages 10–18. In September 2009, FDA approved use of PillCam SB capsules to include use in children from two years of age.

In June 2007, the FDA approved Olympus Capsule Endoscope System Endo Capsule. The FDA noted that when compared to the predicate devices (Given Imaging), Olympus Capsule Endoscope System is equivalent in intended use, method of operation, material, and design to the predicate device. The Olympus FDA-approved indications for use state to be used for visualization of the small intestine mucosa.

**Esophageal:** In October 2004, FDA granted 510(k) marketing clearance for the system for visualization of the esophageal mucosa. Since then, FDA has granted multiple additional clearances for device modifications, new accessories, and new or upgraded software. Use of the PillCam ESO capsule is contraindicated in patients with known or suspected GI obstruction, strictures, or fistulas; swallowing disorders; and cardiac pacemakers or other implanted devices.

**Colon:** In October 2006, Given Imaging received the CE Mark (i.e., approved by the Regulatory Authorities of the European Union) to market PillCam® COLON throughout the European Union. In 2008, the FDA sent Given Imaging a "not substantially equivalent" (NSE) letter regarding its 510(k) application to market PillCam® COLON in the US. In 2009, Given Imaging made various upgrades, releasing PillCam® COLON 2 which has also received the CE Mark.

**Other:** In May 2006, the FDA granted marketing clearance for the Given AGILE™ Patency System. 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. In September 2009, FDA approved use of the AGILE Patency System to include use in children from two years of age. In June 2006, the FDA granted marketing clearance for RAPID® Access RT (real-time), a handheld device that enables real-time viewing during a PillCam endoscopy procedure and RAPID Access, the software installed on the device. RAPID Access also allows physicians to remotely initialize a Data Recorder to administer the PillCam video capsules to patients at satellite sites. Data can then be sent to a central location for processing and interpretation.

### **Literature Review**

Evidence in published, peer-reviewed, scientific literature supports the use of capsule endoscopy in patients with OGIB, suspected Crohn's disease, suspected small bowel tumor and celiac disease, in which standard endoscopic and imaging evaluations are inconclusive and show no suspected obstruction or stricture. As long as contraindications are applied to patient selection, the small bowel capsule is considered safe. Small bowel capsule endoscopy can identify pathologies missed by standard endoscope; having a positive impact on clinical decision-making.

**Obscure Gastrointestinal Bleeding (OGIB):** Many studies have demonstrated that capsule endoscopy is safe and accurate in the evaluation of OGIB (Redondo-Cerezo, et al., 2007; Apostolopoulos, et al., 2007; Carey, et al., 2006; Apostolopoulos, et al., 2006; Tatar, et al., 2006; Lai, et al., 2006; Triester, et al., 2005; Neu, et al., 2005; Hartmann, et al., 2005; Carlo, et al., 2005; Maieron, et al., 2004). Few studies are proposing capsule endoscopy for first line testing; the majority of studies and the American Gastroenterological Association (AGA) (Raju, et al., 2007) support standard testing first.

**Suspected Crohn's Disease:** Studies evaluating the use of capsule endoscopy in suspected Crohn's disease (CD) have generally shown that capsule endoscopy detects early inflammatory lesions of the small bowel with a higher yield compared with alternative techniques (Park, et al., 2007; Fidder, et al., 2007; Girelli, et al., 2007; de Leusse, et al., 2007; Triester, et al., 2006; Maieron, et al., 2004; Sturniolo, et al., 2006; Qvigstad, et al., 2006; Hara, et al., 2006; Gay, et al., 2006; Dubcenco, et al., 2005; Eliakim, et al., 2004). Few studies are proposing capsule endoscopy for first line testing; the majority of studies, the American College of Gastroenterology (Lichtenstein, et al., 2009) and the American Society for Gastrointestinal Endoscopy (ASGE) (Leighton, et al., 2006) all support standard testing first.

Recurrence of symptoms has been predicted by the early endoscopic appearance of lesions following ileocolonic resection for CD. There is insufficient evidence in the published peer-reviewed scientific literature to support the use of capsule endoscopy for the detection of postoperative recurrence of small bowel CD. The gold standard for assessing CD recurrence after ileo-colonic resection remains conventional ileocolonoscopy (Mergener, et. al., 2007; Pons Beltrán, et al., 2007; Biancone, et al., 2007).

