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Coverage Policy

Cigna covers small bowel capsule endoscopy (i.e., Pillcam® SB, Endo Capsule) (CPT code 91110) as medically necessary in adults and children two years of age or older, when standard endoscopic and imaging evaluations (i.e., upper and lower endoscopy) 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 covers capsule endoscopy for surveillance of the small bowel in an individual with an inherited polyposis syndrome (e.g., familial adenomatous polyposis, Peutz-Jeghers syndrome) and no contraindication (e.g., known or suspected obstruction or stricture).

Cigna does not cover small bowel capsule endoscopy for any other indication because it is considered experimental, investigational or unproven.

Cigna does not cover esophageal capsule endoscopy (e.g., Pillcam® ESO) (CPT code 91111) for any indication because it is considered experimental, investigational or unproven.

Cigna does not cover colon capsule endoscopy (e.g., Pillcam® COLON) (CPT code 0355T) for any indication because it is considered experimental, investigational or unproven.
Cigna does not cover the patency capsule (e.g., Given AGILE™ Patency System) (CPT code 91299) for any indication because it is considered experimental, investigational or unproven.

Note: For Wireless Gastrointestinal Motility Monitoring System (SmartPill®) (CPT Code 91112), see Omnibus Codes Coverage Policy.

General Background

Capsule endoscopy (CE), also known as wireless capsule endoscopy (WCE) or video capsule endoscopy (VCE) 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. Capsule endoscopy is generally proposed after negative upper and lower endoscopy (esophagogastroduodenoscopy [EGD], push enteroscopy, colonoscopy, and small bowel radiography).

Indications

Commonly proposed indications for the small bowel capsule include: obscure gastrointestinal bleeding (OGIB) with or without iron deficiency anemia; suspected Crohn’s disease; suspected small bowel tumor; celiac disease; and small bowel surveillance in individuals with inherited polyposis syndromes. Additional proposed indications include surveillance in individuals with Lynch syndrome, identifying nonsteroidal anti-inflammatory drug (NSAID)-induced small bowel damage, and abdominal pain of unclear etiology.

Proposed indications for the esophageal capsule include use in esophageal varices, gastroesophageal reflux (GERD), Barrett’s Esophagus, esophageal cancers and screening or surveillance of esophageal varices in cirrhotic persons.

Originally the colon capsule was proposed for the detection of colon polyps in patients following an incomplete colonoscopy with adequate preparation, when a complete evaluation of the colon was not technically possible. A newly proposed indication includes the detection of colon polyps in patients with evidence of bleeding of lower GI origin. Eligible patients are those with major risks for colonoscopy or moderate sedation, but who can tolerate colonoscopy and moderate sedation in the event a clinically significant colon abnormality is identified on CE.

Limitations

Some limitations to CE include: the device has no therapeutic capabilities; it does not permit tissue sampling or therapeutic intervention; 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. The capsule may not reach the cecum within recording time. An incomplete exam is more likely in patients who have undergone small bowel surgery, been hospitalized, had moderate or poor bowel cleaning, or have a gastric transit time of longer than 45 minutes.

Contraindications

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).

The FDA first approved a small bowel capsule in August 2001. Several versions have been approved since then. The Pillcam® SB3 (Given® Imaging, Ltd., Yqoneam, Israel) and the Olympus Capsule Endoscope System with Endo Capsule (Olympus Medical Systems Corporation, Tokyo, Japan) include the capsule that is swallowed, the data recorder (worn around patient’s waist) and a computer workstation (with software and
viewer/monitor). The Given AGILE™ Patency System is an optional accessory to the PillCam video capsule and is intended to validate patency of the GI tract. The MiroCam® Capsule Endoscope System (IntroMedic Co., Ltd., Seoul, Korea) was FDA-approved in 2012 and uses a novel mode of transmission called electric field propagation, which uses the human body as a conductive medium to transmit images.

