



Capsule Endoscopy Clinical Coverage Criteria

Overview

With capsule endoscopy, also known as wireless capsule endoscopy or video capsule endoscopy, is a noninvasive procedure that uses a swallowed capsule-shaped miniature camera for direct visual and diagnostic evaluation of gastrointestinal disease. Although originally intended as a tool to examine the small intestine, which is mostly beyond the reach of conventional endoscopy, capsule endoscopy is now also being used to examine the entire length of the gastrointestinal tract. Endoscopic delivery is available for patients who have difficulty swallowing (e.g., dysphagia, gastroparesis, known or suspected anatomical abnormalities). The capsule is propelled by peristalsis through the gastrointestinal track until it is excreted naturally. A significant drawback of capsule endoscopy is the inability to fully control the movement of the device or obtain a biopsy.

Policy

This Policy applies to the following Fallon Health products:

- Fallon Medicare Plus, Fallon Medicare Plus Central (Medicare Advantage)
- MassHealth ACO
- NaviCare HMO SNP (Dual Eligible Medicare Advantage and MassHealth)
- NaviCare SCO (MassHealth-only)
- PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)

Capsule endoscopy of the small bowel (CPT 91110), esophagus (CPT Code 91111) and colon (CPT Code 91113) require prior authorization.

Fallon Health Clinical Coverage Criteria

Capsule Endoscopy of the Small Bowel (Esophagus Through Ileum) (CPT Code 91110)

Fallon Health Clinical Coverage Criteria for capsule endoscopy of the small bowel (esophagus through ileum) apply to Fallon Medicare Plus, Fallon Medicare Plus Central and Community Care members.

Effective for dates of service on or after 12/01/2024, Fallon Health will use InterQual® Criteria when making medical necessity determinations for capsule endoscopy of the small bowel (esophagus through ileum) (CPT 91110).

For coverage criteria, refer to the InterQual® Criteria in effect on the date of service:

- InterQual® CP:Procedures Capsule Endoscopy
- InterQual® CP:Procedures Capsule Endoscopy (Pediatric)

Fallon Health makes InterQual criteria available to the public through the transparency tool on our website, effective January 1, 2024.

Capsule Endoscopy of the Esophagus (CPT Code 91111)

Fallon Health Clinical Coverage Criteria for capsule endoscopy of the esophagus apply to all plan members.

Capsule endoscopy of the esophagus may be considered medically necessary for the evaluation of esophageal varices when all the following criteria are met:

- The patient is diagnosed with cirrhosis and portal hypertension and has no prior variceal bleeding (Hwang et al., 2014), and
- Capsule endoscopy is being used as an alternative to esophagogastroduodenoscopy (EGD), at the request of the treating physician for a patient who cannot or will not undergo EGD. EGD is widely accepted as the gold standard method to detect esophageal varices (Richardson et al, 2020).

The optimal surveillance intervals for esophageal varices have not been determined. For patients with compensated cirrhosis found to have no varices on initial screening endoscopy, repeat endoscopy every 2 to 3 years has been suggested, whereas patients with small varices should undergo repeat endoscopy every 1 to 2 years. Esophageal varices may develop faster in patients with cirrhosis secondary to alcohol abuse, decompensated liver disease, and in those with small varices with high-risk stigmata (red wale marks or red spots) on endoscopic examination. This subgroup of patients should undergo yearly upper endoscopy, even when no or only small varices are seen on initial screening (Hwang et al., 2014).

Capsule Endoscopy of the Colon (CPT Code 91113)

Fallon Health Clinical Coverage Criteria for capsule endoscopy of the colon apply to MassHealth ACO and Community Care members.

Fallon Health has adopted National Government Services, Inc. coverage criteria for colon capsule endoscopy (L38571 Revision Effective Date For services performed on or after 02/15/2022).

Capsule endoscopy of the colon is considered medically necessary when either of the following criteria are met:

1. Primary procedure in patients with major risks for optical colonoscopy or moderate sedation as indicated from an evaluation of the patient by a board-certified or board eligible gastroenterologist, a surgeon trained in endoscopy, or a physician with equivalent endoscopic training when either of the following criteria are met:
 - a. Surveillance of colon polyp(s) in previously diagnosed patients, or
 - b. Diagnostic procedure when any of the following criteria are met:
 - i. Fecal occult blood test (FOBT) positive (guaiac or immunochemical) or
 - ii. Multitarget stool DNA (sDNA) test positive or
 - iii. Other evidence of lower GI bleeding in hemodynamically stable patients
2. Secondary procedure after an incomplete optical colonoscopy with adequate preparation, and a complete evaluation of the colon was not technically possible when either of the following criteria are met:
 - a. Detection or surveillance of colon polyp(s), or
 - b. Diagnostic procedure when any of the following criteria are met:
 - i. Fecal Occult Blood Test (FOBT) positive (guaiac or immunochemical) **OR**
 - ii. Multitarget Stool DNA (sDNA) Test positive **OR**
 - iii. Other evidence of lower GI bleeding in hemodynamically stable patients

Exclusion Criteria

1. Patient with known or suspected gastrointestinal obstruction, stricture, or fistula.
2. Patient with a cardiac pacemaker or another implanted electro-medical device that emits a radiofrequency or other interfering signal.
3. Patient with a swallowing disorder.
4. Patient with a known contraindication or allergy to any medication or preparation agent used before or during the procedure.
5. May not be performed in conjunction with CT colonography.
6. May not be performed for colorectal cancer screening, regardless of family history or other risk factors for the development of colonic disease.

Medicare Variation

Medicare statutes and regulations do not have coverage criteria for capsule endoscopy. Medicare does not have an NCD for capsule endoscopy. National Government Services, Inc., the Part A/B Medicare Administrative Contractor (MAC) with jurisdiction in the Plan's service area does not have an LCD for capsule endoscopy of the small bowel (esophagus through ileum) or esophagus. National Government Services, Inc. does have an LCD for Colon Capsule Endoscopy (CCE) (L38571) (Medicare Coverage Database search 9/5/2025).