**Suspected Small Bowel Tumor:** Small bowel tumors of all types have been a significant finding in most studies of capsule endoscopy (Mergener, et. al., 2007; Bailey, et. al., 2006; Urbain, et. al., 2006; Cobrin, et. al., 2006; Wong, et. al., 2006; van Tuyl, et. al., 2006). The studies support the use of capsule endoscopy in diagnoses such as hamartoma, cystic lymphangioma, polyps in familial adenomatous polyposis (FAP) and Peutz Jegher's syndromes, carcinoid or neuroendocrine tumor, adenocarcinoma, and gastrointestinal stromal tumor (GIST).

**Celiac Disease:** Celiac disease is recognized as being under-diagnosed, as many affected patients do not present with classical symptoms of malabsorption. Small retrospective and prospective studies support the use of capsule endoscopy in detecting the mucosal changes consistent with celiac disease (Rondonotti, et al., 2007; Hopper, et al., 2007; Culliford, et al., 2005; Petroniene, et al., 2005).

**Children:** Fritscher-Ravens et al. (2009) prospectively studied 83 children with OGIB, suspected Crohn's disease, abdominal pain of unknown etiology, protein-losing enteropathy and malabsorptive disorders were enrolled into the study if a standard barium meal and follow-through to the terminal ileum, or abdominal magnetic resonance imaging and upper GI endoscopy and colonoscopy to the cecum with biopsies carried out prior to the study were negative or excluded small intestinal obstruction. Initially, all were offered "swallowing" for capsule introduction. Group 1 consisted of 20 (24%) children aged 4.0–7.9 years (mean, 6.9 years) children who were willing (or could be persuaded) to swallow the capsule; while Group 2 consisted of 63 (76%) children aged 1.5–7.9 years (mean, 5.25 years) patients who were unable to swallow the capsule, and required endoscopic placement of the capsule into the duodenum. Mucosal trauma occurred in four patients. No further complication was noted and no capsule retention occurred, with the smallest child weighing 22 pounds. Abnormalities were found in 55% of these children. The AGILE Patency System was not utilized.

**Esophageal Pathology:** An esophageal capsule endoscopy procedure appears to be safe, providing contraindications are applied to patient selection. However, evidence in the peer-reviewed scientific literature demonstrates that the accuracy of the esophageal capsule is inferior to that of upper endoscopy in diagnosing esophageal pathologies. Evidence indicates sensitivity rates fall within the 60 – 80 percentile range. Overall accuracy rates were not provided in the studies. The majority of the studies are prospective, observational cohort studies comparing capsule endoscopy to standard upper endoscopy (EGD) which was utilized as the gold standard. In the majority of the studies, the procedures were performed on the same day. Limitations of these studies include small sample size and study populations with a high pretest probability of having pathology. This may give an overestimation of capsule endoscopy performance in detecting esophageal pathology. Additionally, the diagnostic utility esophageal capsule endoscopy can provide compared with upper endoscopy with biopsy, and in what specific population, remains unclear.

Sharma et al. (2008) evaluated 94 adults; 41 were screened for Barrett's esophagus (gastroesophageal reflux disease [GERD] symptoms) and 53 for surveillance of Barrett's esophagus. The gold standard in this study was the findings noted at the time of upper endoscopy (presence/absence of suspected Barrett's esophagus and severity of erosive esophagitis). Results showed the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of capsule endoscopy for diagnosing Barrett's esophagus in patients undergoing EGD for GERD symptoms, were 67%, 87%, 60%, and 90%, respectively. The sensitivity, specificity, PPV, and NPV of capsule endoscopy in patients undergoing surveillance for Barrett's esophagus were 79%, 78%, 94%, and 44%, respectively. With regards to erosive esophagitis diagnosed at upper endoscopy, capsule endoscopy resulted in a sensitivity, specificity, PPV, and NPV of 50%, 90%, 56% and 88%, respectively.

