MEDICAL POLICY

Medical Policy Title	**Capsule Endoscopy**
Policy Number	**6.01.27**
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Next Review Date	**October 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Capsule endoscopy (CE) (CPT 91110, 91111) is considered **medically necessary** for **ANY** of the following indications:

A. To investigate suspected small bowel bleeding when conventional diagnostic workup failed to identify the source of bleeding (e.g., persistent or recurrent iron-deficiency anemia, positive fecal occult blood test, or visible bleeding);

B. For the initial diagnosis of suspected Crohn's disease (CD) when conventional diagnostic work-up failed to reveal evidence of disease, and there remains a strong clinical suspicion of CD (e.g., chronic diarrhea, abdominal pain, weight loss, fatigue, fever, anemia, elevated white blood cell (WBC) count, or elevated laboratory markers of inflammation);

C. For re-evaluation of members with an established diagnosis of Crohn's disease who remain symptomatic despite appropriate medical therapy;

D. Surveillance of the small bowel in members with a diagnosis of hereditary polyposis syndromes (i.e., familial adenomatosis polyposis [FAP] or Peutz-Jeghers syndrome);

E. For re-evaluation of members with an established diagnosis of celiac disease who remain symptomatic despite adherence to appropriate medical therapy;

F. Screening or surveillance of esophageal varices, in cirrhotic patients with significantly compromised liver function (e.g., Child-Pugh score of Class B or greater), where a standard upper endoscopy with sedation or anesthesia is contraindicated.

II. CE is considered **investigational** for the evaluation or diagnosis of **ANY** other indication, including but not limited to:

A. Disease of the esophagus, other than as stated above;

B. Disease in the small bowel, other than as stated above;

C. Confirmation of lesions/pathology found by other diagnostic means;

D. Other GI diseases/conditions not presenting with GI bleeding (e.g., irritable bowel syndrome, portal hypertensive enteropathy, unexplained chronic abdominal pain);

E. Disease of the stomach (e.g., NaviCam, CPT 0651T);

F. Disease of the large intestine/colon (e.g., detection of colonic polyps or colon cancer) (e.g., PillCam COLON2).

G. GI motility disorder (e.g., gastroparesis) (e.g., MotiliCap, Atmo Gas Capsule CPT 91112);

H. GI stricture(s) or obstruction (e.g., Pillcam Patency Capsule, CPT 91299);

I. Disease evaluation by magnetic capsule endoscopy (e.g., NaviCam, CPT 0651T);

J. Detection of GI blood (Pill Sense System, CPT 0977T).

RELATED POLICIES

Corporate Medical Policy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. CE must be performed under the supervision of a gastroenterologist with expertise in this technology and performed only when there is no suspected or confirmed gastrointestinal (GI) obstruction.

II. In the case of suspected small bowel bleeding, because of low lesion detection rate, a small bowel follow-through or enteroclysis is not necessarily required prior to CE. A small bowel follow-through may be beneficial in some cases, at the discretion of the clinician, prior to or after CE, in the detection of small bowel lesions and in their anatomical localization.

DESCRIPTION

CE, also known as wireless capsule endoscopy (WCE) or video capsule endoscopy (VCE), is a non-invasive diagnostic imaging device used to visualize segments of the esophagus, stomach, small bowel, and colon. The CE capsule is swallowed by the patient, propelled by peristalsis or magnetically controlled through the gastrointestinal tract, and either dissolves (e.g., patency capsule) or is naturally excreted. As the capsule is propelled through the gastrointestinal (GI) tract, the capsule records and transmits data (e.g., images or electrical signals) for interpretation.

Small Bowel Capsule Endoscopy (SBCE)

The primary indications for capsule endoscopy including identifying the source of suspected small bowel bleeding when conventional diagnostic work-up failed to provide a definitive diagnosis; for the initial diagnosis of suspected Crohn's disease when conventional diagnostic work-up failed to provide a definitive diagnosis, to evaluate refractory celiac disease; and screen/surveillance of tumors in the small bowel in people diagnosed with polyposis genetic syndromes.

Colon Capsule Endoscopy (CCE)

Screening for colon cancer is suboptimal in the United States. To improve acceptability of screening, the colon capsule (PillCam Colon Capsule, Given Imaging) was developed as a non-invasive technique

to explore the colon without intubation, sedation, and air insufflation. Bowel preparation is crucial with CCE since it is not possible to clean the colon during the procedure and even the smallest amount of debris could interfere with identifying colonic polyps.

CCE is being investigated as a screening tool for colorectal polyps, including for individuals with an incomplete colonoscopy despite adequate bowel preparation. In such cases, full visualization of the colon is not technically achievable, limiting the ability to detect polyps and guide subsequent clinical decisions. Contributing factors to an incomplete colonoscopy include patient discomfort, diverticulosis, tortuosity, adhesions due to prior surgeries, angulation or fixation of bowel loops, ineffective sedation, and endoscopist and technician expertise.

Blood Detection Capsule

A novel device intended to detect blood in the GI tract, the capsule features sensors that detect blood and wirelessly transmit data to an external receiver. The capsule makes its way through the gastrointestinal tract and is then passed naturally from the body. The reusable receiver collects and displays real-time information gathered by the capsule. The receiver interprets the data and displays a sensor output value. It plots these values on a chart using data acquisition and when completed displays a "blood detected" or "no blood detected" message. The software supports entering of the patient information, pairing of the receiver and capsule and data interpretation and display.

Esophageal Capsule

Capsule endoscopy is proposed as an option to visualize and detect mucosal disease of the esophagus (e.g., esophageal varices) and could triage patients for endoscopy if either the sensitivity or the specificity is high. Traditional endoscopy could then be performed on the appropriate group to determine false-positives or false-negatives, having spared the group with a high positive predictive value an endoscopy procedure.

A novel diagnostic ingestible capsule sponge device, the Cytosponge Cell Collection Device, is being investigated as a diagnostic tool for a wide range of upper GI conditions. The endoscopic cell collection device consists of a compressed spherical sponge inside a capsule, which is attached to a suture. The capsule is swallowed and dissolves in the stomach releasing the self-expanding sponge that collects cells from the outer layer of the esophageal tissue. The sponge is removed using the attached suture and the esophageal surface cells undergo cytological and histological analysis.

Magnetically Controlled Capsule Endoscopy

Magnetically controlled capsule endoscopy, also referred to as magnetically assisted capsule endoscopy (MACE), is being investigated for visualization of the stomach and duodenum to evaluate unexplained abdominal pain. The indication for use includes adults aged 22 years and older with a BMI less than 38. The system can be used in clinics and hospitals, including ER settings. This non-invasive system consists of a single-use ingestible capsule and magnet linked to a physician-operated console. The capsule contains a camera that wirelessly captures images of the desired anatomy. The console allows the operator to control the motion and direction of the capsule, ensuring visualization of the entire stomach. The capsule’s camera captures images and transmits the images to a data recorder for interpretation. The procedure does not require sedation and has a procedural time of

approximately 15 to 20 minutes. The capsule leaves the body in 24 hours on average but may take as long as two (2) weeks. The device is contraindicated for use in patients with gastrointestinal obstruction, stenosis, fistula, or those with dysphagia. Other contraindications include patients with cardiac pacemakers or other implantable electronic medical devices as well as pregnant women, those less than 22 years of age, and those with a body mass index of 38 or greater.