Coverage criteria for colon capsule endoscopy (CPT 91113) are fully established by Medicare in National Government Services, Inc. LCD L38571.

Coverage criteria for capsule endoscopy of the esophagus through ileum (small bowel) (CPT 91110) and capsule endoscopy of the esophagus (CPT 91111) are not fully established by Medicare; therefore, the Plan's coverage criteria are applicable.

[Link](#): Colon Capsule Endoscopy (CCE) (L38571)

MassHealth Variation

MassHealth has Guidelines for Medical Necessity Determination for Capsule Endoscopy (MassHealth website search 9/5/2025). The Guidelines state: "*These guidelines apply to duodenal and small intestinal CE (capsule endoscopy). PA requests for esophageal or colonic capsule endoscopy require additional documentation of medical necessity including, but not limited to, documentation of contraindication for EGD or colonoscopy.*"

Criteria in the MassHealth Guidelines apply to capsule endoscopy of the small bowel (CT 91110). Fallon Health Clinical Coverage Criteria apply to requests for capsule endoscopy of the esophagus (CPT 91111) and capsule endoscopy of the colon (CPT 91113).

[Link](#): Guidelines for Medical Necessity Determination for Capsule Endoscopy

Exclusions

- Capsule endoscopy is contraindicated in patients with known or suspected intestinal obstruction, strictures, or fistulas and in patients with cardiac or other implanted electrical devices (ASGE Technology Status Evaluation Report Video Capsule Endoscopy, 2021).
- Patency capsule testing. The purpose of the patency capsule is to inform the decision to proceed to capsule endoscopy by confirming adequate patency of the gastrointestinal tract in patients with known or suspected strictures. Published studies do not provide evidence for the clinical utility of this capsule. It is important to note that there is no specific procedure code for patency capsule testing. The appropriate code is CPT 91299. No part of this service may be reported as a covered service. The ingestion of the capsule is part of the test, and an Evaluation & Management (E&M) service may not be billed for this purpose. An X-ray or other imaging technique to confirm passage or detect a patency capsule remaining in the GI tract is not covered.
- Wireless Gastrointestinal Motility Monitoring System (SmartPill®) (CPT 91112).
- Magnetically controlled capsule endoscopy (CPT 0651T) is considered experimental/investigational and not medically necessary for the visualization of the stomach in the evaluation of unexplained upper abdominal complaints and all other indications.

Summary of Evidence

Capsule Endoscopy of the Esophagus

Esophageal varices and bleeding are complications of portal hypertension and decompensated liver disease. Traditional evaluation of varices is with esophagogastroduodenoscopy (EGD), which allows for biopsy of suspicious areas and concurrent treatment.

Effective prophylactic treatments exist for patients with esophageal varices to prevent variceal bleeding. There are no reliable methods for predicting which cirrhotic patients will have esophageal varices without endoscopy. The most recent American Association for the Study of Liver Disease (AASLD) and Baveno V consensus guidelines suggest that all patients who have been diagnosed with cirrhosis undergo screening endoscopy to assess for esophageal and gastric varices. If esophageal varices are identified on endoscopy, they should be graded as small or large (>5 mm) and the presence of red wales or spots should be noted because these findings have been identified as risk factors for future bleeding. The optimal surveillance intervals for esophageal varices have not been determined. For patients with compensated cirrhosis found to have no varices on initial screening endoscopy, repeat endoscopy every 2 to 3 years has been suggested, whereas patients with small varices should undergo repeat endoscopy every 1 to 2 years. Esophageal varices may develop faster in patients with cirrhosis secondary to alcohol abuse, decompensated liver disease, and in those with small varices with high-risk stigmata (red wale marks or red spots) on endoscopic examination. This subgroup of patients should undergo yearly upper endoscopy, even when no or only small varices are seen on initial screening (Hwang et al., 2014).

The potential role of capsule endoscopy in managing varices was noted in a meta-analysis of 1,328 patients conducted by McCarty et al., 2017. Most of the studies were assessed to have a low risk of bias although, in eight studies, a high risk of bias was found. The diagnostic accuracy of wireless capsule endoscopy in the diagnosis of esophageal varices was 90% [95% confidence interval (CI), 0.88-0.93]. The diagnostic pooled sensitivity and specificity were 83% (95% CI, 0.76-0.89) and 85% (95% CI, 0.75-0.91), respectively. The diagnostic accuracy of wireless capsule endoscopy for the grading of medium to large varices was 92% (95% CI, 0.90-0.94). The pooled sensitivity and specificity were 72% (95% CI, 0.54-0.85) and 91% (95% CI, 0.86-0.94), respectively, for the grading of medium to large varices. The authors concluded that capsule endoscopy could not replace upper endoscopy as the initial procedure of choice for patients with varices or variceal bleeding, but that it may have a role in patients who cannot or will not undergo EGD.