Heresbach et al. (2010) retrospectively compared the accuracy of upper endoscopy (esophageal gastroduodenoscopy [EGE]) with capsule endoscopy (ECE) in 63 patients at risk of esophageal squamous cell cancer (SCC) secondary to a history of head and neck neoplasia. The gold standard was combined result of without and with iodine staining EGE (39 neoplastic lesions comprising five low grade dysplasia, eight high grade dysplasia and 26 SCC). The sensitivity of ECE for the diagnosis of dysplasia was 31%; for neoplastic lesions overall it was 46%. Specificity could not be calculated. Accuracy remains unknown.

De Franchis et al. (2008) studied 288 individuals with or at risk for esophageal varices (195 for screening, 93 for surveillance). Specifically, patients had either: symptoms of portal hypertension, without previous diagnosis of esophageal varices, with clinical indication for screening endoscopy for the detection of varices; or, prior endoscopic diagnosis of esophageal varices and indication for surveillance endoscopy. With EGD as the gold standard, the esophageal capsule had a sensitivity of 84% and a specificity of 88%, a PPV of 92%, and a NPV of 77% for the detection of varices. The esophageal capsule had a sensitivity of 74% and a specificity of 83% for the detection of portal hypertensive gastropathy (PHG).

Galmiche et al. (2008) evaluated 77 adults with reflux symptoms who were referred for conventional endoscopy. The diagnostic yields of capsule endoscopy to detect esophagitis and endoscopically suspected esophageal metaplasia (ESEM) were as follows: sensitivity 79% and 60%, specificity 94% and 100%, PPV 83% and 100%, NPV 92% and 95%, respectively. Frenette et al. (2008) prospectively compared capsule endoscopy to EGD

(most performed on the same day) in 50 adults with cirrhosis. Patients were scheduled for EGD for variceal screening or surveillance and to determine the need for treatment or prophylaxis of esophageal varices. Two patients (4%) had gastric varices. It was not possible to gauge the location of the varices based on the capsule photographs. In determining the presence or absence of portal hypertensive gastropathy (PHG) using EGD as the gold standard, sensitivity was 96%, specificity was 17%, and accuracy was 57%. In determining need for prophylaxis using EGD as the gold standard, sensitivity of capsule endoscopy was 63%, specificity was 82%, and accuracy was 74%. Grainek et al. (2008) prospectively compared capsule endoscopy to EGD (performed on the same day) in 28 adults with known or suspected esophageal disease. The sensitivity, specificity, PPV and NPV of capsule endoscopy compared with the gold standard of EGD, for the detection of suspected Barrett's esophagus and erosion esophagitis were 100% and 80%, 74% and 87%, 64% and 57%, 100% and 95%, respectively. This study did not address esophageal varices. Delvaux et al. (2008) prospectively compared capsule endoscopy to EGD (performed within 48 hours of each other) in 98 individuals with known or suspected esophageal disease. EGD was normal in 34 patients and showed esophageal findings in 62 (esophagitis 28, hiatus hernia 21, varices 21, Barrett's esophagus 11, others 7). Compared with EGD, the PPV of capsule endoscopy was 80.0 % and the NPV was 61.1 %.

Lin et al. (2007) prospectively evaluated the accuracy of esophageal capsule endoscopy compared with EGD for the identification of biopsy-proven Barrett's esophagus. Included were 90 patients scheduled for upcoming EGD for the indications of chronic gastroesophageal reflux symptoms (n=66, screening group) or Barrett's esophagus (n=24, surveillance group). Esophageal capsule endoscopy identified 14 of 21 patients with true Barrett's esophagus (sensitivity, 67%) and 58 of 69 patients without Barrett's esophagus (specificity, 84%). The PPV was 22%, and the NPV was 98% for Barrett's esophagus (calculated for screening patients only).

Eisen et al. (2006) performed capsule endoscopy on 32 patients with cirrhosis who had prior endoscopic confirmation of esophageal varices and were undergoing clinically indicated EGD for screening or surveillance for esophageal varices. The gold standard, EGD, was performed the same day following capsule endoscopy. For the detection of esophageal varices, capsule endoscopy had a sensitivity of 100%, and a specificity of 89% in comparison with EGD. For the detection of portal hypertensive gastropathy, capsule endoscopy had a sensitivity of 100%, a specificity of 77%, a positive likelihood ratio of 4.3, and a negative likelihood ratio of 0.0, in comparison with EGD.