Motility Capsule

The motility capsule is an alternative to gastric scintigraphy, which is considered the reference standard for diagnosing gastroparesis. The American Gastroenterological Association (AGA) defines gastroparesis as delayed gastric emptying of the stomach, possibly due to issues with the stomach muscles, nerves, or brain and spinal cord nerves. Gastroparesis is not a mechanical block in the stomach. Symptoms of gastroparesis are often nonspecific and may mimic other gastrointestinal tract disorders. Gastroparesis can be caused by many conditions, with most common causes including idiopathic, diabetic, or post-surgical. During wireless GI motility monitoring, the individual swallows a small capsule that contains sensors to measure gastrointestinal transit times and assess GI motility disorders.

Patency Capsule

The patency capsule (e.g., Pillcam Patency Capsule) is a dissolvable capsule developed to verify adequate patency of the gastrointestinal tract prior to administration of the wireless CE in patients with known or suspected strictures. Once the patient ingests the patency capsule, it is propelled through the GI tract by normal peristalsis. If the patency capsule is excreted structurally whole, then this indicates patency of the patient's GI tract, and a PillCam capsule can be administered.

SUPPORTIVE LITERATURE

Small Bowel Capsule Endoscopy

Suspected Small Bowel Bleeding

For individuals who have suspected small bowel bleeding (previously referred to as obscure gastrointestinal [GI] bleeding) who receive (WCE), the evidence includes numerous case series and a randomized controlled trial (RCT). The evidence has demonstrated that CE can identify a bleeding source in a substantial number of patients who cannot be diagnosed by other methods, with a low incidence of adverse events. Because there are few other options for diagnosing obscure small bowel bleeding in patients with negative upper and lower endoscopy, this technique likely improves health outcomes by directing specific treatment when a bleeding source is identified. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

A small randomized controlled trial (RCT) compared CE with mesenteric angiography in patients with acute melena or hematochezia (Leung 2012). While CE had a higher diagnostic yield (DY), secondary outcomes such as transfusion, hospitalization, and mortality did not differ significantly between groups. A large number of uncontrolled studies have evaluated the use of CE in the evaluation of patients with suspected small bowel bleeding. These studies have consistently reported that a substantial proportion of patients receive a definitive diagnosis following this test when there are few other diagnostic options.

A meta-analysis of 24 studies estimated that the DY in this patient population was approximately half of the included patients and was higher in patients with documented iron-deficiency anemia (Koulaouzidis 2012). Capsule endoscopy appears to locate the source of bleeding at least as well as other diagnostic methods and direct treatment to the source of bleeding.

Crohn's Disease (CD)

The evidence is sufficient to determine that CE for suspected and established diagnosis of CD results in an improvement in the net health outcome.

The Selecting Therapeutic Targets in Inflammatory Bowel Disease (STRIDE) initiative began in 2015, with an updated STRIDE-II published by Turner et al (2021). STRIDE-II encompasses evidence- and consensus-based recommendations for treat-to-target strategies in adults and children with inflammatory bowel disease (IBD). Consensus recommends endoscopic and transmural assessment of healing by sigmoidoscopy or colonoscopy; however, when not feasible, alternatives can include CE. The authors acknowledge that transmural healing in Crohn's disease is becoming an important adjuvant assessment of the depth of treatment response; however, more research is needed to determine the incremental gain derived from the goal and whether the gain is worth the therapy-related risks and costs.

Choi et al (2017) conducted a meta-analysis comparing CE with various modalities for diagnosing CD. The analysis consisted of 24 trials (RCT, nonrandomized, and diagnostic accuracy studies) with suspected or established CD. In the pooled analysis, in patients with suspected CD, the sensitivity of CE ranged from 89.6% to 92.0% and the specificity was 100%.

Kopylov et al (2017) published a systematic review of studies evaluating the use of CE for CD. Reviewers included prospective studies comparing CE with magnetic resonance enterography (MRE) and/or small bowel (SB) contrast ultrasound in patients who had suspected or established CD. In the pooled analyses of the 11 studies that included patients with established CD, the diagnostic yield of CE for detection of active small bowel CD was similar to that of MRE and to ultrasound. The outcomes were similar for the subgroups of suspected versus established CD and adult versus pediatric patients. CE was superior to MRE for proximal SB CD. The summary of results demonstrate that all have similar DY for the detection of SB CD; none of the modalities can be considered superior over the others and their utilization should be tailored to the specific clinical situations. CE is the preferred modality for detection of proximal small bowel involvement.

Bruining et al (2020) reported results from the multicenter, prospective BLINK trial comparing the diagnostic accuracy of CE compared to ileocolonoscopy (IC) and/or MRE in patients with established CD. The per-protocol analysis included 99/158 enrolled subjects with 16 patients tested by all three modalities. The reference standard was defined as the presence or absence of inflammation as designated by the modality-specific scoring system at prospective interpretation by expert central readers. Overall sensitivity for active enteric inflammation (CE vs MRE and/or IC) was 94% vs 100% (p=0.125) and specificity was 74% vs 22% (p=0.001). Sensitivity of CE was superior to MRE for enteric inflammation in the proximal small bowel (97% vs 71%, p=0.021), and similar to MRE and/or IC in the terminal ileum and colon (p=0.500-0.625). There were seven serious adverse events of which three were related to the CE device. Several limitations to this study are noted. The authors

concluded that this study demonstrates the powerful potential of panenteric CE to provide accurate Crohn's disease assessments and panenteric CE should be considered for utilization in non-structuring Crohn's disease evaluations.

Elosua et al (2022) evaluated the therapeutic impact of CE in patients with established CD in a retrospective, single-center study. Therapeutic impact was defined as change in CD-related treatment recommended based on CE results. A total of 305 patients with established CD underwent a SBCE between January 2008 and December 2019. From the 432 procedures performed, 87.5% were conclusive. Active disease was present in 63 patients; 41.6% mild inflammation and 21.9% moderate-to-severe activity. Disease activity demonstrated by CE results was correlated with therapeutic changes. A change of management was guided by SBCE in 51.3% of procedures. Mucosal healing assessed via CE was the only independent factor that predicted therapy de-escalation. Study limitations include the retrospective study design and limited heterogeneity due to a limited group of research gastroenterologists.

Celiac Disease

For a suspected diagnosis of celiac disease, the clinical validity of wireless CE for diagnosing celiac disease has not been established and its diagnostic performance is currently insufficient to replace standard modalities or to effectively triage patients to other diagnostic approaches. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

A meta-analysis by El-Matary et al (2009) compared the diagnostic performance of CE with a reference standard of duodenal biopsy. The pooled analysis of three studies showed a sensitivity of 83% and a specificity of 98%. Rokkas and Niv (2012) conducted a meta-analysis to compare the diagnostic performance of CE with biopsy, summarizing six studies (N=166 subjects). The overall pooled sensitivity was 89%, and the specificity was 95%. Capsule endoscopy detected involvement of intestines beyond the duodenum; however, the clinical significance of detecting the extent of celiac disease is uncertain. Given the less than 90% sensitivity of CE for celiac disease, it does not appear to be an adequate alternative method of making an initial diagnosis.

Kurien et al (2013) conducted a non-randomized study of 62 patients with an equivocal diagnosis of celiac disease and 69 patients with confirmed celiac disease who were unresponsive to standard treatment were evaluated with CE. Results were combined with human leukocyte antigen typing and response to gluten challenge, with the final diagnosis made by three expert physicians who received the information from all three sources. The main outcome was the increase in diagnostic yield after CE combined with the other tests. The diagnostic yield was greatest in cases with antibody-negative villous atrophy where a diagnosis of celiac disease was made in nine of 32 patients (28%). In eight of the 69 nonresponsive celiac disease patients (12%), CE identified two cases of enteropathy-associated lymphoma, four type 1 refractory disease cases, one fibroepithelial polyp, and one case of ulcerative jejunitis. This study was limited by the small sample size and use of other tests in conjunction with CE to ascertain a final diagnosis.

