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Subject: Wireless Capsule Endoscopy

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Wireless capsule endoscopy (capsule endoscopy) is a device intended to visualize portions of the bowel which are not accessible via upper or lower endoscopy, primarily the small bowel. Patients swallow the capsule, and it records images of the intestinal mucosa as it passes through the gastrointestinal (GI) tract. The capsule is collected after being excreted and the images interpreted.

Several systems, devices, and components for gastrointestinal imaging have received U.S. Food and Drug Administration (FDA) 510(k) clearance (e.g., Given® Diagnostic Imaging System, Given® Diagnostic System with the PillCam™ ESO, Given® AGILE Patency System, Olympus Capsule Endoscope System, and PillCam® COLON 2 Capsule Endoscopy System, NaviCam™).

Summary of Evidence: Cash et al (2021) colon capsule endoscopy (CCE) has shown promise for colorectal neoplasia detection compared with optical colonoscopy (OC) but has not been compared with other screening tests in average risk screening patients. Patients 50 to 75 years of age (African Americans, 45-75 years) were randomized to CCE or CT colonography (CTC) and subsequent blinded OC. The primary endpoint was diagnostic yield of polyps ≥6 mm with CCE or CTC. Secondary endpoints included accuracy for size and histology, examination completeness, number/proportion of subjects with polyps and adenomas ≥6 mm and ≥10 mm, subject satisfaction, and safety. From 320 enrolled subjects, data from 286 (89.4%) were evaluable. The proportion of subjects with any polyp ≥6 mm confirmed by OC was 31.6% for CCE versus 8.6% for CTC (pPr non-inferiority and superiority=0.999). The diagnostic yield of polyps ≥10 mm was 13.5% with CCE versus 6.3% with CTC (pPr non-inferiority=0.9954). The sensitivity and specificity of CCE for polyps ≥6 mm was 79.2% and 96.3% while that of CTC was 26.8% and 98.9%. The sensitivity and specificity of CCE for polyps ≥10 mm was 85.7% and 98.2% compared with 50% and 99.1% for CTC. Both tests were well tolerated/safe. The authors concluded that CCE was superior to CTC for detection of polyps ≥6 mm and non-inferior for

identification of polyps ≥10 mm. CCE should be considered comparable or superior to CTC as a colorectal neoplasia screening test, although neither test is as effective as OC.

Fireman et al (2003) evaluated the effectiveness of wireless capsule endoscopy in patients with suspected Crohn's disease (CD) of the small bowel undetected by conventional modalities, and to determine the diagnostic yield of the M2A Given Capsule. The small bowel is the most commonly, affected site of CD although it may involve any part of the gastrointestinal tract. The current methodologies for examining the small bowel are x ray and endoscopy. Seventeen patients (eight males, mean age 40 (15) years) with suspected CD fulfilled study entry criteria: nine had iron deficiency anemia (mean hemoglobin 10.5 (SD 1.8) g%), eight had abdominal pain, seven had diarrhea and three had weight loss. Small bowel x ray and upper and lower gastrointestinal endoscopic findings were normal. Mean duration of symptoms before diagnosis was 6.3 (SD 2.2) years. Each subject swallowed an M2A Given Capsule containing a miniature video camera, batteries, a transmitter, and an antenna. Recording time was approximately eight hours. The capsule was excreted naturally in the patient's bowel movement, and the data it contained were retrieved and interpreted the next day. Of the 17 study participants, 12 (70.6%, six males, mean age 34.5 (12) years) were diagnosed as having CD of the small bowel according to the findings of the M2A Given Capsule. Wireless capsule endoscopy diagnosed CD of the small bowel (diagnostic yield of 71%). It was demonstrated as being an effective modality for diagnosing patients with suspected CD undetected by conventional diagnostic methodologies.

Enns et al (2017) video capsule endoscopy (CE) provides a noninvasive option to assess the small intestine, but its use with respect to endoscopic procedures and cross-sectional imaging varies widely. consensus includes 21 statements focused on the use of small-bowel CE and colon capsule endoscopy. CE was recommended for patients with suspected, known, or relapsed Crohn's disease when ileocolonoscopy and imaging studies were negative if it was imperative to know whether active Crohn's disease was present in the small bowel. It was not recommended in patients with chronic abdominal pain or diarrhea, in whom there was no evidence of abnormal biomarkers typically associated with Crohn's disease. CE was recommended to assess patients with celiac disease who have unexplained symptoms despite appropriate treatment, but not to make the diagnosis. In patients with overt gastrointestinal bleeding, and negative findings on esophagogastroduodenoscopy and colonoscopy, CE should be performed as soon as possible. CE was recommended only in selected patients with unexplained, mild, chronic iron-deficiency anemia. CE was suggested for surveillance in patients with polyposis syndromes or other small-bowel cancers, who required small-bowel studies. Colon capsule endoscopy should not be substituted routinely for colonoscopy. Patients should be made aware of the potential risks of CE including a failed procedure, capsule retention, or a missed lesion. Standardized criteria for training and reporting in CE should be defined. The authors concluded that CE generally should be considered a complementary test in patients with gastrointestinal bleeding, Crohn's disease, or celiac disease, who have had negative or inconclusive endoscopic or imaging studies.