Colli et al., 2014 conducted a Cochrane Review to determine the diagnostic accuracy of capsule endoscopy for the diagnosis of esophageal varices in children or adults with chronic liver disease or portal vein thrombosis, irrespective of the etiology. Sixteen eligible studies, in which only adults with cirrhosis were included. In one study, people with portal thrombosis were also included. Most of the studies were classified as at high risk of bias. One study assessed the accuracy of capsule endoscopy for the diagnosis of large (high-risk) esophageal varices. In the remaining 15 studies that assessed the accuracy of capsule endoscopy for the diagnosis of esophageal varices of any size in people with cirrhosis, 936 participants were included; the pooled estimate of sensitivity was 84.8% (95% confidence interval (CI) 77.3% to 90.2%) and of specificity 84.3% (95% CI 73.1% to 91.4%). Eight of these studies included people with suspected varices or people with already diagnosed or even treated varices, or both, introducing a selection bias. Seven studies including only people with suspected but unknown varices were at low risk of bias; the pooled estimate of sensitivity was 79.7% (95% CI 73.1% to 85.0%) and of specificity 86.1% (95% CI 64.5% to 95.5%). Six studies assessed the diagnostic accuracy of capsule endoscopy for the diagnosis of large esophageal varices, associated with a higher risk of bleeding; the pooled sensitivity was 73.7% (95% CI 52.4% to 87.7%) and of specificity 90.5% (95% CI 84.1% to 94.4%). Two studies also evaluated the presence of red marks, which are another marker of high risk of bleeding; the estimates of sensitivity and specificity varied widely. Two studies obtained similar results with the use of a modified device as index test (string capsule). Due to the absence of data, the authors could not perform all planned subgroup analyses. Interobserver agreement in the interpretation of capsule endoscopy results and any adverse event attributable to capsule endoscopy were poorly assessed and reported. Only four studies evaluated the interobserver agreement in the interpretation of capsule endoscopy results: the concordance was moderate. The participants' preferences for capsule endoscopy or EGD were reported differently but seemed in favor of capsule endoscopy in nine of 10 studies. In 10 studies, participants reported some minor discomfort on swallowing the capsule. Only one study identified other significant

adverse events, including impaction of the capsule due to previously unidentified oesophageal strictures in two participants. No adverse events were reported as a consequence of the reference standard. The authors concluded that they could not support the use of capsule endoscopy as a triage test in adults with cirrhosis, administered before EGD, despite the low incidence of adverse events and participant reports of being better tolerated. Thus, the authors could not conclude that EGD can be replaced by capsule endoscopy for the detection of oesophageal varices in adults with cirrhosis. The authors found no data assessing capsule endoscopy in children.

De Franchis et al., 2008 conducted a multicenter trial designed to assess the diagnostic performance of capsule endoscopy in comparison with EGD. Patients undergoing EGD for screening or surveillance of esophageal varices underwent a capsule study previously. The study was designed as an equivalence study, assuming that a difference of $\leq 10\%$ between capsule endoscopy and EGD in diagnosing esophageal varices would demonstrate equivalence. Two hundred eighty-eight patients were enrolled. 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 capsule endoscopy was 85.8%; the kappa score was 0.73. Capsule endoscopy had a sensitivity, specificity, positive predictive value, and negative predictive value of 84%, 88%, 92%, and 77%, respectively. The difference in diagnosing esophageal varices was 15.6% in favor of EGD. There was complete agreement on variceal grade in 227 of 288 cases (79%). In differentiating between medium/large varices requiring treatment and small/absent varices requiring surveillance, the sensitivity, specificity, positive predictive value, and negative predictive value for capsule endoscopy were 78%, 96%, 87%, and 92%, respectively. Overall agreement on treatment decisions based on esophageal varices size was substantial at 91% (kappa = 0.77). The authors recommend that EGD be used to screen patients with cirrhosis for large esophageal varices. However, the minimal invasiveness, good tolerance, and good agreement of capsule endoscopy with EGD might increase adherence to screening programs.

Magnetically Controlled Capsule Endoscopy

Capsule endoscopy (CE) has been used for decades and represents an alternative to gastroscopy. Although CE plays more and more important role in the diagnosis and management of diseases through esophagus, small bowel and colon, its application has not yet been expanded to stomach. The anatomical and physiological characteristics of stomach demand traditional passive capsule to be actively controlled by endoscopists. Years of studies have suggested that steerable capsules with external magnetic field may be the most viable approaches for active control, and several explorations have shown promising benefits.

Several different methods of controlling the magnetic capsule within the stomach have been developed, including but not limited to hand-held magnets, an MRI-type magnetically guided capsule endoscope (MGCE) system jointly developed by Olympus Medical Systems Corporation and Siemens Healthcare, a robotic-type magnetically controlled capsule endoscopy (MCE) system developed by ANKON Technologies Co. Ltd., Wuhan, China (Navicam Capsule Endoscope System), and a standing-type magnetically controlled capsule endoscopy (SMCE), (JIFU Medical Technologies Co., Ltd, Shenzhen, China).

Hand-Held Magnetic Navigator

Clinical studies have evaluated capsule endoscopy controlled by a hand-held magnet. In 2016, Rahman et al. conducted a study to test the degree of visualization and maneuverability of the the MiroCam-Navi (Intromedic Ltd., Seoul, South Korea) navigation system in 26 healthy volunteers. Volunteers subsequently underwent a standard gastroscopy. The study results showed that visualization and imaging (obtaining clear views) differed across different parts of the stomach. Optimal visualization, defined as a non-obscure view that enabled clear identification of landmarks and mucosa, was best in the stomach body and pylorus (100%) and poorest at the cardia (88%); notably, clear views were best obtained following optimal pre-procedural stomach preparation. The capsule identified erosions and gastritis in four patients each, and gastroscopy confirmed these lesions. However, gastroscopy successfully diagnosed a 5 mm sized

submucosal lesion, which was missed by the capsule owing to suboptimal preparation and difficulty with obtaining clear views of the cardia. Moreover, maneuverability was poor in the proximal stomach because the distance between the magnet and the ventral surface was greater than that between the magnet and distal stomach.

In contrast to the previous study that included healthy volunteers, Ching et al. 2019 used the MiroCam-Navi system in 49 patients with recurrent or refractory iron deficiency anemia to identify pathological lesions in the stomach and compared their findings with those obtained after esophagogastroduodenoscopy (EGD). Comparisons of total (upper GI and small bowel) and upper GI diagnostic yields, gastric mucosal visibility, and patient comfort scores were the primary end points. Combined upper GI and small bowel examination using the magnetically assisted capsule detected more pathology than EGD alone (113 vs. 52; $P < 0.001$) in patients with recurrent or refractory IDA.

