01-91000-05

Original Effective Date: 11/15/02

Reviewed: 12/7/23

Revised: 12/15/23

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).

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.

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. Blue Cross Blue Shield Association Evidence Positioning System®. 6.01.33 Wireless Capsule Endoscopy for Gastrointestinal (GI) Disorders, 01/23.
4. 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]
5. Eisen GM, Eliakim R, Zaman A, Schwartz J, Faigel D, Rondonotti E, Villa F, Weizman E, Yassin K, deFranchis R. 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.

6. Eliakim R, Sharma VK, Yassin K, Adler SN, Jacob H, Cave DR, Sachdev R, Mitty RD, Hartmann D, Schilling D, Riemann JF, Bar-Meir S, Bardan E, Fennerty B, Eisen G, Faigel D, Lewis BS, Fleischer DE. 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.
7. Eliakim R, Yassin K, Shlomi I, Suissa A, Eisen GM. A novel diagnostic tool for detecting oesophageal pathology: the PillCam oesophageal video capsule. Aliment Pharmacol Ther. 2004; 20(10): 1083-9.
8. 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.
9. 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.
10. 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]
11. 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.
12. 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.
13. 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.
14. Hartmann D, Schmidt H; Bolz G, Schilling D, Kinzel F, Eickhoff A, Huschner W, Moller K, Jakobs R, Reitzig P, Weickert U; Gellert K, Schultz H, Guenther K, Hollerbuhl H, Schoenleben K, Schulz HJ, Riemann JF. 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.
15. 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.
16. 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.
17. Kopylov U, Seidman EG. Role of capsule endoscopy in inflammatory bowel disease. World Journal of Gastroenterology 2014; 20(5): 1155-1164.
18. Lapalus MG, Dumortier J, Fumex F, Roman S, Lot M, Prost B, Mion F, Ponchon T. Esophageal capsule endoscopy versus esophagogastroduodenoscopy for evaluating portal hypertension: a prospective comparative study of performance and tolerance. Endoscopy. 2006; 38(1): 36-41.
19. 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.
20. 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.

21. Lichtenstein GR, Hanauer SB, Sandborn WJ. Management of crohn's disease in adults. American Journal of Gastroenterology 2009.Mata A, Llach J, Castells A, Rovira JM, Pellise M, Gines A, Fernandez-Esparrach G, Andreu M, Bordas JM, Pique JM. 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.

22. 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.

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

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

25. 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.

26. Mishkin DS, Chuttani R, Croffie J, Disario J, Liu J, Shah R, Somogyi L, Tierney W, Song LM, Petersen BT; Technology Assessment Committee, American Society for Gastrointestinal Endoscopy. ASGE Technology Status Evaluation Report: wireless capsule endoscopy. Gastrointest Endosc. 2006; 63(4): 539-45.

27. 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.

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

29. 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.

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

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

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

33. Qureshi W, Adler DG, Davila R, Egan J, Hirota W, Leighton J, Rajan E, Zuckerman MJ, Fanelli R, Wheeler-Harbaugh J, Baron TH, Faigel DO; 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.

34. 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.

35. 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.

36. 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.

37. 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.

38. 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.

39. 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]
40. 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.
41. 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.
42. 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.
43. 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.
44. 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.
45. 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.
46. 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.
47. US Preventive Services Task Force, Bibbins-Domingo K, Grossman DC et al. Screening for colorectal cancer: US Preventive Services Task Force Recommendation Statement. JAMA 2016. Jun 21: 315(23): 2564-2575.
48. 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.
49. 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.
50. 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 12/7/23.

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.