**Small Bowel:** The PillCam SB capsule is intended for visualization of the small bowel mucosa. Indications for Use include:

- It may be used as a tool in the detection of abnormalities of the small bowel and is intended for use in adults and children from two years of age.
- It may be used in the visualization and monitoring of lesions that may indicate Crohn's disease not detected by upper and lower endoscopy.
- It may be used in the visualization and monitoring of lesions that may be a source of obscure bleeding (either overt or occult) not detected by upper and lower endoscopy.
- It may be used in the visualization and monitoring of lesions that may be potential causes of iron deficiency anemia not detected by upper and lower endoscopy.

The Olympus Small Intestinal Capsule Endoscope system and the MiroCam Capsule Endoscope System are intended for visualization of the small intestine mucosa.

**Esophageal:** The PillCam ESO capsule is intended for the visualization of esophageal mucosa in adults and children from 18 years of age.

**Colon:** In February 2014 the FDA determined that the PillCam® COLON 2 Capsule Endoscopy System can be classified as a class II device with the establishment of special controls for class II (K123666), a de novo device with low to moderate risk that has no predicate on the market. The FDA approved PillCam COLON 2 as a minimally invasive follow-up for patients receiving an incomplete colonoscopy. It may be used for detection of colon polyps in patients for whom a complete evaluation of the colon was not technically possible. This device is indicated for visualization of the colon and the detection of colon polyps in patients after an incomplete optical colonoscopy with adequate preparation, and a complete evaluation of the colon was not technically possible. In 2016, the FDA cleared PillCam COLON 2 capsule for the evaluation of polyps in patients with major risks for colonoscopy or moderate sedation but who could tolerate colonoscopy and moderate sedation in the event a clinically significant colon abnormality was identified on CE.

**Patency:** The AGILE™ Patency System is intended to verify adequate patency of the gastrointestinal tract prior to administration of the PillCam video capsule in patients from two years of age with known or suspected strictures.

**Small Bowel Literature Review:** The indications for CE of the small bowel are evolving. Numerous studies in the peer-reviewed, scientific literature supports the use of CE when standard endoscopic and imaging evaluations (i.e., upper and lower endoscopy) are inconclusive and show no suspected obstruction or stricture in patients with: obscure gastrointestinal bleeding (OGIB) with or without iron deficiency anemia; suspected Crohn’s disease; suspected small bowel tumor; and celiac disease. As long as contraindications are applied to patient selection, the small bowel capsule is considered safe. Small bowel CE can identify pathologies missed by standard endoscope; having a positive impact on clinical decision-making. Few studies are proposing CE for first line testing; the majority of studies and professional societies support standard testing first.

CE has been proposed for small bowel surveillance in individuals with inherited polyposis syndromes including but not limited to familial adenomatous polyposis (FAP) and Peutz-Jeghers syndrome (PJS). Small intestinal polyps are the most problematic aspect of FAP and PJS. Small bowel neoplasms occur in greater than 90% of individuals with FAP and 75% in PJS (Burke, et al., 2005). Studies in the scientific literature are small (due to disease prevalence) but primarily prospective, with some blinded or controlled. Studies support the use of CE for small bowel surveillance in individuals with FAP and PJS (Caspari, et a., 2004; Mata, et al., 2005; Burke, et al., 2005; Schulmann, et al., 2005; Wong, et al., 2006; Brown, et al., 2006; Katsinelos, et al., 2009; Gupta, et al., 2010; Tescher, et al., 2010; Urquhart, et al., 2014).
Screening for gastric and proximal small duodenal polyps in FAP should be performed by upper endoscopy (using a forward viewing EGD scope and a side viewing ERCP scope) starting at age 25 to 30 years. In FAP, it is been demonstrated that CE was effective in detecting additional polyps in the jejunum and ileum in 24% to 57% of patients in two prospective studies totaling 54 patients. Other studies show the rate of jejunal and ileal polyps was estimated to be between 30-75%. Please note that proximal duodenal polyps may be missed by CE and therefore an EGD should be done concurrently.

Studies including individuals with PJS have noted that CE detected statistically significant more small polyps (6–10 mm) than magnetic resonance enterography (MRE). Studies show conflicting CE diagnostic yield in larger polyps. In PJS there is concern for small bowel polyps in children beginning 8 years of age. Screening in general begins at age 8 followed by every 2 to 3 years thereafter. In PJS the polyps may give rise to intussusception, bleeding, obstruction and small bowel malignancy.

