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 requires prior authorization.

Medicare Advantage
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).

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 but does have an LCD for Colon Capsule Endoscopy (CCE) (L38571) (Medicare Coverage Database search 10/28/2024).

Link: **Colon Capsule Endoscopy (CCE) (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 and therefore the Plan's coverage criteria are applicable.

Coverage criteria for colon capsule endoscopy (CPT 91113) are fully established by Medicare in L38571, therefore the Plan's coverage criteria are not applicable.

MassHealth ACO
Fallon Health 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.

MassHealth has Guidelines for Medical Necessity Determination for Capsule Endoscopy. 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**

NaviCare HMO SNP, NaviCare SCO
For plan members enrolled in NaviCare, Fallon Health first follow's 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.

PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
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.

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® 2024, Mar. 2024 Release, CP:Procedures Capsule Endoscopy
- InterQual® 2024, Mar. 2024 Release, 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.

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).
- PillCam 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.
- Wireless Gastrointestinal Motility Monitoring System (SmartPill®) (CPT 91112).

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 < or=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.

Analysis of Evidence (Rationale for Determination)

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.

Coding

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

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
91113	Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), colon, with interpretation and report

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Policy history

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