Shapiro and Niv (2025) conducted a systematic review and meta-analysis to assess the diagnostic yield of VCE in patients with CD. Analyzing data from 22 studies involving 1,585 patients, the authors found that VCE identified pathognomonic features of CD (e.g., villous atrophy, scalloping, mosaic

patterns, fissuring, ulcers, and erosions) in approximately 60% of cases. The pooled effect size for any diagnostic pathology was 0.601, with higher yields observed in patients with refractory CD. VCE achieved complete small bowel visualization in over 96% of patients, which the authors concluded demonstrate its utility as a non-invasive, high-resolution imaging modality for evaluating mucosal abnormalities, especially when conventional endoscopy is inconclusive or incomplete. Study limitations include small sample sizes, unblinded studies, and high heterogeneity across studies. The authors concluded that their findings suggest that VCE offers a moderate diagnostic yield for celiac disease, with a possible role in early management and diagnosis of refractory celiac disease (RCD). Future studies should aim to standardize protocols and explore the effectiveness of VCE using artificial intelligence and machine learning to complement existing diagnostic methods.

Inherited Polyposis Syndromes

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; Urquhard 2014).

Lynch Syndrome

At present, the evidence is insufficient to determine that the technology results in an improvement in the net health outcome and surveillance of the small bowel is not generally recommended as a routine intervention for patients with Lynch syndrome.

Saurin et al (2010) conducted a small prospective, blinded, comparative study of CE and computed tomography (CT) enteroclysis with 35 asymptomatic patients with Lynch syndrome. Small bowel neoplasms were diagnosed in three patients (8.6%). Capsule endoscopy identified all neoplasms, and CT enteroclysis raised suspicion of one neoplasm (adenocarcinoma) but missed the two others. The clinical usefulness of systematic small-bowel screening in these patients should be confirmed through large prospective studies.

Haanstra et al (2015) evaluated 200 patients with Lynch syndrome who underwent video CE to determine the prevalence of small-bowel neoplasia in asymptomatic patients with Lynch syndrome. Small bowel neoplasia was detected in the duodenum in two patients (one adenocarcinoma, one adenoma). In another patient, a duodenal cancer was diagnosed seven months after a negative video CE, which is considered a lesion missed by CE. All three neoplastic lesions were within reach of a conventional gastroduodenoscope.

Valdivia et al (2024) report that the role of small bowel (SB) cancer surveillance by CE in Lynch syndrome patients has been investigated, with contradicting results. The authors conducted a systematic review and meta-analysis to evaluate the diagnostic yield (DY) of CE as a screening tool in asymptomatic LS patients. Five studies, comprising 428 patients and 677 CE procedures, were included for data extraction and statistical analysis. The estimated pooled DY for CE-identified pathological findings was 8% in the first screening round and 6% in the second. Limiting the analysis to histologically confirmed pathological findings, the pooled DY of second-round screening dropped to 0%. The included studies showed a significantly different prevalence of pathogenic variants in mismatch repair (path_MMR) genes, which underlie different cumulative incidences of extracolonic

cancers. SB surveillance by CE with a 2-year interval in asymptomatic LS individuals does not appear to be an effective screening strategy. Confirmatory prospective studies in this context are needed, considering the different cumulative incidence of SB tumors according to underlying path_MMR defects. The authors concluded that, although the DY of CE is high in detecting small bowel lesions in LS, the low number of positive examinations eventually resulted in an even lower number of true-positive patients after histological confirmation, with a pooled yield proximate to 0%. SB surveillance by CE with a 2-year interval in asymptomatic LS individuals does not appear to be an effective screening strategy.

Blood Detection Capsule Endoscopy

Akiki et al (2024) reported findings from a prospective, open-label, single-arm comparative clinical trial to evaluate the safety and efficacy of the PillSense System, a novel ingestible capsule designed to rapidly detect upper gastrointestinal bleeding (UGIB). Physicians conducting the esophagogastroduodenoscopy (EGD) were blinded to the PillSense results. The study involved 126 adults with suspected UGIB who received the capsule followed by EGD within four hours. Compared with EGD results, the capsule correctly detected the presence of blood in 26 of 28 cases and the absence of blood in 87 of 96 cases. Sensitivity and specificity were 92.9% (P = .02) and 90.6% (P < .001), respectively. Among the 126 patients in the safety population, 23 (18.3%) experienced at least 1 AE. This industry sponsored study concluded that the novel blood-sensing capsule device provides highly accurate and rapid detection of UGIB. However, future studies are needed to identify and validate the performance of the PillSense system in a real-world clinical setting.

Colon Capsule Endoscopy

CCE has been proposed as an alternative imaging modality to explore mucosa of the entire colon. CCE does not allow for biopsy or polyp removal; therefore, patients with lesions detected typically require subsequent colonoscopy for further evaluation and/or treatment. Studies looking at the efficacy of colon capsule endoscopy compared with standard colonoscopy have reached variable results. Most studies report sensitivities for detecting polyps ≥6 mm between 70 and 88 percent (range 39 to 88 percent), and specificities between 80 and 90 percent (range 64 to 93 percent) (Cave et al., 2024). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Given Imaging conducted an 884-patient, 16-site clinical trial that studied the accuracy and safety of PillCam COLON 2, compared to optical colonoscopy, in detecting adenomas six 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 six mm in size. The FDA based its clearance decision on an analysis of this clinical trial data, which used a more restrictive methodology for matching polyps. In this analysis, which was conducted on hyperplastic polyps and adenomas, the positive percent agreement for PillCam COLON and optical colonoscopy was 69%, and negative percent agreement was 81% for polyps at least six millimeters in size. The wireless capsule had not been adequately studied in the large intestine. The colon was not well-visualized due to stool obscuring the colonic mucosa. Adequate visualization of the colon was also hampered by the colon's larger diameter which made it possible for the capsule camera to miss suspicious areas.

Eliakim et al (2006) conducted a prospective study to determine whether CE of the colon can provide similar detection rates of pathological colonic conditions, compared to conventional colonoscopy. Conventional colonoscopy detected more polyps compared to wireless CE: 70% were identified with the capsule and 16/20 (80%) were identified by conventional colonoscopy. In comparison with conventional colonoscopy, false-positive findings on PillCam Colon capsule examination were recorded in 15/45 cases (33%). Additional studies are needed, to evaluate the accuracy of PillCam Colon endoscopy in patient populations with different prevalence levels of colonic disease.

Parodi et al (2018) stated that CCE has been recognized as an alternative for colorectal cancer (CRC) screening in average-risk people; however, in first-degree relatives (FDRs) of patients with inherited predispositions to CRC have a much higher increased risk of developing CRC but compliance with colonoscopy screening by FDRs remains suboptimal. The researchers conducted a prospective study to assess the accuracy of CCE as a screening tool in FDRs of people with CRC. An optical colonoscopy (OC) with segmental unblinding was the reference standard. In this study, 177 FDRs underwent both CCE and optical colonoscopy (OC), with segmental unblinding of CCE findings used to validate results. CCE demonstrated a sensitivity of 91% for detecting polyps ≥6 mm, identifying 51 of 56 cases, and a specificity of 88%, correctly classifying 107 of 121 participants without lesions of this size. The positive predictive value (PPV) and negative predictive value (NPV) for polyps ≥6 mm were 78% and 95%, respectively. For polyps ≥10 mm, CCE achieved a sensitivity of 89% (24 of 27 cases) and a specificity of 95% (142 of 150 cases). Limitations to the present analysis include the study design and lack of analysis of FDRs' compliance with CCE screening. The authors concluded that the results showed both high technical feasibility and accuracy of CCE as a primary screening test for FDRs of patients with CRC, supporting its use for such an indication.