A prospective multi-center study comparing the diagnostic accuracy of capsule endoscopy to EGD was conducted in 106 patients with chronic gastroesophageal reflux diseases (93 GERD; 13 Barrett) (Eliakim, et al., 2005). The gold standard in this study was defined as either the findings noted at the time of the EGD or the decision of the adjudication committee following review of the endoscopic findings, photographs, and capsule endoscopy results. In patients diagnosed with Barrett's esophagus based on the gold standard, the capsule endoscopy demonstrated a sensitivity of 97%, specificity of 99%, PPV of 99%, and an NPV of 97%. In patients diagnosed with esophagitis based on the gold standard, the capsule endoscopy demonstrated a sensitivity of 89% in detecting esophagitis and an NPV of 94% for ruling out esophagitis. Specificity and PPV were estimated as 99% and 97%, respectively.

California Technology Assessment Forum (CTAF) evaluated PillCam capsule for the evaluation of esophageal disease (October, 2008) and concluded that most of the research to date has found that capsule endoscopy is a relatively safe technology and is significantly preferred by patients over EGD. EGD usually requires sedation and is rated as less pleasant and more inconvenient than capsule endoscopy. Some patients simply refuse to undergo EGD. However, since EGD is generally a safe and widely available procedure, capsule endoscopy cannot be recommended as an alternative until its performance is substantially equivalent to EGD.

**Colon Pathology:** There is insufficient evidence in the peer-reviewed scientific literature to support the safety or accuracy of colon capsule endoscopy. Additional larger trials are needed comparing capsule colonoscopy to conventional colonoscopy, barium radiography, and virtual (computed tomography or magnetic resonance) colonography.

Rokkas et al. (2010) reported results in a meta-analysis from four studies that contained data concerning polyps found (of any size). The pooled data (random effects analysis) showed colon capsule endoscopy sensitivity of 73% and specificity of 89%. The total number of patients included in the four studies is not reported.

Gay et al. (2010) prospectively compared colonoscopy and capsule endoscopy in a cohort of 128 patients in whom colonoscopy was scheduled. Colonoscopy was the gold standard and was performed the day after capsule endoscopy. The primary outcome of the study was the decision made by the capsule endoscopy reader to indicate a colonoscopy, compared with the final result of the colonoscopy. Secondary outcomes were the agreement between capsule endoscopy and colonoscopy for making a diagnosis of colorectal disease, as well as detection rate, number, and size of polyps. Two patients were excluded: one did not swallow the capsule and the other was diagnosed with a jejunal stenosis by the capsule. Results showed the sensitivity of capsule endoscopy to detect colonic findings was 87.5% and its specificity was 75.8 %. The sensitivity of capsule endoscopy for the detection of polyps of any size was 65.9 %. The authors reported that the PPV and NPV of capsule endoscopy to indicate a colonoscopy were 78.9% and 85.4 %, respectively. It should be noted that the accuracy of the capsule endoscopy to select patients who deserve a colonoscopy was assessed by calculating the PPV and NPV of the capsule endoscopy, according to a range of prevalence of colonic diseases obtained from data in literature and in the study.

Van Gossum et al. (2009) conducted a prospective, observational cohort study including 320 patients scheduled to undergo a colonoscopy because they were either known to have colonic disease or suspected of having colonic disease. There were 112 patients (35.0%) with known colonic disease (57 were  $\geq 50$  years of age) and 208 (65.0%) with suspected colonic disease (201 were  $\geq 50$  years of age). The purpose of the study was to determine the accuracy of capsule endoscopy in detecting colonic polyps, advanced adenomas, and carcinomas. Colonoscopy was the standard against which capsule endoscopy was compared, and it was performed after capsule endoscopy (after capsule excretion or at least ten hours after capsule ingestion, whichever came first), on either the same day as ingestion or the next morning. The sensitivity and specificity of capsule endoscopy for the detection of polyps was 72% and 78%. The sensitivity and specificity of capsule endoscopy for the detection of advanced adenoma was 85% and 50%. The sensitivity and specificity of capsule endoscopy for the detection of colorectal cancer was 74% and 74%. Overall accuracy was not calculated.