A prospective multicenter study Bruining et al (2020) was performed in subjects with established Crohn's disease. Individuals with proven small bowel patency underwent a standardized bowel preparation, followed by capsule endoscopy (CE) ingestion and ileocolonoscopy (IC) either the same or following day. magnetic resonance enterography (MRE), IC, and CE interpretations were performed by blinded central readers using validated scoring systems. The primary endpoint was the overall sensitivity of CE vs MRE and/or IC in Crohn's disease subjects. Study enrolment included 158 subjects from 21 sites in the USA, Austria, and Israel. Of those, 99 were included in the analysis. Imaging modality scores

indicated none to mild inflammation in the proximal small bowel and colon, but discrepant levels of inflammation in the terminal ileum. 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 advents of which three were related to the CE device. The authors concluded that panenteric CE is a reliable tool for assessing Crohn's disease mucosal activity and extent compared with more invasive methods. This study demonstrates high performance of the panenteric CE as compared to MRE and/or IC without the need for multiple tests in non-stricturing Crohn's disease.

In a review of colon capsule endoscopy (CCE) with a focus on its recent developments, technological improvements, and current and potential future indications. Findings included that CCE II demonstrates comparable polyp detection rates as optical colonoscopy and CT colonography, and improved cost-effectiveness. The main limitation to patient acceptance is the requirement of a rigorous bowel preparation. Preliminary studies show good correlation between CCE and optical colonoscopy for assessment of colonic disease activity in inflammatory bowel disease (IBD). CCE II is currently FDA, approved as an adjunctive test in patients with prior incomplete colonoscopy, and in the evaluation of patients with suspected lower gastrointestinal bleeding. The test is approved in Europe as one of the options for average-risk colorectal cancer screening, and high-risk screening in patients with contraindications or unwilling to undergo colonoscopy. CCE has a potential role in the evaluation and monitoring of colonic disease activity in IBD. Future technological advances should focus on minimizing bowel preparation, improvement in reading times, and development of therapeutic capabilities. • With technological improvements, the second-generation colon capsule has a significantly higher sensitivity than the first-generation capsule for detection of colon polyps. Colon capsule endoscopy has been approved in Europe as an option for average-risk colorectal cancer screening, and high-risk screening in patients with contraindications or unwilling to undergo colonoscopy. Colon capsule endoscopy has received FDA approval as an option for colorectal cancer screening in patients with prior incomplete colonoscopy, and in evaluation of patients with suspected lower gastrointestinal bleeding. Colon capsule endoscopy may have a role in evaluation and monitoring of inflammatory bowel disease. Colon capsule endoscopy currently requires a bowel preparation that is more rigorous than colonoscopy (Pasha, 2018).

In a review Nakamura et al (2022) described the appropriate use of the patency capsule (PC) for evaluating small bowel disorders, including contraindications, and proposes a novel strategy to minimize the risks of capsule retention in small bowel capsule endoscopy (SBCE). The retention of the capsule used during SBCE is a serious complication that can occur in patients with known or suspected small bowel stenosis, and a prior evaluation of the patency of the gastrointestinal (GI) tract is therefore essential. Patency capsule (PC) is a non-diagnostic capsule the same size as the diagnostic SBCE. The PC test provides the useful information prior to SBCE; however, confirmation of GI tract patency is sometimes difficult. Several methods to evaluate the PC localization have been proposed, but no gold standard has yet been established. Therefore, future studies should focus on optimizing PC localization to improve the safety of this procedure. To date, there are no clear guidelines regarding the contraindications for undergoing a PC evaluation prior to SBCE. Each small bowel disorder has specific occasions to inhibit the progress of PC and SBCE, even though they do not have any stenotic symptoms or abnormalities on imaging.

Silva et al (2019) in a prospective single-center study including Crohn's disease (CD) patients with clinical indication for small-bowel capsule endoscopy. PillCam® patency capsule (PC) examination was performed on all patients to assess small-bowel patency. On all patients with a positive identification of the PC using a radiofrequency identification tag (RFIT) scanner, 30 h after ingestion, an abdominal computed tomography (CT) was performed in order to identify its precise location. Fifty-four patients were included. The PC retention rate, according to evaluation with the RFIT scanner, was 20% (in 11 patients) 30 h after ingestion. These patients were then submitted to abdominal CT, which revealed that there was small-bowel retention in 5 cases (9%). Higher CRP levels, penetrating disease, and a history of abdominal surgery were associated with an increased risk of PC retention ($p = 0.007$, $p = 0.011$, and $p = 0.033$, respectively). On multivariate analysis, there was an independent association between small-bowel PC retention and CRP levels >5 mg/dL (OR = 15.5; $p = 0.03$). The small-bowel PC retention rate (9%) was considerably lower than those found in previous reports. The authors noted that their results show that, with this protocol, the false-positive cases of RFIT scans or plain abdominal X-rays may be avoided. This may contribute to more extensive application of capsule endoscopy without the risk of small-bowel retention. The authors concluded that this is one of the largest series evaluating gastrointestinal patency in CD patients, performed in a single center, following the same PC protocol. The small bowel PC retention rate of 9% in this prospective study was considerably lower than the rates previously reported. The results show that, with this protocol, false-positive cases from RFIT scanning or plain abdominal X-ray may be avoided, since abdominal CT, with reduced radiation exposure, is useful for identifying capsule retentions in the colon caused by delayed bowel transit. This may contribute to more extensive application of CE without the risk of small-bowel retention. Utilization of RFIT scanners is justified, because they allow better selection of patients requiring CT. Also, the authors believe that in the future, that the newly available LDCT with reported radiation doses of around 0.62 mSv, i.e., even lower than those from plain abdominal X-ray could replace plain abdominal X-ray in patients in whom the PC was not excreted within the defined time frame.