In prospective cohort study, Ching et al. 2019 compared the diagnostic performance of the MiroCam-Navi system compared to EGD in 33 patients with suspected acute upper GI bleeding (ClinicalTrials.gov: NCT02690376). No statistically significant difference was observed in the detection of significant lesions that are likely causes of bleeding by magnetic capsule endoscopy (peptic ulcers, esophageal varices, and gastric varices) and those detected by EGD (14 vs. 13, $p = 1$), which identified esophageal varices, gastric varices, gastric ulcers, and duodenal ulcers. magnetic capsule endoscopy could identify lesions missed by EGD and these included esophageal and duodenal bulb ulcers in one and four patients, respectively. Capsule endoscopy identified an additional cause for bleeding in the small bowel in 18% and was better tolerated than EGD.

Lien et al., 2018 developed a novel hand-held magnetic-assisted capsule endoscope system to visualize the entire upper GI tract and evaluated the safety and feasibility of the system for the examination of the upper GI tract, including the esophagus, stomach, and duodenum in 10 healthy volunteers with a mean age and body mass index of 47.7 years and 25.6 kg/m², respectively. One volunteer withdrew because of difficulty in swallowing the capsule. In total, nine volunteers underwent the magnetic-assisted capsule endoscope examination. The average examination time was 27.1 min. The maneuverability of the capsule was assessed as good and fair in 55.6 and 44.4% of the participants, respectively. The overall completeness of the examination in the esophagus, stomach, and duodenum was 100, 85.2, and 86.1%, respectively. No severe adverse events occurred during this study.

Electromagnetic Coil System

The magnetic capsule endoscope system developed by Olympus and Siemens uses an electromagnetic coil system similar to existing MRIs to advance the capsule in the gastric cavity. The feasibility of using an electromagnetic coil system to advance a magnetic capsule was demonstrated by Rey et al. 2010. In a pilot study involving 61 patients (Rey et al., 2012) 58.3% of gastric lesions were detected by both MGCE and gastroscopy. MGCE missed 14 findings, and gastroscopy missed 31 findings seen with MGCE. Overall diagnostic yield was similar for both modalities.

In 2015, Denzer et al. prospectively evaluated blinded MRI-type MGCE compared to blinded conventional gastroscopy in the diagnosis of major gastric lesions (defined as lesions that require conventional gastroscopy for biopsy or resection) in patients with upper gastrointestinal symptoms. Examination of the esophagus and duodenum was not included in this comparative study (ClinicalTrials.gov NCT01555840), which was conducted in France. If results of the blinded MGCE and blinded gastroscopy differed, then a subsequent unblinded gastroscopy was performed. Biopsies were taken whenever appropriate. Among 189 symptomatic patients (105 male; mean age 53 years), a total of 23 major lesions were found in 21 patients. The diagnostic accuracy of MGCE was 90.5% [95% confidence interval (CI), 85.4%-94.3%] with a specificity of 94.1% (95% CI, 89.3%-97.1%) and a sensitivity of 61.9% (95% CI, 38%-82%). The positive predictive value (PPV) and negative predictive value (NPV) were 56.5% (95% CI, 34.5% to 76.8%) and 95.2% (95% CI, 90.7% to 97.9%), respectively. Among the remaining 168 patients,

94% had minor and mostly multiple lesions, and the diagnostic accuracy of MGCE was 88.1% (95% CI, 82.2%-92.6%). No complications of capsule or conventional gastroscopy were noted. Patient preference for capsule use for a future gastroscopy, if indicated, was 100%. In this study, the authors concluded that MGCE was feasible in practice and clearly preferred by patients; however, further studies are needed to define its role in the clinical setting.

Robotic-Type Magnetically Controlled Capsule Endoscopy

The Navicam Capsule Endoscope System is a novel robot-controlled magnetic-controlled capsule endoscopy (MCE) system developed by ANKON Technologies Co. Ltd. (Wuhan, China). The system includes a capsule endoscope, a guidance magnet robot, a data recorder, and a computer workstation with software for real-time view and control. The Navicam Capsule Endoscope System is currently the only FDA-approved magnetically controlled capsule endoscopy system in the U.S. (510(k) Product Code QRX), and is being marketed by AnX Robotica, Inc. (Plano, Tx).

Liao et al. 2012, assessed the feasibility and safety of the robot-controlled magnetic-controlled capsule endoscopy (MCE) system in 34 healthy volunteers (mean age 41.3±13.1 years; mean body mass index 23.2±3.2 kg/m²). This study was conducted in China. Feasibility was evaluated through two end points: (1) overall maneuverability of MCE (good, the MCE followed control and moved to targeted anatomical landmark precisely; moderate, the MCE followed control and moved towards the direction of anatomical landmark but did not reach target precisely; poor, the MCE did not follow control); and (2) visualization of gastric mucosa (good, >75% of mucosa was observed; moderate, 50% to 75% was observed; poor, <50% of the gastric mucosa was observed) and primary anatomical landmarks (cardia, fundus, body, angulus, antrum and pylorus of stomach). Maneuverability of the MCE was graded as good in 29 (85.3%) subjects and moderate in 5 (14.7%) subjects. Visualization of the gastric mucosa was assessed as good (>75%) in 27 (79.4%) subjects and moderate (50% to 75%) in 7 (20.6%) subjects. Polyp and erosive lesions were found in 7 subjects. The patients had a high degree of acceptance in the preparation before and during the examination, and there were no adverse events.