Eliakim et al. (2009) also conducted a prospective, observational cohort study to test the sensitivity of an updated (second-generation) capsule. Colonoscopy was performed after capsule endoscopy. A total of 98 patients scheduled to undergo a colonoscopy because they have known or suspected colonic disease, were included. The capsule sensitivity for the detection of patients with polyps'  $\geq 6$  mm was 89 % and for those with polyps'  $\geq 10$  mm it was 88 %, with specificities of 76 % and 89 %, respectively.

Eliakim et al. (2006) evaluated 84 patients referred for colonoscopy for colorectal cancer screening (43%), postpolypectomy surveillance (26 %), rectal bleeding (14%), iron deficiency anemia (8%) and "other" (9%). PillCam COLON endoscopy and conventional colonoscopy were performed the same day. Based upon the principal investigator's reading and compared with conventional colonoscopy in the detection of any polyp, the sensitivity, specificity, PPV and NPV of capsule endoscopy were 56%, 69%, 57%, and 67%, respectively. For the detection of significant polyps, the sensitivity, specificity, and positive and negative predictive values of capsule endoscopy were 50%, 83%, 40%, and 88%, respectively. For the detection of diverticulosis, the sensitivity, specificity, and positive and negative predictive values of capsule endoscopy were 78%, 76%, 47%, and 93%, respectively.

Schoofs et al. (2006) prospectively evaluated 36 patients referred for screening colonoscopy or there if was suspicion of polyps or colorectal cancer. Compared with conventional colonoscopy in the detection of any polyp, the sensitivity, specificity, PPV and NPV of CE were 76%, 64%, 83%, and 54%, respectively. For the detection of three polyps or more, the sensitivity, specificity, PPV and NPV of capsule endoscopy were 63%, 68%, 36%, and 86%, respectively. The authors noted that results are encouraging, and that additional larger trials are needed. The future role of capsule colonoscopy in colon cancer screening and surveillance remains to be determined.

**Patency Capsule:** Some small retrospective and prospective studies have evaluated the patency capsule. These studies do not demonstrate that the patency capsule can safely be used in lieu of conventional evaluations to rule out stricture or obstruction prior to capsule endoscopy; therefore, the medical necessity of the patency capsule is unclear (Herrerias, et al., 2008; Spada, et al., 2007; Signorelli, et al., 2006 ; Delvaux, et al., 2005)

## **Professional Societies/Organizations**

**American Gastroenterological Association (AGA):** The AGA medical position statement on obscure gastrointestinal bleeding (Raju, et al., 2007) supports the use of capsule endoscopy once all the findings on standard examinations (EGD and colonoscopy) are negative.

**American Society for Gastrointestinal Endoscopy (ASGE):** The ASGE Report on Emerging Technology “Capsule Endoscopy of the Colon” (October, 2008) states that colon capsule endoscopy is an emerging form of colon imaging that may be useful to improve compliance with colorectal cancer screening, but published experience with this device is extremely limited. Because the technology is currently only diagnostic, any positive findings require conventional colonoscopy for tissue sampling or polypectomy. Significant research on this topic is required, and many fundamental questions for this technology remain unaddressed.”

The ASGE published a “Technology Status Evaluation Report: wireless capsule endoscopy” in April 2006 (Mishkin, et al., 2006). Mishkin stated “wireless capsule endoscopy is a relatively new technology for assessment of the digestive tract. Small intestinal applications are the most extensively studied, and it has quickly become a first-line test for visualizing the mucosa of the small intestine. Further research and experience are still necessary to better define its role. The esophageal capsule uses similar technology but clinical data on its use are limited.”

Endoscopy in the Diagnosis and Treatment of Inflammatory Bowel Disease (Leighton, et al., 2006) notes that capsule endoscopy has been shown to be more sensitive than radiologic and endoscopic procedures for detecting small-bowel lesions (based upon observational studies).