There is controversy regarding screening for small bowel cancers by CE in Lynch syndrome (LS) (also known as hereditary non-polyposis colorectal cancer [HNPCC]). The risk of developing this cancer in carriers of an MLH1 or MSH2 mutation is approximately 5%. The tumors in LS families are mainly located in the proximal small bowel (43%) and the jejunum (33%); 7% are located in the ileum. Studies supporting the use of CE for small bowel surveillance in individuals with Lynch syndrome are lacking (Saurin, et al., 2010; Haanstra, et al., 2015).

Professional Societies/Organizations: The American Society for Gastrointestinal Endoscopy (ASGE) guideline on the role of endoscopy in the management of suspected small bowel bleeding (2016) noted that video capsule endoscopy (VCE) enables visualization of the entire small intestine in the majority of patients undergoing CE but lacks the potential for therapeutic intervention. Given its high diagnostic yield, VCE is considered the test of choice in the evaluation of small-bowel bleeding after unrevealing standard endoscopic examinations. The diagnostic yield of VCE is higher if performed within two weeks (greatest yield in 48 to 72 hours) of an overt bleeding episode.

The ASGE guideline on the role of endoscopy in inflammatory bowel disease (2015) recommends
- CE to evaluate the small intestine in patients with suspected Crohn’s disease (CD) who have no obstructive symptoms and negative ileocolonoscopy results
- a patency capsule, small-bowel follow-through, CT enterography, or magnetic resonance enterography should be performed before CE in patients with known small-bowel CD involvement.
- CE in patients with known CD and unexplained symptoms only when abnormalities detected with CE will alter management

The American College of Gastroenterology (ACG) Clinical Guideline Diagnosis and Management of Small Bowel Bleeding (Gerson, et al., 2015) recommends the following in regards to use of VCE:
- VCE should be considered as a first-line procedure for small bowel evaluation after upper and lower GI sources have been excluded, including second-look endoscopy when indicated (strong recommendation, moderate level of evidence).
- If a source of bleeding is found by VCE and/or deep enteroscopy in the small intestine that is associated with significant ongoing anemia or active bleeding, then the patient should be managed with endoscopic therapy (strong recommendation, low level of evidence). If after appropriate small bowel investigation no source of bleeding is found, the patient should be managed conservatively with oral iron or by intravenous infusion as is dictated by the severity and persistence of the associated iron-deficiency anemia. In this context, a small vascular lesion found on CE does not always need treatment (strong recommendation, very low level of evidence). If bleeding persists in either of the above situations with worsening anemia, a further diagnostic workup should include a repeated upper and lower endoscopy, VCE, deep enteroscopy, CT or MRI enterography as is appropriate for the clinical situation and availability of investigative devices (strong recommendation, low level of evidence).

The ACG clinical guideline Genetic Testing and Management of Hereditary Gastrointestinal Cancer Syndromes (Syngal, et al., 2015) does not provide a formal recommendation regarding capsule endoscopy.

ASGE 2013 Technology Status Evaluation Report states CE can be feasible and safe in patients with known or suspected polyposis syndromes such as familial adenomatous polyposis or Peutz-Jeghers syndrome, even after
prior intestinal surgery. The authors concluded studies suggest that CE may have a role in the evaluation of small bowel tumors, but a negative examination should not preclude further work-up if a lesion is highly suspected.

The ASGE Standards of Practice Committee published an Appropriate Use of GI Endoscopy Guideline in 2012 that states CE is generally indicated for:

- evaluation of obscure GI bleeding in a patient in whom upper and lower endoscopy have not identified a cause.
- evaluation of iron deficiency anemia in a patient in whom upper and lower endoscopy have not identified a cause.
- evaluation of the small bowel in patients with known or suspected Crohn’s disease.
- screening and surveillance of the small bowel in patients with inherited polyposis syndromes.
- suspected small intestinal tumors.
- suspected or refractory malabsorptive syndromes (eg, celiac disease).
- visualization of the esophagus

The ACG guideline for Diagnosis and Management of Celiac Disease (Rubio-Tapia, et al., 2013) notes the following recommendations:

- CE should not be used for initial diagnosis except for patients with positive-celiac specific serology who are unwilling or unable to undergo upper endoscopy with biopsy. (Strong recommendation, moderate level of evidence)
- CE should be considered for the evaluation of small-bowel mucosa in patients with complicated celiac disease. (Strong recommendation, moderate level of evidence).