Kjolhede et al (2020) reported a systematic review and meta-analysis of the diagnostic accuracy of CE compared to colonoscopy with stratified results for polyps of any size, polyps ≥ 6 mm, and polyps ≥ 10 mm. Across analyzed patients in the 12 eligible studies, the indications for endoscopy included colorectal cancer screening or history of polyps or colorectal cancer (n=1200; 63.2%), positive fecal immunochemical test (n=493; 26%), first-degree relatives of patients with colorectal cancer (n=177; 9.3%), or unspecified (n=28; 1.5%). The rate of patients with an adequate bowel preparation ranged from 40% to 100%. The rates of complete CE transits ranged from 57% to 100%. The authors note that the relatively high rate of incomplete CE investigations limits the utility of CE in the colorectal cancer setting. All but one study was assessed to have a high risk of bias and applicability concerns for the reference standard.

Cash et al (2021) evaluated the diagnostic characteristics of CE using subsequently performed colonoscopy as the reference standard. Randomizing patients to colon CE or computed tomography (CT) colonography followed by optical colonoscopy. Data from 286 patients revealed that the proportion of enrollees with any polyp 6 mm or larger confirmed by subsequent blinded optical colonoscopy was 31.6% for colon CE versus 8.6% for CT colonography. The sensitivity and specificity of colon CE for polyps 6 mm or larger was 79.2% and 96.3%, respectively, while that of CT colonography was 26.8% and 98.9%. For polyps 10 mm or larger, the sensitivity and specificity of colon CE was 85.7% and 98.2% compared with 50% and 99.1% for CT colonography. The authors concluded that colon CE should be considered comparable or superior to CT colonography as a screening test; however, neither test was as effective as optical colonoscopy.

Lei et al (2025) conducted a systematic review and meta-analysis evaluating follow-up endoscopy rates (FERs) as a measure of effectiveness in colon capsule endoscopy (CCE). Analyzing data from 19 studies involving 2,850 patients, the study found that 42% of individuals undergoing CCE required a follow-up endoscopic or radiologic investigation, which is significantly higher than FERs for colonoscopy (10–15%) and CT colonography (25%). Reinvestigation was more frequent with the newer CCE2 capsules, likely due to improved diagnostic performance Despite applying meta-regression and subgroup analyses, substantial heterogeneity was observed across study results, largely attributable to multiple confounding variables. The authors concluded that further research is needed to reduce CCE FERs, which is essential for improving patient outcomes and ensuring CCE becomes a viable and widely adopted service in clinical practice.

Colon Capsule Endoscopy (CCE) Following Incomplete Optical Colonoscopy

Hussey et al (2018) state that CCE is a new, noninvasive technique for exploring the large intestine, with recent studies demonstrating good correlation between OC and CCE in detecting both significant and non-significant large bowel pathology. The researchers conducted an observational, prospective, single-center study to assess the efficacy of same-day CCE following incomplete OC in an unselected patient cohort. Patients (n=50) with an incomplete OC for reasons other than obstruction or inadequate bowel preparation were recruited. CCE was performed using the second-generation PillCam colon capsule (Medtronic/Given Imaging, Yokneam, Israel) after a minimum one-hour recovery period following OC. Although only 76% (n=38) of CCEs were complete, full colonic views were obtained in 84% (n=42) of cases. OC findings prior to CCE were normal in 76% (n=38), diverticular disease in 24% (n=12) and polyps which were removed in 12% (n=6). CCE findings were normal in 26% (n=13), polyps 38% (n=19), inflammation 22% (n=11), diverticular disease 25% (n=12), angiodysplasia 3% (n=1), and cancer 3% (n=1). Among patients with polyps (n=19), seven (36%) were deemed to have significant polyps requiring referral for polypectomy. Of these, four patients had a polyp > 6 mm and three patients had ≥3 polyps. Subsequent histology of the referred polyps (n=14) revealed tubulovillous adenoma with low-grade dysplasia in 57% of cases (n=8), tubulovillous adenoma with high-grade dysplasia in 7% (n=1), sessile-serrated adenoma in 14% (n=2) and hyperplastic polyps in 21% (n=3). Significant small bowel findings were identified in three cases, including Crohn's disease and a neuroendocrine tumor. A major adverse event occurred in one patient due to capsule retention which required surgical resection. The authors acknowledged several study limitations; however, they concluded that same-day CCE following incomplete OC is a safe and feasible alternative for assessing unexplored segments of the colon in selected patients.

Baltes et al (2018) conducted a prospective multicenter observational study in Germany to evaluate the ability of PillCamColon2 to visualize colonic segments missed during incomplete optical colonoscopy (OC) and to assess the DY. Data from 74 patients were analyzed (51% in group A; 49% in group B). Reasons for referral to colonoscopy were CRC screening (22%), anemia (15%), hematochezia (15%), irregular stool (12%), abdominal pain (12%), B symptoms (7%), colitis (5%) and other reasons (12%). Bowel cleansing was adequate in 67% of cases, and CCE could visualize colonic segments missed by incomplete colonoscopy in 90% of patients under protocol A and 97% of patients under protocol B (p = 0.35). Significant polyps, including adenocarcinoma, were detected in 24% of cases. Detection rates for all polyps and significant polyps per patient were similar in both protocols. Polyps were found predominantly in the right colon (86%) in segments that were not

reached by optical colonoscopy. Extracolonic findings (e.g., reflux esophagitis, suspected Barrett esophagus, upper GI-bleeding, gastric polyps, gastric erosions) were identified in eight patients. PillCamColon2 capsule was retained in the ileum of one patient without symptoms. The authors report that the second-generation CCE using low-volume bowel preparations is useful, well tolerated, and capable of detecting additional relevant lesions. Although the risk of capsule retention is low, comparable to that of small bowel capsule endoscopy, it must still be considered. Future studies should focus on improving colon cleansing and the completeness of CCE following incomplete OC.

Esophageal Capsule

Capsule endoscopy has been used to diagnose portal hypertensive enteropathy (PHE) particularly in patients with portal hypertension and suspected small-bowel bleeding or anemia. Based on the outcomes of small studies comparing the Pill Cam ESO to upper endoscopy in patients with portal hypertension and esophageal varices, the PillCam ESO represents an accurate, non-invasive alternative to EGD for the detection of esophageal varices and portal hypertensive gastropathy (Eisen 2006; Lapalus 2006; Penna 2008; Lu 2009). While further studies are required to validate these initial findings, the use of wireless CE for those patients with significantly compromised liver function, who cannot tolerate sedation or anesthesia, appears reasonable.

Barrett Esophagus

Capsule endoscopy is being investigated as a diagnostic screening technique for esophageal conditions (e.g., Barrett esophagus); however, the clinical validity of wireless CE for monitoring esophageal disorders has not been established. Other available modalities are superior to CE for monitoring esophageal disorders. The diagnostic characteristics of CE are inadequate to substitute for other modalities or to triage patients to other modalities.