Zou et al (2015) further evaluated the diagnostic accuracy of MRI-type MCE compared to conventional gastroscopy in 68 patients (32 men, 36 women; mean age 48 years, range 24–70 years) with upper abdominal complaints suitable for gastroscopic examination. The study was conducted at 2 tertiary referral centers in China. The capsule was swallowed, and water was ingested with no problems in any patient. Eight patients needed to drink more than the usual 1000mL of water to maintain stomach distension. The mean total examination time of MCE was 29.1 ± 8.5 minutes (range 8–53 minutes) vs. 5.0 ± 1.0 minutes (range 3.0–7.2 minutes) for the standard gastroscopy (P<0.001). Following the MCE examination by the first endoscopist, patients then underwent a standard gastroscopy examination, which was performed 4–24 hours later by another endoscopist. When necessary, biopsy specimens were obtained. The patient and second endoscopist were blinded to the results of MCE. A comparison between MCE and standard gastroscopy for determining whether gastric areas appeared normal vs. abnormal showed that findings in 14 patients were normal and 48 were abnormal by both methods. These data resulted in a negative percent agreement of 77.8 %, a positive percent agreement of 96.0 %, an overall agreement of 91.2% (95 %CI 84.4%–97.9 %), and a kappa value of 0.765 (two-sided exact, P<0.001). The McNemar test showed a P value of 0.687, indicating the results provided by the two examinations were not significantly different. A total of 68 pathological findings were detected, of which 53 were identified by both methods. The MCE and standard gastroscopy missed seven and eight findings, respectively. In this study, the authors concluded that MCE showed a diagnostic accuracy similar to that of standard gastroscopy, suggesting that MCE is a promising alternative to gastroscopy for noninvasive screening of gastric diseases. Technical modifications are needed, and the quality of gastric preparation procedures requires further improvement.

In 2016, Liao et al. evaluated the accuracy of magnetic CE as compared with conventional gastroscopy in 350 patients (mean age, 46.6 y) with upper abdominal complaints in a prospective, multicenter, blinded comparison study involving seven hospitals in China

(Clinicaltrials.gov number: NCT02219529). All patients underwent magnetic CE followed by conventional gastroscopy 2 hours later, without sedation. The primary outcome of the study was an evaluation of gastric focal lesions. Overall, with conventional gastroscopy as the gold standard, magnetic CE detected gastric focal lesions in the whole stomach with 90.4% sensitivity (95% CI, 84.7% to 96.1%), 94.7% specificity (95% CI, 91.9% to 97.5%), and. The PPV and NPV were 87.9% (95% CI, 81.7% to 94%) and 95.9% (95% CI, 93.4% to 98.4%), respectively. MCE detected focal lesions in the upper stomach (cardia, fundus, and body) with 90.2% sensitivity (95% CI, 82.0%-98.4%) and 96.7% specificity (95% CI, 94.4%-98.9%). MCE detected focal lesions in the lower stomach (angulus, antrum, and pylorus) with 90.6% sensitivity (95% CI, 82.7%-98.4%) and 97.9% specificity (95% CI, 96.1%-99.7%). MCE detected 1 advanced gastric carcinoma, 2 malignant lymphomas, and 1 early stage gastric tumor. No lesions of significance were missed by magnetic CE. Additionally, 335 (95.7%) patients preferred magnetic CE over conventional gastroscopy and only 5 patients reported an adverse event; the majority of these events were considered to be related to gastric preparation. The authors concluded that magnetic CE can be used to screen for gastric diseases without sedation.

Lai et al., 2020 evaluated the feasibility and safety of a standing-type magnetic CE in a prospective, multicenter study conducted at three tertiary referral hospitals in China. Ability to detect gastric lesions was compared between SMCE and gastroscopy. The SMCE system (JIFU Medical Technologies Co., Ltd, Shenzhen, China) comprises a capsule endoscope, a guidance magnetic robot, and imaging computer. The magnetic robot is a standing-type system without arms and contains wireless receivers. Adult patients between 18 and 70 years who had upper abdominal complaints and were scheduled for gastroscopy were eligible. Patients with any of the following were excluded: (i) various acute types of enteritis, such as bacterial dysentery, acute ulcerative colitis, asphyxia etc.; (ii) known or suspected gastrointestinal obstruction, stenosis, and fistula; (iii) acute phase of upper gastrointestinal perforation; (iv) severe throat disease; (v) acute phase of corrosive esophagitis; (vi) severe gastric dysmotility; (vii) electronic device implanted; (viii) previous history of allergy; and (ix) pregnancy. A total of 171 patients were enrolled and 165 completed the protocol. SMCE was conducted first. Six anatomical landmarks (cardia, fundus, body, angulus, antrum, and pylorus) were observed. When the patient stood with his/her left side close to the machine, the capsule moved to the fundus, cardia and body; when the patient stood with the abdomen close to the machine, the capsule moved to the angulus, antrum, and pylorus. Gastroscopy with intravenous anesthesia was performed 4 hours after SMCE by two endoscopists who were blinded to the results of SMCE. Six landmarks were observed and photographed. If clinically necessary, pathological biopsy specimens were taken. Operator recorded all the results of gastroscopy, including lesion location, size, and characteristics. Average time to conduct SMCE was 24.17 ± 7.48 min (range, 7–47 min), whereas average time to conduct the gastroscopy was 7.06 ± 4.18 min (range, 2–32 min). One hundred and six patients were determined as negative and 55 as positive. These findings lead to a positive agreement of 92.0% (95% CI: 80.77%–97.78%), a negative agreement of 95.5% (89.80%, 98.52%), an overall agreement of 94.41% (89.65%, 97.41%), and a kappa-value of 0.870 (two-sided exact, $P < 0.0001$). McNemar's test indicated a P-value of 0.11 ($P = 0.74$), suggesting that the results obtained from both investigations were not significantly different. Sixty-four pathological findings were identified, of which 50 lesions were detected by both procedures. Gastroscopy identified seven extra lesions that were overlooked by SMCE, together with one erosion, two polyps, one atrophic gastritis, and three SMT. SMCE also detected seven lesions that were overlooked by gastroscopy including five erosions, one polyp, and one ulcer. The polyps not detected by gastroscopy were confirmed and treated by another endoscopic procedure. Abdominal X-ray confirmed that there was no capsule retention during follow up. Of the 165 subjects included in the safety set, 152 (92.1%) subjects had confirmed capsule excretion in the feces during the follow-up period (2 weeks), and the remaining 13 (7.9%) subjects finally confirmed excretion within 2 weeks by X-ray. Adverse reactions were reported in three (1.8%) of the 165 patients who finished the study. One patient had nausea and vomiting, one patient had oral pain, and one patient had dizziness. Nausea and vomiting were considered a result of the gastric preparation procedure. All described symptoms disappeared within 24 h after the SMCE

procedure. Among the 165 patients, 99 (60.0%) preferred SMCE, and 66 (40.0%) patients preferred gastroscopy.