Sawada et al 2017 in a retrospective single-center study of 282 consecutive patients referred for patency capsule (PC) examination was performed. Patients in which the PC could not pass through the small bowel within 33 h were classified into the 'no patency' group. The 'no patency' group was investigated for evidence of significant stenosis upon further examinations, including capsule endoscopy (CE), double-balloon endoscopy, and small bowel follow-through after PC examination. Clinical factors related to small bowel patency and false-positive cases were evaluated. The authors included 161 male (57.1%) and 121 female (42.9%) patients with a mean age of 47.5 ± 17.7 years. Of the 282 patients enrolled, 27 patients exhibited 'no patency' upon PC examination. Multivariate analysis showed that clinical factors related to 'no patency' included Crohn's disease, abdominal symptoms, stenosis upon imaging, and previous abdominal surgery. Upon further examination, nine cases in the 'no patency' group had significant stenosis. Sensitivity, specificity, and negative and positive predictive values of PC examination for detecting small bowel stenosis were 93.8%, 96.6%, 99.6%, and 62.5%, respectively, and the only clinical factor related to false-positive cases was constipation ($p < 0.05$). The authors found a relatively low positive predictive value of PC examination and that constipation was related to false-positive results. To extend the implications of CE indications, clinical study focusing on these results is expected.

Wang et al (2023) conducted a systematic review to summarize the research progress of magnetically controlled capsule endoscopy (MCCE) and artificial intelligence (AI) in the diagnosis and treatment of gastrointestinal diseases (GID). MCCE was confirmed to have the same performance as conventional

gastroscopy and WCE in detecting common GID, while it lacks research in detecting early gastric cancer (EGC). The body position and cleanliness of the gastrointestinal tract are the main factors affecting imaging quality. The applications of AI in screening intestinal diseases have been comprehensive, while in the detection of common gastric diseases such as ulcers, it has been developed. MCCE can perform some additional functions, such as observations of drug behavior in the stomach and drug damage to the gastric mucosa. Furthermore, it can be improved to perform a biopsy. The authors noted that MCCE is in the primary stage of development, and clinical evidence for the detection of gastric lesions (particularly of gastric cancer) is limited. It does not have the advantages of conventional endoscopy in detecting gastric fluid, biopsy of lesions, or endoscopic treatment. MCCE with biopsy ability is in the basic research stage of preclinical application. Compared to conventional endoscopy, it takes a longer time to examine the gastrointestinal tract, has higher requirements for gastrointestinal preparation, and incurs a higher examination cost. In the future research and development of MCCE, performance parameters (e.g., imaging resolution, examination time, etc.) should be improved. The accuracy and efficiency of automatic image interpretation algorithms with AI technology should also be increased. MCCE functions should be expanded to biopsy, treatment, local drug delivery, and drug behavior monitoring. A large number of samples should be used to validate its effectiveness and feasibility in the diagnosis and treatment of GID. In addition, reducing the cost of MCCE could popularize it for EGC screening in large populations. Multifunctional imaging is also a future direction for the improvement of MCCE The authors concluded that their comprehensive review showed that the MCCE technology has made great progress, but studies on GID detection and treatment by MCCE are in the primary stage. Further studies are required to confirm the performance of MCCE.

Kopylov et al (2017) performed a systematic review and meta-analysis for trials comparing the accuracy of capsule endoscopy (CE), magnetic resonance enterography (MRE) and small bowel intestinal contrast ultrasound (SICUS) for detection of active small bowel (SB) inflammation in patients with suspected and/or established Crohn's disease (CD). Only prospective studies comparing CE with another additional diagnostic modality were included in the final analysis. Pooled odds ratios (ORs) for the diagnostic yield (DY) of the three modalities were calculated. A total of 112 studies were retrieved; following selection, 13 studies were eligible for analysis. The DY of CE for detection of active SB CD was similar to that of MRE (10 studies, 400 patients, OR 1.17; 95% CI 0.83-1.67) and SICUS (5 studies, 142 patients, OR 0.88; 95% CI 0.51-1.53). 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 (7 studies, 251 patients, OR 2.79; 95% CI 1.2-6.48); the difference vs SICUS was not significant. The authors concluded that CE, MRE and SICUS have similar DY for detection of SB CD in both suspected and established CD. CE is superior to MRE for detection of proximal SB disease however the risk of capsule retention should be considered.