The Cytosponge cell collection device (Medtronic), an ingestible capsule containing a ‘sponge on a string,’ is being investigated as a minimally invasive method of sampling surface esophageal cells in patients who require screening or surveillance of esophageal pathologies such as Barrett’s Esophagus (BE). However, current evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Eliakim et al (2004) conducted a feasibility case series study to compare the PillCam ESO to conventional upper endoscopy in patients with suspected disorders of the esophagus (n= 17 patients). The negative predictive value for any esophageal disorder was 100%, while the positive predictive value was 92% (sensitivity 100%, specificity 80%). The authors stated that further, large-scale studies are necessary to fully assess this diagnostic tool.

Eliakim et al (2005) conducted a larger, multi-center study of 106 patients with either GERD or Barrett’s esophagus. The authors reported esophageal abnormalities in 66/106 patients, providing a sensitivity of 92% and specificity of 95%.

Lin et al (2007) conducted a prospective, multi-center, blinded study to evaluate the accuracy of esophageal capsule endoscopy (ECE) in diagnosing Barrett's esophagus. Of the 96 subjects enrolled, 90 (94%) completed the study, including 66 screening and 24 surveillance patients. ECE demonstrated a sensitivity of 67% and a specificity of 84% for identifying Barrett's esophagus,

correctly diagnosing 14 of 21 biopsy-confirmed cases. Among screening patients, the positive predictive value was 22%, and the negative predictive value was 98%. Sensitivity was similar for both short- and long-segment Barrett's esophagus. The authors concluded that ECE has only moderate sensitivity and specificity for detecting Barrett's esophagus, and while not suitable as a primary screening tool in its current form, ECE may be considered for patients unwilling to undergo esophagogastroduodenoscopy (EGD).

Iqbal et al (2018) conducted a systematic review to analyze the efficacy and safety of a minimally invasive cell sampling device (Cytosponge) in the diagnosis of esophageal pathology. A total of 13 studies were included in the review, with six studies observing the efficacy of the Cytosponge in diagnosis Barrett's esophagus (BE) undergoing EGD and three in diagnosing eosinophilic esophagitis (EoE). The pooled sensitivity and specificity of diagnosing BE through the sponge devices were 81 and 91%, respectively. The pooled sensitivity and specificity of detecting EoE was calculated at 76.3% and 98.8%, respectively. Although published studies have good quality and showed promising results, the major limitation is that the majority were performed by a single group of authors. The authors concluded that given the current favorable results, the product should be independently verified to avoid the potential biases and conflicts inherent to the current literature.

Xu et al (2019) conducted a pilot study, SUGAR, to explore the feasibility of combining serological testing with Cytosponge technology to screen for upper gastrointestinal adenocarcinoma risk. Blood samples from 56 patients with Barrett's esophagus and 202 non-Barrett controls who previously took part in a trial assessing the accuracy of the Cytosponge for Barrett's esophagus were assessed for serum pepsinogen (PG) 1 and 2, gastrin-17, trefoil factor 3 (TFF3) and Helicobacter pylori infection.

The researchers found that low serum PG1 levels were significantly associated with gastric symptoms but not with Barrett's esophagus, suggesting its potential utility in identifying patients at risk for gastric pathology. Patients without a diagnosis of Barrett's esophagus had significantly lower serum values for PG1 levels (100.7 vs 292.0 ng/mL), PG2 (6.0 vs 13.9 ng/mL) and G17 (4.8 vs 13.4 ng/mL) than those with Barrett's metaplasia ($p<0.001$). Patients with Barrett's esophagus did not show pathologically altered serum PGs. Although serum trefoil factor 3 (TFF3) has been reported as a stable marker for gastric atrophy, assessment of TFF3 did not add further value to that of PG1. Prospective validation is needed to assess if the combination of a serum markers for gastric pathology with the minimally invasive Cytosponge test for Barrett's esophagus could be a potentially complimentary strategy to identify patients at risk for upper gastrointestinal adenocarcinoma.

Fitzgerald et al (2020) conducted the Barrett's Esophagus Screening Trial 3 (BEST3) study to investigate whether offering the Cytosponge-trefoil factor 3 (TFF3) to patients on medication for gastro-esophageal reflux would increase the detection of Barrett's esophagus compared with standard management. This multicenter, pragmatic, RTC was real-world implementation of the Cytosponge-TFF3, conducted in 109 socio-demographically diverse general practice clinics in England. Randomization occurred at both the general practice clinic level (cluster randomization) and at the individual patient level, and the results for each type of randomization were analyzed separately before being combined. Participants received either standard management for gastroesophageal reflux (usual care group), in which endoscopy was performed only if deemed necessary by the general practitioner, or usual care plus an offer of the Cytosponge–TFF3 procedure, followed by

endoscopy if TFF3-positive cells were identified (intervention group). The primary outcome was the diagnosis of Barrett's esophagus at 12 months after enrollment, expressed as a rate per 1000 person-years, in all participants in the intervention group (regardless of whether they had accepted the offer of the Cytosponge-TFF3 procedure) compared with all participants in the usual care group. Based on the number who had an endoscopy following a Cytosponge-TFF3 procedure but did not have Barrett's esophagus or cancer (n=90), and on the number who successfully swallowed the Cytosponge-TFF3 but did not have Barrett's esophagus or cancer (n=1523), the researchers estimated the specificity of the Cytosponge-TFF3 procedure to detect Barrett's esophagus, dysplasia or cancer to be 94%. The authors concluded that offering Cytosponge–TFF3 testing to patients with gastroesophageal reflux improves detection of Barrett's esophagus.

Tan et al (2025) conducted the DELTA study to evaluate the real-world implementation of capsule sponge testing combined with biomarker risk stratification for surveillance of Barrett's esophagus. This prospective, multicenter UK study involved patients with non-dysplastic Barrett's esophagus who underwent both capsule-sponge testing and endoscopy. Among the 910 patients in the cohort, 138 (15%) were classified as high risk, 283 (31%) as moderate risk, and 489 (54%) as low risk according to the capsule-sponge risk stratification score. The high-risk group demonstrated a 37.7% positive predictive value for dysplasia or worse, with the highest risk observed in those with both atypia and abnormal p53 expression. In contrast, the low-risk group had a 0.4% prevalence of high-grade dysplasia or cancer and a 97.8% negative predictive value, suggesting that these patients could be safely monitored using capsule-sponge testing alone. The authors concluded that the capsule sponge risk stratification classifier enables clinicians to triage high-risk patients for earlier endoscopy while safely deferring invasive procedures for low-risk individuals.

Magnetic Capsule Endoscopy (CE)

Studies evaluating the diagnostic characteristics of magnetic CE as compared to conventional gastroscopy in the target population have generally demonstrated similar accuracy, sensitivity, and specificity, with increases in patient preference and an acceptable safety profile with the magnetic CE approach. However, the diagnostic characteristics of magnetic CE are inadequate to substitute for other modalities or to triage patients to other modalities based on the current literature. Direct evidence of improved outcomes or a strong chain of evidence to improved outcomes is lacking. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Denzer et al (2015) prospectively evaluated a magnetically guided gastric capsule compared to conventional gastroscopy in 189 patients with upper abdominal complaints (e.g., upper abdominal pain and/or anemia) from two French centers. In this first large study to evaluate magnetically guided capsule gastroscopy in patients with upper abdominal symptoms, the authors concluded that this technique was feasible in practice and clearly preferred by patients; however, further studies are needed to define its role in the clinical setting (e.g., as a filter test to stratify patients to undergo conventional gastroscopy or some other role). This non-US study reported a low sensitivity and provided an limited discussion of the types of upper abdominal complaints experienced by enrolled patients. No discussion in terms of the severity and duration of the complaints, as well as prior testing and treatment was undertaken, which makes determination of the appropriate place in

therapy for magnetic CE in patients with unexplained upper abdominal complaints difficult.