Analysis of Evidence (Rationale for Determination)

Capsule Endoscopy of the Esophagus

Two systematic reviews conclude that capsule endoscopy cannot replace esophagogastroduodenoscopy (EGD) in the diagnosis of esophageal varices, but capsule endoscopy may have a role in patients with portal hypertension and decompensated liver disease who cannot or will not undergo EGD.

Magnetically Controlled Capsule Endoscopy

In diagnostic accuracy studies, MCE demonstrates high diagnostic accuracy comparable to esophagogastroduodenoscopy (EGD) for detecting gastric conditions, suggesting it could be an effective noninvasive alternative. 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 use of a magnetically controlled wireless capsule (e.g., NaviCam®) is considered experimental/ investigational.

Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

Note CPT 91110-91113 may not be reported for the same patient on the same date of service.

Code	Description
91110	Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy); esophagus through ileum, with physician interpretation and report
91111	Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus with interpretation and report
91112	Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report.
91113	Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), colon, with interpretation and report
0651T	Magnetically controlled capsule endoscopy, esophagus through stomach, including intraprocedural positioning of capsule, with interpretation and report

References

1. Mishkin DS, Chuttani R, Croffie J, et al; Technology Assessment Committee, American Society for Gastrointestinal Endoscopy. ASGE Technology Status Evaluation Report: Wireless Capsule Endoscopy. *Gastrointest Endosc.* 2006 Apr;63(4):539-45.
2. Muhammad A, Pitchumoni CS. Newly Detected Celiac Disease by Wireless Capsule Endoscopy in Older Adults with Iron Deficiency Anemia. *J Clin Gastroenterol.* 2008 Oct;42(9):980-3.
3. Apostolopoulos P, Liatsos C, Gralnek IM et al., The Role of Wireless Capsule Endoscopy in Investigating Unexplained Iron Deficiency Anemia After Negative Endoscopic Evaluation of the Upper and Lower Gastrointestinal Tract. *Endoscopy.* 2006 Nov;38(11):1127-32.
4. Moy L, Levine J. Wireless Capsule Endoscopy in the Pediatric Age Group: Experience and Complications. *J Pediatr Gastroenterol Nutr.* 2007 Apr;44(4):516-20.
5. Saperas E, Dot J, Videla S, et al. Capsule Endoscopy versus Computed Tomographic or Standard Angiography for the Diagnosis of Obscure Gastrointestinal Bleeding. *Gastroenterol.* 2007 Apr;102(4):731-7.
6. Saurin JC, Delvaux M, Vahedi K, et al. Clinical Impact of Capsule Endoscopy Compared to Push Enteroscopy: 1-Year Follow-up Study. *Endoscopy.* 2005 Apr;37(4):318-23.

7. Hindryckx P, Botelberge T, De Vos M et al. Clinical Impact of Capsule Endoscopy on Further Strategy and Long-Term Clinical Outcome in Patients with Obscure Bleeding. *Gastrointest Endosc.* 2008;68:98-104.
8. Van Gossum A, Navas MM, Fernandez-Urien I, et al. Capsule Endoscopy Versus Colonoscopy for the Detection of Polyps and Cancer. *N Engl J Med.* 2009;361(3):264-70.
9. Redondo-Cerezo E, Sánchez-Capilla AD, De La Torre-Rubio P, De Teresa J. Wireless capsule endoscopy: perspectives beyond gastrointestinal bleeding. *World J Gastroenterol.* 2014 Nov 14;20(42):15664-73.
10. Neumann H, Fry LC, Nägel A, Neurath MF. Wireless capsule endoscopy of the small intestine: a review with future directions. *Curr Opin Gastroenterol.* 2014 Sep;30(5):463-71.
11. Song HJ, Shim KN. Current status and future perspectives of capsule endoscopy. *Intest Res.* 2016 Jan;14(1):21-9.
12. Choi M, Lim S, Choi MG, Shim KN, Lee SH. Effectiveness of capsule endoscopy compared with other diagnostic modalities in patients with small bowel Crohn's disease: a meta-analysis. *Gut Liver.* 2017;11(1):62-72.
13. Enns RA, Hookey L, Armstrong D, et al. Clinical practice guidelines for the use of video capsule endoscopy. *Gastroenterology.* 2017;152(3):497-514.
14. Chetcuti Zammit S, Sanders DS, Sidhu R. Capsule endoscopy for patients with coeliac disease. *Expert Rev Gastroenterol Hepatol.* 2018 Aug;12(8):779-790.
15. Sealock RJ, Thrift AP, El-Serag HB, Sellin J. Long-term follow up of patients with obscure gastrointestinal bleeding examined with video capsule endoscopy. *Medicine (Baltimore).* 2018 Jul;97(29):e11429.
16. Hosoe N, Takabayashi K, Ogata H, Kanai T. Capsule endoscopy for small-intestinal disorders: Current status. *Dig Endosc.* 2019 Jan 17.
17. MassHealth Guidelines for Medical Necessity Determination for Capsule Endoscopy. Policy Effective Date: June 1, 2018. Policy Revision Effective Date: 5/3/2023. Available at: <https://www.mass.gov/guides/masshealth-guidelines-for-medical-necessity-determination-for-capsule-endoscopy>. Accessed 09/05/2025.
18. National Government Services, Inc. Local Coverage Determination (LCD): Colon Capsule Endoscopy (CCE) (L38571). Original Effective Date For Services Performed on or after 04/15/2021. Revision Effective Date For Services Performed on or after 02/15/2022. Available at: <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=38571>. Accessed 09/05/2025.
19. National Government Services, Inc. LCD Reference Article: Billing and Coding: Colon Capsule Endoscopy (CCE) (A58294). Original Effective Date 04/15/2021. Revision Effective Date 01/01/2022 Available at: <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=58294&ver=7>. Accessed 09/05/2025.
20. Boivin ML, Lochs H, Voderholzer WA. Does passage of a patency capsule indicate small-bowel patency? A prospective clinical trial? *Endoscopy.* 2005;37:808-815.
21. Gay G, Delvaux M, Laurent V, et al. Temporary intestinal occlusion induced by a "patency capsule" in a patient with Crohn's disease. *Endoscopy.* 2005;37:174-177.
22. Herrerias JM, Leighton JA, Costamagna G, et al. Agile patency system eliminates risk of capsule retention in patients with known intestinal strictures who undergo capsule endoscopy. *Gastrointest Endosc.* 2008 May;67(6):902-9.
23. Melson J, Trikudanathan G, Abu Dayyeh BK, et al. Video capsule endoscopy. *Gastrointest Endosc.* 2021 Apr;93(4):784-796.
24. Hwang JH, Shergill AK, Acosta RD, et al. American Society for Gastrointestinal Endoscopy. The role of endoscopy in the management of variceal hemorrhage. *Gastrointest Endosc.* 2014 Aug;80(2):221-7.
25. Sharma P, Wani S, Rastogi A, et al. The diagnostic accuracy of esophageal capsule endoscopy in patients with gastroesophageal reflux disease and Barrett's esophagus: a blinded, prospective study. *Am J Gastroenterol.* 2008;103:525-32.
26. Bhardwaj A, Hollenbeak CS, Pooran N, et al. A meta-analysis of the diagnostic accuracy of esophageal capsule endoscopy for Barrett's esophagus in patients with gastroesophageal reflux disease. *Am J Gastroenterol.* 2009;104:1533-9.