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. 57, 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 entire stomach with 90.4% sensitivity (95% CI, 84.7% to 96.1%), 94.7% specificity (95% CI, 91.9% to 97.5%), and 93.4% accuracy (95% CI, 90.83% to 96.02%). The PPV and NPV were 87.9% (95% CI, 81.7% to 94%) and 95.9% (95% CI, 93.4% to 98.4%), respectively. 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. 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 detects upper abdominal focal lesions with comparable accuracy to conventional gastroscopy and is a promising alternative for screening for gastric diseases; however, similar to the prior study, this non-US study provided no discussion of the types of upper abdominal complaints experienced by patients or prior tests or treatments undertaken.

POSITION STATEMENT:

Wireless capsule endoscopy **meets the definition of medical necessity** for any of the following indications:

- Initial diagnosis in members with suspected Crohn's disease without evidence of disease on conventional diagnostic tests such as small-bowel follow-through (SBFT), and upper and lower endoscopy.
- In members with an established diagnosis of Crohn's disease, when there are unexpected change(s) in the course of disease or response to treatment, suggesting the initial diagnosis may be incorrect and re-examination may be indicated.
- Suspected small bowel bleeding, as evidenced by prior inconclusive upper and lower gastrointestinal endoscopic studies performed during the current episode of illness.
- Surveillance of the small bowel in members with hereditary GI polyposis syndromes, including familial adenomatous polyposis and Peutz-Jeghers syndrome.
- Suspected small bowel tumor.

Wireless capsule endoscopy is considered **experimental or investigational** for all other indications including, but not limited to the following. The evidence is insufficient to determine the effects of the technology on health outcomes.

- Evaluation of the extent of involvement of established Crohn's disease or ulcerative colitis.
- Evaluation of the esophagus, in members with gastroesophageal reflux (GERD) or other esophageal pathologies.
- Evaluation of other gastrointestinal diseases not presenting with gastrointestinal bleeding, including but not limited to celiac sprue, irritable bowel syndrome, small bowel neoplasm, Lynch syndrome, portal hypertensive enteropathy, and unexplained chronic abdominal pain.
- Evaluation of the colon including, but not limited to, detection of colonic polyps (colorectal polyps) or colon cancer.
- PillCam COLON 2 for all indications.
- Initial evaluation of members with acute upper gastrointestinal (GI) bleeding.

The patency capsule (e.g., Given® AGILE Patency System) is considered **experimental or investigational**, for all indications, including use to evaluate patency of the gastrointestinal tract prior to wireless capsule endoscopy. The evidence is insufficient to determine the effects of the technology on health outcomes.

Magnetic capsule endoscopy is considered **experimental or investigational**, for all indications, including use of evaluation of members with unexplained upper abdominal complaints. The evidence is insufficient to determine the effects of the technology on health outcomes.

BILLING/CODING INFORMATION:

CPT Coding:

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 **(investigational)**
91113	Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), colon, with interpretation and report (**investigational**)
0651T	Magnetically controlled capsule endoscopy, esophagus through stomach, including intraprocedural positioning of capsule, with interpretation and report (**investigational**)

NOTE: 91110 have both a technical and a professional component. 91110 include provision of the capsule, hook-up and recording equipment, downloading of the digital data with processing of the video images, and physician review and interpretation with report.

ICD-10 Diagnosis Codes That Support Medical Necessity for 91110:

D13.2	Benign neoplasm of duodenum
D13.30	Benign neoplasm of unspecified part of small intestine
D13.39	Benign neoplasm of other parts of small intestine
K50.00	Crohn's disease of small intestine without complications
K50.011 – K50.019	Crohn's disease of small intestine with complications
K50.80	Crohn's disease of both small and large intestine without complications
K50.811 – K50.819	Crohn's disease of both small and large intestine with complications
K50.90	Crohn's disease, unspecified, without complications
K50.911 – K50.919	Crohn's disease, unspecified, with complications
K55.21	Angiodysplasia of colon with hemorrhage
K57.01	Diverticulitis of small intestine with perforation and abscess with bleeding
K57.11	Diverticulosis of small intestine without perforation or abscess with bleeding
K57.13	Diverticulitis of small intestine without perforation or abscess with bleeding
K57.41	Diverticulitis of both small and large intestine with perforation and abscess with bleeding
K57.51	Diverticulosis of both small and large intestine without perforation or abscess with bleeding
K57.53	Diverticulitis of both small and large intestine without perforation or abscess with bleeding
K92.0	Hematemesis
K92.1	Melena
K92.2	Gastrointestinal hemorrhage, unspecified

Q85.8	Other phakomatoses, not elsewhere classified
Q85.9	Phakomatosis, unspecified

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products:

No National Coverage Determination (NCD) was found at the time of the last guideline reviewed date.