**American College of Gastroenterology (ACG):** The ACG practice parameter for the management of Crohn's disease in adults (Lichtenstein, et al., 2009) supports the use of capsule endoscopy.

The ACG updated guidelines for the diagnosis, surveillance and therapy of Barrett's esophagus (Wang, et al., 2008) discusses capsule endoscopy under Screening. The ACG states that esophageal capsule endoscopy is a new technique that has the potential to provide a noninvasive diagnosis of suspected Barrett's esophagus, i.e. a columnar lined esophagus. The ACG noted “although intriguing, this technique cannot be recommended in the screening setting at this time.”

The ACG Practice Parameter Prevention and Management of Gastroesophageal Varices and Variceal Hemorrhage in Cirrhosis (Garcia-Tsao, et al., 2007) stated “capsule endoscopy may play a future role in screening for esophageal varices if additional larger studies support its use.”

ACG Practice Guidelines for the Management of Dyspepsia (Talley, et al., 2005) state that regarding additional diagnoses and testing in refractory cases, capsule endoscopy “does not yet have an established role here.”

## **Summary**

Studies in the published, peer-reviewed scientific literature support the safety and clinical utility of small bowel capsule endoscopy as an adjunctive diagnostic tool for patients with obscure gastrointestinal bleeding (OGIB), suspected Crohn's disease, and suspected small bowel tumor and celiac disease. Evidence indicates that the accuracy of esophageal capsule endoscopy is inferior to that of upper endoscopy in diagnosing suspected esophageal pathologies. Additionally, the role of capsule endoscopy in diagnosing suspected esophageal pathology has yet to be determined. The safety and diagnostic utility of capsule endoscopy for any other indication (e.g., any screening or surveillance, colon pathology) has not yet been established. Also, there is limited data on patient safety when using the patency capsule versus conventional evaluations to rule out stricture or obstruction prior to capsule endoscopy; therefore, conventional evaluations remain the gold standard for ruling out any known or suspected gastrointestinal obstruction, strictures, and fistulas prior to capsule endoscopy.

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## **Coding/Billing Information**

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

### **Capsule Endoscopy (Pillcam, Endo Capsule), Esophagus through Ileum**

**Covered when medically necessary:**

<b>CPT®*</b> <b>Codes</b>	<b>Description</b>
91110	Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus through ileum, with physician interpretation and report.

<b>ICD-9-CM</b> <b>Diagnosis</b> <b>Codes</b>	<b>Description</b>
152.0–152.9	Malignant neoplasm of small intestine, including duodenum
211.2	Benign neoplasm of duodenum, jejunum, ileum
235.2	Neoplasm of uncertain behavior of stomach, intestines, and rectum
555.0–555.9	Regional enteritis (Crohn's disease)
578.0–578.9	Gastrointestinal hemorrhage
579.0	Celiac disease

**Experimental/Investigational/Unproven/Not Covered:**

<b>ICD-9-CM</b> <b>Diagnosis</b> <b>Codes</b>	<b>Description</b>
153.0 – 153.9	Malignant neoplasm of colon
211.3	Benign neoplasm of other parts of digestive system; colon
538.	Gastrointestinal mucositis (ulcerative)
556.0 – 556.9	Ulcerative colitis
789.0	Abdominal pain
E946.0	Local anti-infectives and anti-inflammatory drugs causing adverse effect in therapeutic use
	All other codes

**Capsule Endoscopy (Pillcam), Esophagus**

**Experimental/Investigational/Unproven/Not Covered:**

<b>CPT* Codes</b>	<b>Description</b>
91111	Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus, with physician interpretation and report

<b>ICD-9-CM</b> <b>Diagnosis</b> <b>Codes</b>	<b>Description</b>
456.0-456.2	Esophageal varices
530.1	Esophagitis
530.85	Barrett's esophagus
	All other codes

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

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## Policy History

<b>Pre-Merger Organizations</b>	<b>Last Review Date</b>	<b>Policy Number</b>	<b>Title</b>
CIGNA HealthCare	2/15/2008	0008	Capsule Endoscopy
Great-West Healthcare	2/02/2006	04.201.02	Wireless Capsule Endoscopy (WCE)

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