The ACG practice parameter for the management of Crohn’s disease in adults (Lichtenstein, et al., 2009) supports the use of CE.

Esophageal Pathology

Literature Review: An esophageal capsule endoscopy (ECE) procedure appears to be safe, it 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. The majority of the studies are prospective, observational cohort studies comparing ECE to standard upper endoscopy (EGD) which is considered the gold standard. Most studies evaluated the use of ECE for:

1) screening and surveillance of esophageal varices in cirrhosis; or
2) detecting Barrett's esophagus in patients with gastroesophageal reflux disease (GERD).

Study limitations include small sample size and study populations with a high pretest probability of having pathology. This may give an overestimation of ECE performance in detecting esophageal pathology. Future indications may include special cases such as screening for esophageal varices in cirrhotic patients with significantly compromised liver function where a standard upper endoscopy with sedation or anesthesia is contraindicated or unable to be performed. However, data suggests that up to 15% of esophageal varices are left undetected with CE. Additionally, therapeutic interventions are unable to be conducted with ECE.

McCarty et al. (2016) conducted a meta-analysis including 17 studies from 2005 to 2015 (n=1328) to evaluate the efficacy of ECE for screening and diagnosis of esophageal varices among patients with portal hypertension. The diagnostic accuracy of ECE in the diagnosis of esophageal varices was 90%. The diagnostic pooled sensitivity and specificity were 83% and 85%, respectively. The authors stated that although EGD remains the gold standard, and should continue to be standard of care for the diagnosis and management of patients with known varices, the study demonstrated that ECE is an effective alternative modality for the diagnosis and grading of esophageal varices and may have a role in cases of refusal or contraindication to EGD. They noted the role for ECE remains limited as this modality lacks any potential therapeutic intervention.

In a Cochrane systematic review, Colli et al. (2014) evaluated the diagnostic accuracy of ECE for the diagnosis of esophageal varices in children or adults with chronic liver disease or portal vein thrombosis, irrespective of the etiology. The review included 15 studies (n=936) that assessed the accuracy of ECE for the diagnosis of esophageal varices of any size in people with cirrhosis. The pooled estimate of sensitivity was 84.8% and of specificity 84.3%. The authors stated that ECE, even if more acceptable to participants, cannot replace EGD for
the detection of esophageal varices as about 15% are left undetected and 15% are not confirmed by endoscopy. The accuracy in detecting large varices or red marks on varices was lower than endoscopy. No data assessing ECE in children and in people with portal thrombosis was found. The authors concluded that ECE is not sufficiently accurate to replace EGD for the detection of esophageal varices in cirrhotic participants.

Lu et al. (2009) conducted a meta-analysis of prospective studies to evaluate CE for detecting esophageal varices using conventional EGD as the standard. The pooled sensitivity and specificity of CE were 85.8% and 80.5%, respectively. In subgroup analysis, the pooled sensitivity and specificity were 82.7% and 54.8% in screened patients, and 87.3% and 84.7% in the screened patients under surveillance, respectively. The authors concluded that CE appears to have acceptable sensitivity and specificity in detecting esophageal varices; however, it seems inaccurate in screening patients based on the present data. There was insufficient data to determine the accurate diagnostic value of CE in patients under surveillance alone.

Bhardwaj et al. (2009) conducted a meta-analysis evaluating the diagnostic accuracy of esophageal CE for detecting Barrett’s esophagus (BE) in patients with gastroesophageal reflux disease (GERD). Nine blinded prospective and retrospective studies (n=618) met the inclusion criteria. The pooled sensitivity and specificity of ECE for the diagnosis of BE using EGD as the reference standard was 78% and 90%. Using histologically confirmed intestinal metaplasia (IM) as the reference standard, pooled sensitivity and specificity was 78% and 73%, respectively. The authors concluded that EGD remains the modality of choice for evaluation of suspected BE.