The following Local Coverage Determination (LCD) was reviewed on the last guideline reviewed date: Wireless Capsule Endoscopy, (L33774) located at fcso.com. Colon Capsule Endoscopy (CCE), (L38805) located at fcsomedicare.com.

DEFINITIONS:

Angiodysplasia: small abnormalities of blood or lymphatic vessels.

Celiac sprue: chronic hereditary intestinal disorder in which an inability to absorb the gliadin portion of gluten results in the gliadin triggering an immune response that damages the intestinal mucosa.

Familial adenomatous polyposis: a disease of the large intestine that is marked by the formation especially in the colon and rectum of numerous adenomatous polyps which typically become malignant if left untreated, that may be either asymptomatic or accompanied by diarrhea or bleeding, and that is inherited as an autosomal dominant trait – abbreviation FAP.

Lynch syndrome: often called hereditary nonpolyposis colorectal cancer (HNPCC), is an inherited disorder that increases the risk of many types of cancer, particularly cancers of the colon (large intestine) and rectum, which are collectively referred to as colorectal cancer.

Obscure GI bleeding: recurrent or persistent iron-deficiency anemia, positive fecal occult blood test, or visible bleeding with no bleeding source found at original endoscopy.

Peutz-Jeghers syndrome: familial polyposis inherited as an autosomal dominant trait and characterized by numerous polyps in the stomach, small intestine, and colon and by melanin-containing spots on the skin and mucous membranes especially of the lips and gums.

Portal hypertensive enteropathy: a condition that describes the pathologic changes and mucosal abnormalities observed in the small intestine of individuals with portal hypertension.

RELATED GUIDELINES:

Esophageal pH Monitoring, 01-91000-01

Ingestible pH and Pressure Capsule, 01-91000-08

OTHER:

Other names used to report Wireless Capsule Endoscopy:

Note: The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another and is not intended to represent a complete listing of all products available.

Capsule Endoscopy
Given Capsule Endoscopy
Ingestible Telemetric Video Endoscopy System
Ingestible Telemetric Video Diagnostic Imaging System
Video Capsule Endoscopy (VCE)
Wireless Motility Capsule (WMC)

REFERENCES:

1. Akin E, Ersoy O. Capsule endoscopy in celiac disease. Gastroenterol Res Pract. 2012; 2012:676073.
2. 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; 38(11): 1127-1132.
3. Baltes P, Bota M, Albert J, et al. PillCamColon2 after incomplete colonoscopy-A prospective multicenter study. World J Gastroenterol. 2018 Aug 21;24(31):3556-3566.
4. Blue Cross Blue Shield Association Evidence Positioning System®. 6.01.33 Wireless Capsule Endoscopy for Gastrointestinal (GI) Disorders, 01/24.
5. Bruining DH, Oliva S, Fleisher MR et al. Panenteric capsule endoscopy versus ileocolonoscopy plus magnetic resonance enterography in Crohn's disease: a multicentre, prospective study. BMJ Open Gastroenterol. 2020 Jun;7(1): e000365.
6. Cash BD, Fleisher MR, Fern S, et al. Multicentre, prospective, randomised study comparing the diagnostic yield of colon capsule endoscopy versus CT colonography in a screening population (the TOPAZ study). Gut. 2021 Nov;70(11):2115-2122. [Abstract]
7. Eisen GM, Eliakim R, Zaman A, et al. The accuracy of PillCam ESO capsule endoscopy versus conventional upper endoscopy for the diagnosis of esophageal varices: a prospective three-center pilot study. Endoscopy. 2006; (1): 31-5.
8. Eliakim R, Sharma VK, Yassin K, et al. A prospective study of the diagnostic accuracy of PillCam ESO esophageal capsule endoscopy versus conventional upper endoscopy in patients with chronic gastroesophageal reflux diseases. J Clin Gastroenterol. 2005; (7): 572-8.
9. Eliakim R, Yassin K, Shlomi I, et al. A novel diagnostic tool for detecting oesophageal pathology: the PillCam oesophageal video capsule. Aliment Pharmacol Ther. 2004; 20(10): 1083-9.
10. Elosua A, Rullan M, Rubio S, et al. Does capsule endoscopy impact clinical management in established Crohn's disease? Dig Liver Dis. 2022 Jan;54(1):118-124.
11. Enns RA, Hookey L, Armstrong D et al. Clinical practice guidelines for the use of video capsule endoscopy. Gastroenterology 2017. Feb; 152(3): 497-514.
12. Fireman Z, Mahajna E, Broide E, et al. Diagnosing small bowel Crohn's disease with wireless capsule endoscopy. Gut. 2003 Mar;52(3):390-2.