26. Rubenstein JH, Inadomi JM, Brill JV, et al. Cost utility of screening for Barrett's esophagus with esophageal capsule endoscopy versus conventional upper endoscopy. *Clin Gastroenterol Hepatol*. 2007;5: 312-8.
27. McCarty TR, Afinogenova Y, Njei B. Use of wireless capsule endoscopy for the diagnosis and grading of esophageal varices in patients with portal hypertension: a systematic review and meta-analysis. *J Clin Gastroenterol*. 2017;51:174-82.
28. Frenette CT, Kuldau JG, Hillebrand DJ, et al. Comparison of esophageal capsule endoscopy and esophagogastroduodenoscopy for diagnosis of esophageal varices. *World J Gastroenterol*. 2008 Jul 28;14(28):4480-5.
29. Grace ND, Groszmann RJ, Garcia-Tsao G, et al. Portal hypertension and variceal bleeding: an AASLD single topic symposium. *Hepatology*. 1998;28:868-880.
30. Garcia-Tsao G, Sanyal AJ, Grace ND, et al. Prevention and management of gastroesophageal varices and variceal hemorrhage in cirrhosis. *Hepatology*. 2007;46:922-38.
31. de Franchis R. Revising consensus in portal hypertension: report of the Baveno V consensus workshop on methodology of diagnosis and therapy in portal hypertension. *J Hepatol*. 2010;53:762-8.
32. de Franchis R, Eisen GM, Laine L, et al. Esophageal capsule endoscopy for screening and surveillance of esophageal varices in patients with portal hypertension. *Hepatology*. 2008 May;47(5):1595-603.
33. Garcia-Tsao G, Abraldes JG, Berzigotti A, Bosch J. Portal hypertensive bleeding in cirrhosis: Risk stratification, diagnosis, and management: 2016 practice guidance by the American Association for the study of liver diseases. *Hepatology*. 2017 Jan;65(1):310-335. Erratum in: *Hepatology*. 2017 Jul;66(1):304.
34. Tisoris A, Marlar CA. Use Of The Child Pugh Score In Liver Disease. [Updated 2023 Mar 13]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK542308/>.
35. Tapper EB, Parikh ND. Diagnosis and Management of Cirrhosis and Its Complications: A Review. *JAMA*. 2023 May 9;329(18):1589-1602.
36. Park J, Cho YK, Kim JH. Current and Future Use of Esophageal Capsule Endoscopy. *Clin Endosc*. 2018 Jul;51(4):317-322.
37. Richardson E, Arastu S, Halegoua-DeMarzio D. PRO: Esophagogastroduodenoscopy Is the Preferred Modality to Screen for the Diagnosis of Esophageal and Gastric Varices When the Diagnosis of Cirrhosis Is Made. *Clin Liver Dis (Hoboken)*. 2020 Sep 4;16(2):43-47.
38. Cardey J, Le Gall C, Michaud L, et al. Screening of esophageal varices in children using esophageal capsule endoscopy: a multicenter prospective study. *Endoscopy*. 2019 Jan;51(1):10-17.
39. Colli A, Gana JC, Turner D, et al. Capsule endoscopy for the diagnosis of oesophageal varices in people with chronic liver disease or portal vein thrombosis. *Cochrane Database Syst Rev*. 2014 Oct 1;2014(10):CD008760.
40. O'Hara F, Walker C, McNamara D. Patency testing improves capsule retention rates but at what cost? A retrospective look at patency testing. *Front Med (Lausanne)*. 2023 Aug 9;10:1046155.