In a multicenter prospective trial, de Franchis et al. (2008) compared CE and EGD in 288 adults with signs/symptoms of portal hypertension, without previous diagnosis of esophageal varices, with clinical indication for screening endoscopy for the detection of varices, or with prior endoscopic diagnosis of esophageal varices and indication for surveillance endoscopy. Endoscopy was for screening in 195 patients and for surveillance of known esophageal varices in 93. Overall agreement for detecting esophageal varices between EGD and ECE was 85.8%. ECE had a sensitivity, specificity, positive predictive value, and negative predictive value of 84%, 88%, 92%, and 77%, respectively. The authors concluded that EGD be used to screen for large esophageal varices in patients with cirrhosis. They noted that ECE may be indicated for selected patients who are unwilling or unable to undergo upper gastrointestinal endoscopy.

**Professional Societies/Organizations:** The American College of Gastroenterology (ACG) updated guidelines for the Diagnosis, Surveillance and Therapy of Barrett’s esophagus (Shaheen, et al., 2016) discusses ECE under Screening. The ACG states that ECE is a well-tolerated, patient-preferred, and noninvasive technique that allows visualization of the distal esophagus. However, because of inadequate accuracy, it is currently not recommended for Barrett’s esophagus screening.

The ASGE guideline on the role of endoscopy in Barrett's esophagus and other premalignant conditions of the esophagus (2012) does not address the use of ECE other than to reference the meta-analysis conducted by Bhardwaj et al. (2009).

The American Gastroenterological Association (AGA) medical position statement on the management of Barrett's esophagus (2011) does not address the use of ECE. The AGA medical position statement on the management of gastroesophageal reflux disease (Kahrilas, et al., 2008) also does not address the use of ECE.

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

**Colon Pathology**

**Literature Review:** Studies in the peer-reviewed scientific literature have demonstrated that colon capsule colonoscopy (CCE) remains diagnostically inferior to conventional procedures including colonoscopy, barium radiography, and virtual (computed tomography or magnetic resonance) colonography.

Spada et al., (2016) conducted a meta-analysis to assess the accuracy of CCE in detecting colorectal polyps and included 14 studies from 2420 patients (1128 for CE COLON 1 [CCE-1] and 1292 for CE COLON 2 [CCE-2]). Colonoscopy with histology was the gold standard in all series. The sensitivity values achieved by CCE-2 (86% and 87% for ≥6 mm and ≥10 mm polyps, respectively) represent a clinically relevant improvement.
compared with the corresponding values shown by CCE-1 (58% and 54% for ≥6 mm and ≥10 mm polyps, respectively). A limitation of the meta-analysis is inclusion criteria that include abstracts and retrospective studies.

Health Quality Ontario (Ontario Health Technology Assessment series, 2015) published an evidenced-based analysis of CCE. Objectives were to evaluate the diagnostic accuracy and safety of CCE for the detection of colorectal polyps among adult patients with signs or symptoms of colorectal cancer or with increased risk of colorectal cancer, and to compare CCE with alternative procedures. Five studies evaluated PillCam Colon 2 (CCE-2). The analysis concluded that in adult patients with signs, symptoms, or increased risk of colorectal cancer, there is low-quality evidence that colon capsule endoscopy using the CCE-2 device has good sensitivity and specificity for detecting colorectal polyps. Additionally low-quality evidence does not indicate a difference in accuracy between CCE and CT colonography.

Rokkas et al. (2010) conducted a meta-analysis to evaluate the effectiveness of CCE in detecting colorectal polyps. Seven studies with 626 individuals were included. Each patient underwent CCE and conventional colonoscopy. Findings were categorized as "significant polyps," a polyp >6 mm in size or 3 or more polyps of any size, or "any polyp," a report of any polyp found, independent of size. Pooled data on sensitivity and specificity with a 95% CI were estimated. For any polyp found, the pooled data showed per-patient CCE sensitivity of 73% and specificity of 89%. For significant polyps, the respective values were 69% and 86%. A limitation of this meta-analysis is the inclusion of studies from abstracts.