13. Franco DL, Leighton JA, Gurudu SR. Approach to Incomplete Colonoscopy: New Techniques and Technologies. Gastroenterol Hepatol (N Y). 2017 Aug;13(8):476-483.
14. Geropoulos G, Aquilina J, Kakos C, et al. Magnetically controlled capsule endoscopy versus conventional gastroscopy: a systematic review and meta-analysis. J Clin Gastroenterol. 2021 Aug 1;55(7):577-585. [Abstract]
15. Giardiello FM, Allen JI, Axilbund JE et al. Guidelines on Genetic Evaluation and Management of Lynch Syndrome: A Consensus Statement by the US Multi-Society Task Force on Colorectal Cancer. American Journal of Gastroenterology 2014; 109(8): 1159-1179.
16. Goldfarb NI, Pizzi LT, Fuhr JP, Salvador C, Sikirica V, Kornbluth A, Lewis Blair. Diagnosing Crohn's Disease: An Economic Analysis Comparing Wireless Capsule Endoscopy with Traditional Diagnostic Procedures. Dis Manag. 2004 Winter; 7(4): 292-304.
17. Hanauer SB,Sandborn W, and The Practice Parameters Committee of the American College of Gastroenterology. Management of crohn's disease in adults. American Journal of Gastroenterology 2001; 96(3): 635-643.
18. Hartmann D, Schmidt H; Bolz G, et al. A prospective two-center study comparing wireless capsule endoscopy with intraoperative enteroscopy in patients with obscure GI bleeding. Gastrointest Endosc. 2005; 61(7): 826-32.
19. Hussey M, Holleran G, Stack R, et al. Same-day colon capsule endoscopy is a viable means to assess unexplored colonic segments after incomplete colonoscopy in selected patients. United European Gastroenterol J. 2018 Dec;6(10):1556-1562.
20. Jiang B, Qian YY, Pan J, et al. Second-generation magnetically controlled capsule gastroscopy with improved image resolution and frame rate: a randomized controlled clinical trial (with video). Gastrointest Endosc. 2020 Jun;91(6):1379-1387.
21. Kjolhede T, Olholm AM, Kaalby L, et al. Diagnostic accuracy of capsule endoscopy compared with colonoscopy for polyp detection: systematic review and meta-analyses. Endoscopy. 2021 Jul;53(7):713-721.
22. Kopylov U, Seidman EG. Role of capsule endoscopy in inflammatory bowel disease. World Journal of Gastroenterology 2014; 20(5): 1155-1164.
23. Kopylov U, Yung DE, Engel T, et al. Diagnostic yield of capsule endoscopy versus magnetic resonance enterography and small bowel contrast ultrasound in the evaluation of small bowel Crohn's disease: Systematic review and meta-analysis. Dig Liver Dis. 2017 Aug;49(8):854-863.
24. Lapalus MG, Dumortier J, Fumex F, et al. Esophageal capsule endoscopy versus esophagogastroduodenoscopy for evaluating portal hypertension: a prospective comparative study of performance and tolerance. Endoscopy. 2006; 38(1): 36-41.
25. Leighton JA, Legnani P, Seidman EG. Role of capsule endoscopy in inflammatory bowel disease: where we are and where we are going. Inflammatory Bowel Diseases 2007; 13(3): 331-7.
26. 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. 2016 Sep;14(9):1266-1273.e1.
27. Lichtenstein GR, Hanauer SB, Sandborn WJ. Management of crohn's disease in adults. American Journal of Gastroenterology 2009.
28. Mata A, Llach J, Castells A, et al. A prospective trial comparing wireless capsule endoscopy and barium contrast series for small-bowel surveillance in hereditary GI polyposis syndromes. Gastrointest Endosc. 2005; 61(6): 721-5.
29. 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. Journal of Clinical Gastroenterology 2017. Feb; 51(2): 174-182.

30. Mekaroonkamol P, Cohn R, Chawla S. Portal hypertensive enteropathy. World Journal of Hepatology 2015; 7(2): 127-138.

31. Melson J, Trikudanathan G, Abu Dayyeh BK, et al. Video capsule endoscopy. Gastrointest Endosc. 2021 Apr;93(4):784-796.

32. Mir A, Nguyen VQ, Soliman Y, et al. Wireless Capsule Endoscopy for Diagnosis and Management of Post-Operative Recurrence of Crohn's Disease. Life (Basel). 2021 Jun 23;11(7):602.

33. 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; 63(4): 539-45.

34. Mitselos IV, Christodoulou DK, Katsanos KH et al. Role of wireless capsule endoscopy in the follow-up of inflammatory bowel disease. World Journal of Gastroenterology 2015; 7(6): 643-651.

35. Moeschler O, Mueller MK. Deep enteroscopy - indications, diagnostic yield and complications. World J Gastroenterol. 2015;21(5):1385-1393.

36. Muhammad A, Pitchumoni CS. Newly detected celiac disease by wireless capsule endoscopy in older adults with iron deficiency anemia. Journal of Clinical Gastroenterology 2008; 42(9): 980-983.