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41. Rahman I, Pioche M, Shim CS, et al. Magnetic-assisted capsule endoscopy in the upper GI tract by using a novel navigation system (with video). *Gastrointest Endosc*. 2016 May;83(5):889-895.e1.
42. Ching HL, Hale MF, Kurien M, et al. Diagnostic yield of magnetically assisted capsule endoscopy versus gastroscopy in recurrent and refractory iron deficiency anemia. *Endoscopy*. 2019 May;51(5):409-418.
43. Ching HL, Hale MF, Sidhu R, et al. Magnetically assisted capsule endoscopy in suspected acute upper GI bleeding versus esophagogastroduodenoscopy in detecting focal lesions. *Gastrointest Endosc*. 2019 Sep;90(3):430-439.
44. Lien GS, Wu MS, Chen CN, et al. Feasibility and safety of a novel magnetic-assisted capsule endoscope system in a preliminary examination for upper gastrointestinal tract. *Surg Endosc*. 2018 Apr;32(4):1937-1944.

45. Kim JH, Nam SJ. Capsule Endoscopy for Gastric Evaluation. *Diagnostics (Basel)*. 2021 Sep 28;11(10):1792.
46. Rey JF, Ogata H, Hosoe N, et al. Feasibility of stomach exploration with a guided capsule endoscope. *Endoscopy*. 2010 Jul;42(7):541-5.
47. Rey J. F., Ogata H., Hosoe N., et al. Blinded nonrandomized comparative study of gastric examination with a magnetically guided capsule endoscope and standard videoendoscope. *Gastrointest Endosc*. 2012;75(2):373–381.
48. Denzer UW, Rösch T, Hoytat B, et al. Magnetically guided capsule versus conventional gastroscopy for upper abdominal complaints: a prospective blinded study. *J Clin Gastroenterol*. Feb 2015; 49(2): 101-7.
49. Liao Z, Duan XD, Xin L, et al. Feasibility and safety of magnetic-controlled capsule endoscopy system in examination of human stomach: a pilot study in healthy volunteers. *J Interv Gastroenterol*. 2012 Oct-Dec;2(4):155-160.
50. Zou WB, Hou XH, Xin L, et al. Magnetic-controlled capsule endoscopy vs. gastroscopy for gastric diseases: a two-center self-controlled comparative trial. *Endoscopy*. 2015 Jun;47(6):525-8.
51. Liao Z, Hou X, Lin-Hu EQ, et al. Accuracy of Magnetically Controlled Capsule Endoscopy, Compared With Conventional Gastroscopy, in Detection of Gastric Diseases. *Clin Gastroenterol Hepatol*. Sep 2016; 14(9): 1266-1273.
52. Lai HS, Wang XK, Cai JQ, et al. Standing-type magnetically guided capsule endoscopy versus gastroscopy for gastric examination: multicenter blinded comparative trial. *Dig Endosc*. 2020 May;32(4):557-564.
53. Wang X, Hu X, Xu Y, et al. A systematic review on diagnosis and treatment of gastrointestinal diseases by magnetically controlled capsule endoscopy and artificial intelligence. *Therap Adv Gastroenterol*. 2023 Oct 27;16:17562848231206991.
54. Yang J, Mao YH, Zeng Q. Diagnostic Accuracy of Tethered Control and Magnetically Controlled Capsule Endoscopy in Esophageal Diseases: A Meta-analysis. *J Clin Gastroenterol*. 2025 Jun 2.
55. Zhang Y, Zhang Y, Huang X. Development and Application of Magnetically Controlled Capsule Endoscopy in Detecting Gastric Lesions. *Gastroenterol Res Pract*. 2021 Dec 30;2021:2716559.
56. Cui J, Wang Z, Li S, Yu Z. Diagnostic accuracy of magnetically controlled capsule endoscopy for gastric conditions: a systematic review and meta-analysis. *Eur J Gastroenterol Hepatol*. 2025 Jun 24.
57. Xiao YF, Wu ZX, He S, et al. Fully automated magnetically controlled capsule endoscopy for examination of the stomach and small bowel: a prospective, feasibility, two-centre study. *Lancet Gastroenterol Hepatol*. 2021 Nov;6(11):914-921.

Policy history

Origination date:	03/01/2004
Review/Approval(s):	Technology Assessment Subcommittee: 06/23/2009, 07/28/2009 Technology Assessment Committee: 02/23/2004, 09/30/2009, 6/25/2013, 09/24/2014 (updated criteria to have consistent across all plans and updated references, removed patency capsule exclusion), 09/23/2015 (updated references), 09/15/2016 (updated references), 09/27/2017 (updated references), 08/22/2018 (updated references), 09/10/2019 (removed definitions, updated references), 07/20/2021 (Added clarifying language related to Medicare Advantage, NaviCare and PACE under policy section), 10/29/2024 (annual review; changed title to Capsule Endoscopy, formerly Wireless Capsule Endoscopy; adopted InterQual® Criteria for capsule endoscopy of the small bowel; added coverage criteria for capsule endoscopy of the esophagus; added coverage criteria for capsule endoscopy of the colon,

updated References), 09/23/2025 (annual review; added exclusion for magnetically controlled capsule endoscopy and updated Summary of Evidence Summary and Analysis of Evidence; no changes to coverage criteria). UM Committee: 11/19/2024 (annual review), 10/21/2025 (annual review, approved with addition of exclusion for magnetically controlled capsule endoscopy and no changes to coverage criteria).

Instructions for Use

Fallon Health complies with CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations for Medicare Advantage members. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health may create internal coverage criteria under specific circumstances described at § 422.101(b)(6)(i) and (ii).

Fallon Health generally follows Medical Necessity Guidelines published by MassHealth when making medical necessity determinations for MassHealth members. In the absence of Medical Necessity Guidelines published by MassHealth, Fallon Health may create clinical coverage criteria in accordance with the definition of Medical Necessity in 130 CMR 450.204.

For plan members enrolled in NaviCare, Fallon Health first follows CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, or if the NaviCare member does not meet coverage criteria in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health then follows Medical Necessity Guidelines published by MassHealth when making necessity determinations for NaviCare members.

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.