Professional Societies/Organizations: The joint AGA/ACG/ASGE Guideline on Genetic Evaluation and Management of Lynch syndrome (Giardiello, et al., 2014) does not state a position statement or recommendation regarding the use of CCE. The joint AGA/ACG/ASGE guideline on Colonoscopy Surveillance After Colorectal Cancer Resection (Kahi, et al., 2016); joint AGA/ACG/ASGE Guideline for colonoscopy surveillance after screening and polypectomy (Lieberman, et al., 2012); ACG Guidelines for Colorectal Cancer Screening (Rex, et al., 2008; corrected 2009); and American Cancer Society/ AGA/ACG/ASGE joint guideline on Screening and Surveillance for the Early Detection of Colorectal Cancer (Levin, et al., 2008) all do not address the use of CCE.

The ASGE Report on Emerging Technology Capsule Endoscopy of the Colon (2008) notes that CCE 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. Further, significant research on this topic is required, and many fundamental questions for this technology remain unaddressed.

Patency Capsule
Some small retrospective and prospective studies have evaluated the patency capsule (PC). These studies do not demonstrate that the PC can safely be used in lieu of conventional evaluations to rule out stricture or obstruction prior to CE; therefore, the medical necessity of the patency capsule is unproven.

Zhang et al, (2014) reported on a meta-analysis evaluate the diagnostic value of PC. The review included five single-center prospective studies of patients (n=203) with suspected small bowel stricture who were evaluated by both PC and a reference standard (following CE and/or surgical pathology and/or endoscopic findings) who were eligible for inclusion. The quality of the eligible studies was assessed using the Quality Assessment for Diagnostic Accuracy Studies-2 criteria. Sensitivity, specificity, likelihood ratios and the area under the receiver operating characteristic curve (AUROC) were calculated. The pooled data indicated PC sensitivity of 97%, specificity of 83% and AUROC of 0.9557. The authors concluded that the findings suggest PC might be of diagnostic value in confirming the GI tract patency before CE; however, large multicenter, prospective trials are still needed to confirm the accuracy of PC.. The meta-analysis was limited by the small number of studies, small sample size, and use of abstracts versus full text articles for two of the five studies.

Use Outside of the US
Currently, the Mallorca group (Vasen, et al., 2013) does not recommend surveillance for Lynch syndrome. As small bowel cancer is frequently located in the duodenum and ileum, they suggest inspection of the distal duodenum during upper gastrointestinal endoscopy (if performed) and also of the ileum during colonoscopy.
European Society of Gastrointestinal Endoscopy (ESGE): The ESGE published a Clinical Guideline on Small-bowel capsule endoscopy and device-assisted enteroscopy for diagnosis and treatment of small-bowel disorders (Pennazio, et al., 2015):