Liao et al (2016) evaluated the accuracy of magnetically controlled CE as compared with conventional gastroscopy in 350 patients with upper abdominal complaints in a prospective, multicenter, blinded comparison study conducted in China. Overall, with conventional gastroscopy as the gold standard, magnetic CE detected gastric focal lesions in the entire stomach with 90.4% sensitivity, 94.7% specificity, and 93.4% accuracy. Similar sensitivity and specificity results were observed with magnetic CE as compared to conventional gastroscopy when detecting focal lesions in the upper or lower stomach specifically. No lesions of significance were missed by magnetic CE. Only five patients reported an adverse event, with the majority of these events considered to be related to gastric preparation. The authors concluded that magnetic CE detects upper abdominal focal lesions with comparable accuracy to conventional gastroscopy and is a promising alternative for screening for gastric diseases.

Meltzer et al (2023) conducted the first pilot study of magnetically controlled capsule endoscopy (MCCE) in the United States. The primary objective was to demonstrate that MCCE could visualize the major anatomic regions of the stomach in symptomatic patients before an EGD. In this prospective, single-arm, single-center, comparative study, included symptomatic adult patients (N=40) who were referred for an EGD as part of a standard evaluation. Participants received MCCE before the EGD. MCCE videos were reviewed by two independent physicians and compared with subsequent EGD. Patients were followed for 30 days for safety outcomes and satisfaction. Of the 40 study patients, MCCE detected each of the 6 preidentified major gastric anatomic landmarks with a greater than 95% rate of visualization. Although every capsule was able to visualize the lower esophagus, the Z-line was only visible between 78% and 85% of cases. Thirty-five patients received a follow-up EGD, and no high-risk lesions were missed with MCCE. The study is limited by the small sample size, low number of pathologic lesions, and unblinded physician interpreting results. The authors concluded that future studies need to further establish the accuracy of MCCE compared with EGD for low-risk symptomatic patients.

Motility Capsule Endoscopy

Studies assessing the utility of motility capsule testing for suspected gastric motor disorders have been limited by study design and small sample sizes. Larger, well-designed studies are needed.

Stein et al (2013) conducted a systematic review for the Agency for Healthcare Research and Quality (AHRQ). Of the 12 studies included, seven studies evaluated the diagnosis of gastric emptying delay. The strength of evidence in available studies on the ingestible capsule for assessing colonic transit times was found to be low overall. No studies were identified that compared the SmartPill to colonic scintigraphy. Accuracy of the ingestible capsule in diagnosing slow-transit constipation was similar to tests using radiopaque markers. A moderate correlation between colonic transit times with the ingestible capsule and tests with radiopaque markers was shown in five studies (range, 0.69-0.71). The authors concluded that although the overall strength of evidence is low, data were relatively consistent and suggested that this modality is no less sensitive than conventional testing. The evidence is insufficient to determine whether use of the wireless motility capsule will improve outcomes of care.

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

Sangnes et al (2020) conducted a small prospective, single center, cohort study to compare the diagnostic reliability of WMC with scintigraphy in individuals with diabetic gastroparesis, with the objective of assessing diagnostic reliability. Although the researchers reportedly found a strong correlation between WMC and 4-hour GES, the study was limited by its small study size (n = 66) and a patient cohort that may have been more severely affected by their disease.

Kuo et al (2025) conducted a multicenter, comparative, prospective cohort study to compare and evaluate the performance characteristics of the Atmo Capsule and the SmartPill Capsule (discontinued reference standard WMC) for measurement of gastric emptying time (GET) and colonic transit time (CTT) in patients with confirmed or suspected disordered gastrointestinal transit. A total of 213 participants aged 22 years or older were enrolled, each meeting at least one of the following criteria: a history of delayed GET from a prior study within the past two years and/or symptoms suggestive of gastroparesis; functional constipation per Rome IV criteria; or constipation-predominant irritable bowel syndrome per Rome IV criteria. Measurements of GET and CTT using the Atmo and SmartPill capsules were strongly correlated, with observed biases within 10% of the delayed transit margin. Delayed GET (68/177) and delayed CTT (56/147) were each identified in 38% of participants, with 84% agreement between the devices for both delayed GET (sensitivity 68%, specificity 91%) and delayed CTT (sensitivity 83%, specificity 85%). No serious adverse device effects were reported. A noted limitation of the study was the lack of diversity in the participant cohort. Additionally, due to the limited number of cases with rapid transit, the study could not assess diagnostic agreement between the devices for identifying rapid transit times. The authors concluded that this comparative prospective study demonstrated that the Atmo Capsule provides reliable measurements of GET and CTT, correlating well with the SmartPill Capsule. With the discontinuation of the SmartPill, these findings suggest that the Atmo Capsule may serve as a clinically useful and viable alternative for evaluating gastrointestinal transit.

Patency Capsule

The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. The overall balance of harm and benefit of using the patency capsule cannot be determined from the existing studies.

Delvaux et al (2005) evaluated the usefulness of this system in 22 patients with suspected intestinal stenosis who were also undergoing CE. The authors stated that the current technical development of the patency capsule limits its use in clinical practice, as it did not detect stenoses undiagnosed by computed tomography (CT) or small bowel follow-through. They also stated that the start of dissolution at 40 hours after ingestion was too slow to prevent episodes of intestinal occlusion. The authors noted that patients with Crohn's disease are most likely to be at risk of blockage of

progression of the capsule and should benefit from a CT investigation before CE. They noted that a careful interview eliciting the patient's medical history and symptoms remains the most useful indicator with regard to suspicion of an intestinal stenosis.

Signorelli et al (2006) evaluated 32 patients. The 26 patients who excreted the patency capsule intact, without experiencing abdominal pain, were deemed eligible for the CE procedure, which was performed uneventfully in the 25 who agreed to undergo the examination. The authors stated that the patency capsule "is 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.

Kim et al (2025) conducted a systematic review and meta-analysis to evaluate the diagnostic accuracy of patency capsule (PC) and cross-sectional imaging (CSI) in predicting capsule retention (CR) during small bowel capsule endoscopy (SBCE), particularly in patients with suspected small bowel stenosis. A total of 23 studies involving 3,273 patients were included: 17 studies assessed PC (n = 3,051), four assessed CSI (n = 140), and two evaluated both PC and CSI (n = 82). The pooled sensitivity and specificity of CSI for predicting CR were 54% and 88%, respectively. In comparison, PC demonstrated a pooled sensitivity of 75% and specificity of 94%. PC showed significantly higher specificity (p = 0.05) and a lower pooled false-negative rate than CSI (p = 0.001).

PROFESSIONAL GUIDELINE(S)

Small Bowel Capsule Endoscopy

In 2017, the American Gastroenterological Association's (AGA) issued a clinical practice guideline on the use of video capsule endoscopy (Enns 2017).

- CE is recommended for patients presenting with clinical features consistent with Crohn's disease (CD), and negative ileocolonoscopy and imaging studies; for patients with CD and clinical features unexplained by ileocolonoscopy or imaging studies; in patients with polyposis syndromes, in suspected small-bowel recurrence of CD; for patients with celiac disease and unexplained symptoms despite treatment and appropriate investigations, and repeated obscure bleeding.
- AGA recommends against CE for patients with suspected celiac disease.