37. Nakamura M, Kawashima H, Ishigami M, et al. Indications and Limitations Associated with the Patency Capsule Prior to Capsule Endoscopy. Intern Med. 2022 Jan 1;61(1):5-13.

38. National Institute for Clinical Excellence (NICE). Interventional procedures overview of wireless capsule endoscopy, 06/04.

39. Negreanu L, Babiuc R, Bengus A, et al. PillCam Colon 2 capsule in patients unable or unwilling to undergo colonoscopy. World J Gastrointest Endosc. 2013 Nov 16;5(11):559-67.

40. Nowak T. A global perspective on capsule endoscopy. Ann Transl Med. 2017;5(21):422.

41. Ohtsuka K, Takenaka K, Kitazume Y, et al. Magnetic resonance enterography for the evaluation of the deep small intestine in Crohn's disease. Intest Res. 2016 Apr;14(2):120-6.

42. Pasha SF. Applications of Colon Capsule Endoscopy. Curr Gastroenterol Rep. 2018 Apr 12;20(5):22. [Abstract]

43. Pennazio M, Rondonotti E, de Franchis R. Capsule endoscopy in neoplastic diseases. World Journal of Gastroenterology 2008; 14(34): 5245-5253.

44. Qureshi W, Adler DG, Davila R, et al. Standards of Practice Committee. ASGE Guideline: the role of endoscopy in the management of variceal hemorrhage, updated July 2005. Gastrointest Endosc. 2005; 62(5): 651-5.

45. Raiteri A, Granito A, Giamperoli A, et al. Current guidelines for the management of celiac disease: A systematic review with comparative analysis. World J Gastroenterol. 2022 Jan 7;28(1):154-175.

46. Raju GS, Gerson L, Das A, Lewis B; American Gastroenterological Association. American Gastroenterological Association (AGA) Institute medical position statement on obscure gastrointestinal bleeding. Gastroenterology. 2007; 133(5): 1694-6.

47. Ramirez FC, Shaukat MS, Young MA, Johnson DA, Akins R. Feasibility and safety of string, wireless capsule endoscopy in the diagnosis of Barrett’s esophagus. Gastrointest Endosc. 2005; 61(6): 741-6.

48. Rauya E, Sha O, Darwazeh R, et al. Efficacy and safety of magnetic guided capsule gastroscopy in gastric diseases. Acta Gastroenterol Belg. 2019 Oct-Dec;82(4):507-513.

49. Redondo-Cerezo E, Sanchez-Cepilla AD, De La Torre-Rubio P et al. Wireless capsule endoscopy: perspectives beyond gastrointestinal bleeding. World Journal of Gastroenterology 2014; 20(42): 15664-15673.

50. Rubio-Tapia A, Hill ID, Semrad C, et al. American College of Gastroenterology Guidelines Update: Diagnosis and Management of Celiac Disease. Am J Gastroenterol. 2023 Jan 1;118(1):59-76.

51. Rubio-Tapia A, Hill ID, Kelly CP et al. ACG clinical guidelines: diagnosis and management of celiac disease. Am J Gastroenterol. 2013;108(5):656-676.

52. Saad RJ. The Wireless Motility Capsule: a One-Stop Shop for the Evaluation of GI Motility Disorders. Curr Gastroenterol Rep. 2016 Mar;18(3):14. [Abstract]

53. Sawada T, Nakamura M, Watanabe O, et al. Clinical factors related to false-positive rates of patency capsule examination. Therap Adv Gastroenterol. 2017 Aug;10(8):589-598.

54. Shaukat A, Kahi CJ, Burke CA, et al. ACG Clinical Guidelines: Colorectal Cancer Screening 2021. Am J Gastroenterol. 2021 Mar 1;116(3):458-479.

55. Shen B, Remizi FH, Santisi J et al. Application of wireless capsule endoscopy for the evaluation of iron deficiency anemia in patients with ileal pouches. Journal of Clinical Gastroenterology 2008; 42(8): 897-902.

56. Sieg A, Friedrich K, Sieg U. Is PillCam COLON capsule endoscopy ready for colorectal cancer screening? A prospective feasibility study in a community gastroenterology practice. American Journal of Gastroenterology 2009; 104(4): 848-854.

57. Silva M, Cardoso H, Cunha R, et al. Evaluation of Small-Bowel Patency in Crohn's Disease: Prospective Study with a Patency Capsule and Computed Tomography. GE Port J Gastroenterol. 2019 Oct;26(6):396-403.

58. Spada C, Pasha SF, Gross SA et al. Accuracy of first- and second-generation colon capsules in endoscopic detection of colorectal polyps: a systematic review and meta-analysis. Clin Gastroenterol Hepatol. 2016;14(11):1533-1543.e8.

59. Spada C, Piccirelli S, Hassan C, et al. AI-assisted capsule endoscopy reading in suspected small bowel bleeding: a multicentre prospective study. Lancet Digit Health. 2024 May;6(5):e345-e353.