1. ESGE recommends small-bowel video capsule endoscopy as the first-line investigation in patients with obscure gastrointestinal bleeding (strong recommendation, moderate quality evidence).
2. In patients with overt obscure gastrointestinal bleeding, ESGE recommends performing small bowel capsule endoscopy as soon as possible after the bleeding episode, optimally within 14 days, in order to maximize the diagnostic yield (strong recommendation, moderate quality evidence).
3. ESGE does not recommend the routine performance of second-look endoscopy prior to small bowel capsule endoscopy; however whether to perform second-look endoscopy before capsule endoscopy in patients with obscure gastrointestinal bleeding or iron-deficiency anemia should be decided on a case-by-case basis (strong recommendation, low quality evidence).
4. In patients with positive findings at small-bowel capsule endoscopy, ESGE recommends device-assisted enteroscopy to confirm and possibly treat lesions identified by capsule endoscopy (strong recommendation, high quality evidence).
5. ESGE recommends ileocolonoscopy as the first endoscopic examination for investigating patients with suspected Crohn’s disease (strong recommendation, high quality evidence). In patients with suspected Crohn’s disease and negative ileocolonoscopy findings, ESGE recommends small-bowel capsule endoscopy as the initial diagnostic modality for investigating the small bowel, in the absence of obstructive symptoms or known stenosis (strong recommendation, moderate quality evidence). ESGE does not recommend routine small-bowel imaging or the use of the PillCam patency capsule prior to capsule endoscopy in these patients (strong recommendation, low quality evidence). In the presence of obstructive symptoms or known stenosis, ESGE recommends that dedicated small bowel cross-sectional imaging modalities such as magnetic resonance enterography/enteroclysis or computed tomography enterography/enteroclysis should be used first (strong recommendation, low quality evidence).
6. In patients with established Crohn’s disease, based on ileocolonoscopy findings, ESGE recommends dedicated cross-sectional imaging for small-bowel evaluation since this has the potential to assess extent and location of any Crohn’s disease lesions, to identify strictures, and to assess for extraluminal disease (strong recommendation, low quality evidence). In patients with unremarkable or non-diagnostic findings from such cross-sectional imaging of the small bowel, ESGE recommends small-bowel capsule endoscopy as a subsequent investigation, if deemed to influence patient management (strong recommendation, low quality evidence). When capsule endoscopy is indicated, ESGE recommends use of the PillCam patency capsule to confirm functional patency of the small bowel (strong recommendation, low quality evidence).
7. ESGE strongly recommends against the use of small-bowel capsule endoscopy for suspected coeliac disease but suggests that capsule endoscopy could be used in patients unwilling or unable to undergo conventional endoscopy (strong recommendation, low quality evidence).

The ESGE published a guideline regarding colon capsule endoscopy (CCE) (Spada, et al., 2012). Recommendations are based on case–control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal, nonanalytic studies (e. g. case reports, case series) and expert opinion.

- CCE is feasible and safe and appears to be accurate when used in average-risk patients
- There is a lack of specific studies based in the setting of screening.
- CCE is a feasible and safe tool for visualization of the colonic mucosa in patients with incomplete colonoscopy and without stenosis.
- Randomized studies comparing CCE with radiological imaging or conventional endoscopic modalities are needed to confirm the efficacy of CCE in this setting and to better define the patients for whom CCE is most suitable
- There are insufficient data to support the use of CCE in the diagnostic work-up or in the surveillance of patients with suspected or known inflammatory bowel disease.

Summary
The published, peer-reviewed scientific literature supports the safety and clinical utility of small bowel capsule endoscopy (CE) as an adjunctive diagnostic tool for individuals with no known or suspected contraindications with obscure gastrointestinal bleeding (OGIB), suspected Crohn’s disease, suspected small bowel tumor and celiac disease.

Small bowel CE may be useful for small bowel surveillance in individuals with inherited polyposis syndromes (e.g., familial adenomatous polyposis, Peutz-Jeghers syndrome). There is not yet enough conclusive data to support CE in Lynch syndrome, also known as hereditary non-polyposis colon cancer (HNPCC).

At this time, studies evaluating esophageal capsule endoscopy (ECE) and colon capsule colonoscopy (CCE) demonstrate both to be diagnostically inferior to established conventional procedures. Important limitations of ECE and CCE include: the device has no therapeutic capabilities; it does not permit tissue sampling or therapeutic intervention; it cannot insufflate air to distend the bowel to enhance mucosal visualization.

There is limited data on patient safety when using the patency capsule versus conventional evaluations to rule out stricture or obstruction prior to CE; therefore, conventional evaluations remain the gold standard for ruling out any known or suspected gastrointestinal obstruction, strictures, and fistulas prior to CE.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

**Capsule Endoscopy: Small Bowel**

Covered when medically necessary:

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<th>Description</th>
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**Capsule Endoscopy: Esophagus, Colon, and Patency Capsule**

Experimental/Investigational/Unproven/Not Covered:

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<tr>
<td>91299†</td>
<td>Unlisted diagnostic gastroenterology procedure</td>
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<tr>
<td>0355T</td>
<td>Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), colon, with interpretation and report</td>
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†Experimental/Investigational/Unproven and Not covered when used to report patency capsule (e.g., Given AGILE™ Patency System)


References

Colon


**Esophagus**


### General / Small Bowel


Inherited Polyposis Syndromes/Lynch Syndrome