The 2017 American Society for Gastrointestinal Endoscopy (ASGE) clinical guideline on the role of endoscopy in the management of suspected small-bowel bleeding suggest video CE as the initial test for patients with overt or occult small-bowel bleeding.

Refractory celiac disease management guidelines, issued by the American Gastroenterological Association's (AGA) (Green et al 2022) recommend:

- Perform small bowel imaging with capsule endoscopy and computed tomography or magnetic

resonance enterography to exclude enteropathy-associated T-cell lymphoma and ulcerative jejunoileitis at initial diagnosis of type 2 refractory celiac disease (RCD2).

- Repeat imaging should be obtained in patients with RCD2 who are clinically worsening due to the increased risk of lymphoma. The presence of strictures, inflammation, erosions, ulcers, or mass lesions on capsule endoscopy or cross-sectional imaging should prompt further evaluation with small bowel enteroscopy to secure a pathologic diagnosis.

Celiac disease diagnosis and management by capsule endoscopy is not addressed in the 2023 American College of Gastroenterology (ACG) guideline update (Rubio-Tapia et al 2023).

In 2023, the European Society of Gastrointestinal Endoscopy (ESGE) issued guideline recommendations on small-bowel capsule endoscopy and device-assisted enteroscopy for diagnosis and treatment of small-bowel disorders (Pennazio 2023).

- Recommend: small-bowel capsule endoscopy as the first-line examination, before consideration of other endoscopic and radiological diagnostic tests for suspected small-bowel bleeding. (Strong recommendation, moderate quality evidence)
- Does not recommend: routine second-look endoscopy prior to small-bowel capsule endoscopy in patients with suspected small-bowel bleeding or iron-deficiency anemia. (Strong recommendation, low-quality evidence)
- Recommend: the performance of small-bowel capsule endoscopy as a first-line examination in patients with iron-deficiency anemia when small bowel evaluation is indicated. (Strong recommendation, high-quality evidence)
- Recommend: small-bowel capsule endoscopy in patients with suspected CD and negative ileo-colonoscopy findings as the initial diagnostic modality for investigating the small bowel, in the absence of obstructive symptoms or known bowel stenosis. (Strong recommendation, high-quality evidence)
- Recommend: in patients with established CD, the use of a patency capsule before small-bowel capsule endoscopy to decrease the capsule retention rate. (Strong recommendation, moderate quality evidence).

<u>Polyposis Syndromes</u>

In 2020, the American Society for Gastrointestinal Endoscopy (ASGE) guideline on the role of endoscopy in familial adenomatous polyposis syndromes recommends screening sigmoidoscopy or colonoscopy in suspected FAP (Yang 2020). However, the ASGE acknowledges that with the advent of CE, it has become the preferred imaging modality, because false-negative rates in contrast studies are up to 42% for polyps >10 mm in FAP patients. When compared with magnetic resonance enterography (MRE), CE is also more sensitive for detecting smaller polyps. The two tests performed equally for detecting polyps >15 mm, although MRE was more reliable for determining the location and size of polyps. MRE also has the advantage of imaging outside the GI tract, including detecting desmoid tumors.

In 2022, the US Multi-Society Task Force on Colorectal Cancer (USMSTF) recommended that individuals diagnosed with Peutz-Jeghers syndrome undergo a baseline small bowel surveillance, using video CE or MRE, performed between ages 8-10 years or earlier if the patient is symptomatic (Boland et al 2022). If no polyps are found at the initial examination, surveillance should resume at age 18. (Strong recommendation, low quality of evidence)

Lynch Syndrome

The 2019 European Society of Gastrointestinal Endoscopy (ESGE) guideline on endoscopic management of Lynch syndrome and of familial risk of colorectal cancer does not address the use of capsule endoscopy (van Leerdam 2019).

Colon Capsule Endoscopy

In 2020, the European Society of Gastrointestinal Endoscopy (ESGE) and European Society of Gastrointestinal and Abdominal Radiology (ESGAR) issued updated best practice guidelines for imaging alternatives to colonoscopy: CT colonography (CTC) and colon capsule endoscopy (CCE) specific to patients undergoing screening or with suspicion of colorectal neoplasm (Spada et al 2020). Consensus recommendations include:

- For previously incomplete colonoscopy: CCE may be considered (weak recommendation, low-quality evidence).
- For patients with symptoms suggestive of colorectal cancer, but a colonoscopy is contraindicated or not possible:
    - for patients with alarm symptoms: due to a lack of evidence, CCE is not recommended in this situation (very low-quality evidence).
    - for patients without alarm symptoms: CCE may be considered (weak recommendation, low-quality evidence).
- For colorectal cancer screening: CCE is not suggested as a first-line screening test (weak recommendation, low-quality evidence).
- There is insufficient evidence to recommend CCE for:
    - following curative-intent resection of colorectal cancer.
    - surveillance after polypectomy.

The 2021 American College of Gastroenterology (ACG) clinical guidelines for colorectal cancer screening suggest consideration of the colon capsule for screening [conditional recommendation; very low quality] (Shaukat et al 2021).

The 2021 U.S. Preventive Services Task Force (USPSTF) final recommendation statement for colorectal cancer screening specifically indicates that USPSTF recommendation does not include capsule endoscopy for colorectal cancer screening due to limited available evidence on these tests and because other effective tests (i.e., the recommended screening strategies) are available.

The 2026 National Comprehensive Cancer Network (NCCN version 2.2026) clinical practice guidelines for colorectal cancer screening do not include capsule endoscopy as an image-based colorectal

cancer screening modality. However, NCCN footnotes state, “for patients who have had incomplete colonoscopy, consider CE as alternative exam for completing the screening.”

GI Bleed Detection Capsule Endoscopy

There are currently no recommendations from professional medical societies supporting the use of GI bleed detection capsule endoscopy for any clinical indication.

Esophageal Capsule

The 2019 American Society for Gastrointestinal Endoscopy (ASGE) guidelines on screening and surveillance of Barrett’s esophagus (BE) acknowledge the significant potential of emerging screening technologies beyond standard upper endoscopy. These include esophageal capsule endoscopy, Cytosponge (Medtronic), tethered capsule endomicroscopy, and electronic nose devices. However, the ASGE panel ultimately endorsed screening for BE in at-risk populations based on the available evidence regarding BE prevalence in specific groups.

The 2022 clinical practice update from the American Gastroenterological Association (AGA) on new technologies for BE screening and surveillance reaffirmed that upper endoscopy with biopsies remains the gold standard for diagnosing BE (Muthusamy 2022). Nonetheless, the AGA issued best practice advice supporting the consideration of nonendoscopic cell-collection devices—such as Cytosponge (Medtronic GI Solutions), EsoCheck (Lucid Diagnostics), and EsophaCap (Capnostics) as screening options for BE. While all three devices have demonstrated excellent tolerability, safety, and sensitivity for BE diagnosis, the AGA emphasized the need for further data to validate patient selection criteria and determine the optimal settings for their use in the United States.

The 2023 European Society of Gastrointestinal Endoscopy (ESGE) guidelines on the diagnosis and management of Barrett esophagus (BE) recommends that a swallowable non-endoscopic cell collection device (e.g., Cytosponge) can be used as an alternative to endoscopy for case finding of Barrett’s esophagus (strong recommendation, high-quality evidence) (Weusten et al 2023). The recommendation was based on findings from observational case-controlled studies and one randomized controlled trial.

Magnetic Capsule Endoscopy (CE)

There are currently no recommendations from professional medical societies supporting the use of magnetic capsule endoscopy for any clinical indication.