60. Stein E, Berger Z, Hutfless S, et al. Wireless Motility Capsule versus Other Diagnostic Technologies for Evaluating Gastroparesis and Constipation: A Comparative Effectiveness Review. Comparative Effectiveness Review No. 110. (Prepared by Johns Hopkins Evidence-based Practice Center under Contract No. 290 2007 10061-I.) AHRQ Publication No. 13-EHC060-EF. Rockville, MD: Agency for Healthcare Research and Quality; May 2013.

61. Triantafyllou K, Beintaris I, Dimitriadis GD. Is there a role for colon capsule endoscopy beyond colorectal cancer screening? A literature review. World Journal of Gastroenterology 2014; 20(36): 13006-13014.

62. Trifan A, Singeap AM, Cojocariu C, et al. Small bowel tumors in patients undergoing capsule endoscopy: a single center experience. Journal of Gastrointestinal and Liver Diseases 2010; 19(1): 21-25.

63. US Preventive Services Task Force, Davidson KW, Barry MJ, Mangione CM, et al. Screening for Colorectal Cancer: US Preventive Services Task Force Recommendation Statement. JAMA. 2021 May 18;325(19):1965-1977.

64. Van Gossum A, Munoz-Navas M, Fernandez-Urien I et al. Capsule endoscopy versus colonoscopy for the detection of polyps and cancer. New England Journal of Medicine 2000; 361: 264-270.

65. 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.

66. 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.

67. Zhu SG, Qian YY, Tang XY, et al. Gastric preparation for magnetically controlled capsule endoscopy: A prospective, randomized single-blinded controlled trial. Dig Liver Dis. 2018 Jan; 50(1):42-47.

68. Zuckerman GR, Prakash C, Askin MP, Lewis BS. AGA technical review on the evaluation and management of occult and obscure gastrointestinal bleeding. Gastroenterology. 2000; 118(1): 201-21.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 12/5/24.

GUIDELINE UPDATE INFORMATION:

11/15/02	New Medical Coverage Guideline.
05/15/03	Reviewed and revised; investigational status changed.
09/15/03	Added coding clarification note.
01/01/04	Annual HCPCS coding update.
05/15/04	Scheduled review and revision of guideline; consisting of updated references additional indication for coverage and deletion of G0262.
05/15/05	Scheduled review and revision of guideline; consisting of updated references.
10/15/05	Revision to guideline; consisting of the addition of an investigational statement for wireless capsule endoscopy of the esophagus and updated references.
06/15/06	Scheduled review and revision of guideline consisting of updated references.
10/30/06	Revision to guideline consisting of the addition of Program Exception verbiage for Medicare Advantage products.
01/01/07	HCPCS coding update consisting of the addition of 91111.
03/15/07	Scheduled review and revision of guideline consisting of updated references.
06/15/07	Reformatted guideline; updated references.
07/15/08	Review and revision of guideline consisting of updated references.
11/15/09	Annual review. Added experimental or investigational statement for the Given® Patency System. Added program exception for Medicare, ICD-9 codes that support medical necessity for 91110 and 91111. Updated references.
01/01/11	Revision; added related ICD-10 codes.
03/15/11	Added smart pill to section titled “Other”.
11/15/11	Annual review; maintain medical necessity position statement. Revised description; FDA statement. Updated experimental or investigational position statement, added evaluation of the colon including, but not limited to, detection of colonic polyps or colon cancer. Revised/updated definitions. Updated reference.
01/01/13	Annual HCPCS coding update; revised 91110 and 91111 code descriptor.
7/15/14	Annual review; Updated description section. Added “performed during the current episode of illness” to meets the definition of medical necessity statement; Obscure gastrointestinal (GI) bleeding suspected of being of small bowel origin, as evidenced by prior inconclusive upper and lower gastrointestinal endoscopic studies “performed during the current episode of illness”. Added “suspected small bowel tumor” to position statement. Added “ulcerative colitis” and “initial evaluation of patients with acute upper gastrointestinal bleeding (GI) bleeding to experimental or investigational statement.

	Added ICD-9 diagnoses codes: 211.2, 578.0, 578.1 and 759.6. Added Medicare Advantage products program exception. Updated references for 91110.
10/15/15	Review and revision; added evaluation of members with Crohn's disease for unexpected change(s) in the course of disease or response to treatment to position statement, added Lynch syndrome, portal hypertensive enteropathy and unexplained chronic abdominal pain to the experimental or investigational position statement, revised experimental or investigational position statement, and updated references.
11/01/15	Revision: ICD-9 Codes deleted.
02/15/19	Review; no change to position statement. Updated references.
12/15/19	Review; no change to medical necessity position statement. Added PillCam COLON 2 to experimental or investigational position statement. Updated references
01/01/22	Review; no change in position statement. Added 0651T. Updated references. Annual CPT/HCPCS coding update. Added 91113. Deleted 0355T.
12/15/21	Review; no change in position statement. Added 0651T. Updated references.
05/22/23	Update to Program Exceptions section.
12/15/23	Review; no change to position statement. Updated references.
12/15/24	Review; Add statement for magnetic capsule endoscopy. Updated references.