Motility Capsule Endoscopy

In 2021, the United European Gastroenterology (UEG) and European Society for Neurogastroenterology and Motility (ESNM) consensus on gastroparesis did not endorse the statement that wireless motility capsule (WMC) assessment is a valid test of diagnosing gastroparesis [Grade B recommendation] (Schol 2021). Noting the pitfall with WMC is that it is an indigestible solid and, therefore, it empties from the stomach in response to phase 3 migrating motor complexes rather than with the test meal.

The 2022 American Gastroenterological Association (AGA) expert review clinical practice update on management of medically refractory gastroparesis reiterated the EUG/ESNM consensus concern that

because the WMC, an inanimate object, identifies the phase III activity front of the migrating motor complex rather than overall gastric emptying, a meal-based test provides better physiological assessment of gastric emptying and is thus recommended as the first-line test of gastric emptying over the WMC (Lacy 2022).

The American College of Gastroenterology (ACG) updated clinical guidelines on gastroparesis recommends scintigraphy gastric emptying (SGE) as the standard test for the evaluation of gastroparesis in patients with upper GI symptoms (strong recommendation, moderate level of evidence) (Camilleri 2022). The ACG reports that research supports WMC testing as an alternative test to SGE for the evaluation of gastroparesis in patients with upper GI symptoms and made a conditional recommendation (low quality of evidence) that WMC testing may be an alternative to the SGE assessment.

Patency Capsule

The 2017 American Gastroenterological Association (AGA) clinical practice guidelines for the use of video CE states “In patients with known or suspected strictures of the small bowel, we suggest a patency capsule before CE to minimize risk of retention. (GRADE: Conditional recommendation, very low-quality evidence for efficacy, low-quality evidence for safety).” (Enns 2017).

The 2023 European Society of Gastrointestinal Endoscopy (ESGE) guideline on small-bowel capsule endoscopy and device-assisted enteroscopy for diagnosis and treatment of small-bowel disorders recommends, in patients with established Crohn’s disease, the use of a patency capsule before small-bowel capsule endoscopy to decrease the capsule retention rate (Pennazio 2023). (Strong recommendation, moderate quality evidence)

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) regulates capsule endoscopy systems as medical devices. All capsule endoscopy systems including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 Aug 21]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: https://www.fda.gov/medical-devices/medical-device-safety/medical-device-recalls [accessed 2026 Aug 21]

The FDA has cleared several capsule endoscopy devices, including but not limited to devices that visualize small bowel mucosa (e.g., PillCam SB2 and SB3), esophageal mucosa (e.g., PillCam ESO), the colon (e.g., PillCam COLON), and the stomach (e.g., NaviCam Stomach Capsule System). In addition, the FDA has cleared capsules for other diagnostic purposes, such as verifying GI patency (e.g., PillCam Patency Capsule), measuring gastrointestinal transit time (e.g., Atmo Gas Capsule), and detecting the presence of blood in the GI tract (e.g., PillSense System).

Small Bowel Capsule Endoscopy

The Given Diagnostic Imaging System, PillCam SB, received initial Section 510(k) marketing clearance from the FDA on August 1, 2001. The FDA cleared the device for use along with, not as a replacement for, other endoscopic and radiologic evaluations of the small bowel. On July 2, 2003, the FDA approved the PillCam SB as a first-line tool in the detection of abnormalities of the small bowel, removing the adjunctive tool qualifier. On October 29, 2003, the FDA announced that it had expanded its approved indications for the use of wireless CE, PillCam SB, to include visualization of the small bowel and detection of abnormalities in symptomatic children aged 10 to 18 years. This approval was based on data from a small trial where the wireless CE was able to diagnose or definitively exclude a bleeding source, small bowel polyps or Crohn's disease in 29 out of 30 children. In September 2009, the FDA expanded its approval of the PillCam SB for use in children aged two years and up.

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

Ingestible Esophageal Capsule

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

Colon Capsule Endoscopy

Given Imaging received FDA Section 510(k) clearance (Class II) for the PillCam COLON 2 in February 2014. The clearance is intended for use in patients who had an incomplete traditional colonoscopy and still require a better review of the passageway.

Patency Capsule

The FDA approved the Agile patency capsule in May 2006 as an accessory to the Pill Cam video capsule, 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. Medtronic replaced the Agile Patency System with an updated product, PillCam Patency Capsule, which was FDA cleared in 2018.

Motility Capsule Endoscopy

In 2006, the ingestible capsule (SmartPill GI Monitoring System) was FDA-cleared through the Section 510(k) process for the evaluation of delayed gastric emptying. In 2009, the FDA expanded the use of the SmartPill to determine colonic transit time for the evaluation of chronic constipation and to differentiate between slow and normal transit constipation. The SmartPill motility capsule was discontinued in June 2023.

The Atmo Gas Capsule (Atmo Biosciences, Ltd) received FDA premarket approval in June 2025. The capsule measures whole gut and regional gut (stomach, small bowel, and colon) transit times for the evaluation of patients with suspected gastroparesis, and it not for use in pediatric patients.

Magnetic Capsule Endoscopy (CE)

The FDA approved a novel magnetically maneuvered CE system, NaviCam (AnX Robotica, Inc.) in May 2020. The device is contraindicated for use in patients with gastrointestinal obstruction, stenosis, fistula, or those with dysphagia. Other contraindications include patients with cardiac pacemakers or other implantable electronic medical devices as well as pregnant women, those less than 22 years of age, and those with a body mass index of 38 or greater.

Blood Detection Capsule Endoscopy

In February 2023, the FDA approved a novel ingestible GI blood detection capsule, PillSense System (EnteraSense) intended to be used as an adjunct, not a standalone diagnostic device, for clinical decision making. The device is a single-use ingestible capsule uses spectrophotometry (light absorption technology) to detect blood in the upper gastrointestinal tract and wirelessly transmits data to an external receiver.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
91110	Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus through ileum, with interpretation and report
91111	Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus with interpretation and report
91112 (E/I)	Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report
91113 (E/I)	Gastrointestinal tract imaging, intraluminal colon (e.g., capsule endoscopy), with

Code	Description
	interpretation and report
91299 (*E/I)	Unlisted diagnostic gastroenterology procedure *E/I when billed as use of patency capsule and blood detection capsule
0651T (E/I)	Magnetically controlled capsule endoscopy, esophagus through stomach, including intraprocedural positioning of capsule, with interpretation and report
0977T (E/I)	Upper gastrointestinal blood detection, sensor capsule, with interpretation and report

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HCPCS Codes

Code	Description
Not Applicable	

ICD10 Codes

Code	Description
Multiple Codes	

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SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Colon Capsule Endoscopy (CCE) (LCD L38571) [accessed 2026 Aug 21]

Billing and Coding: Colon Capsule Endoscopy (CCE) (A58294) [accessed 2026 Aug 21]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION

Committee Approval Dates

06/20/02, 01/16/03, 01/15/04, 12/16/04, 10/20/05, 09/21/06, 10/18/07, 11/20/08, 10/29/09, 12/16/10, 11/17/11, 10/18/12, 09/19/13, 08/21/14, 08/20/15, 07/21/16, 07/20/17, 07/19/18,

06/20/19, 08/20/20, 08/19/21, 08/18/22, 10/19/23, 10/17/24, 10/16/25, 10/22/26	
Date	**Summary of Changes**
10/22/26	• Annual review, policy intent unchanged.
10/16/25	• Annual review, policy intent unchanged.
01/01/25	• Summary of changes tracking implemented.
06/20/02	• Original effective date