



BlueCross BlueShield
of Alabama

Name of Blue Advantage Policy:

Wireless Capsule Endoscopy (Given[®] Video Capsule)

Policy #: 017
Category: Radiology

Latest Review Date: December 2020
Policy Grade: B

BACKGROUND:

Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
 - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
 - *Furnished in a setting appropriate to the patient's medical needs and condition;*
 - *Ordered and furnished by qualified personnel;*
 - *One that meets, but does not exceed, the patient's medical need; and*
 - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Effective for dates of service on or after January 1, 2022:

For CPT code 91113, refer to LCD 38755 and A58321.

For CPT codes 91110 and 91111, refer to L36427 and A56727.

Effective for dates of service April 12, 2021 through December 31, 2021:

For CPT codes 91110 and 91111, refer to L36427 and A56727.

For CPT code 0355T, refer to L38755 and A58321.

Effective for dates of service March 24, 2020 through April 11, 2021:

For CPT codes 91110 and 91111, refer to L36427 and A56727.

For CPT code 0355T:

Blue Advantage will treat Wireless Capsule Endoscopy/Given® Imaging System, including the disposable PillCam SB capsule and interpretation of the data by the Given® data recorder, as a non-covered benefit and as investigational.

Blue Advantage will treat The Given® AGILE Patency System including the patency capsule and the patency scanner, used to evaluate patency of the gastrointestinal tract before wireless capsule endoscopy, as a non-covered benefit and as investigational.

Effective for dates of service February 26, 2018, through March 23, 2020:

For CPT codes 91110 and 91111, refer to L36427 and A56727.

For CPT code 0355T, refer to LCD L34555.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

The wireless capsule endoscopy (CE) uses a device to visualize segments of the gastrointestinal tract. Patients swallow a capsule that records images of the intestinal mucosa as it passes through the gastrointestinal (GI) tract. The capsule is collected after being excreted and images interpreted.

Wireless Capsule Endoscopy

Wireless capsule endoscopy (CE) is performed using the PillCam Given Diagnostic Imaging System (previously called M2A), which is a disposable imaging capsule manufactured by Given

Imaging. The capsule measures 11 by 30 mm and contains video imaging, self-illumination, and image transmission modules, as well as a battery supply that lasts up to 8 hours. The indwelling camera takes images at a rate of two frames per second as peristalsis carries the capsule through the gastrointestinal tract. The average transit time from ingestion to evacuation is 24 hours. The device uses wireless radio transmission to send the images to a receiving recorder device that the patient wears around the waist. This receiving device also contains localizing antennae sensors that can roughly gauge where the image was taken over the abdomen. Images are then downloaded onto a workstation for viewing and processing.

CE has been proposed as a method for identifying Crohn disease. There is no single criterion standard diagnostic test for Crohn disease; rather, diagnosis is based on a constellation of findings. Thus it is difficult to determine the diagnostic characteristics of various tests used to diagnose the condition and difficult to determine a single comparator diagnostic test to CE.

Magnetic Capsule Endoscopy

The U.S. Food and Drug Administration (FDA) approved a novel magnetically maneuvered CE system (NaviCam™; AnX Robotica, Inc.) in May 2020.² This system consists of a single-use ingestible capsule and magnet linked to a physician-operated console. The capsule contains a camera that wirelessly captures images of the desired anatomy. The console allows the operator to control the motion and direction of the capsule, ensuring visualization of the entire stomach. The system is non-invasive, does not require sedation, and has a procedural time of approximately 15 to 20 minutes. The capsule leaves the body in 24 hours on average but may take as long as 2 weeks. The device is contraindicated for use in patients with gastrointestinal obstruction, stenosis, fistula, or those with dysphagia. Other contraindications include patients with cardiac pacemakers or other implantable electronic medical devices as well as pregnant women, those <22 years of age, and those with a body mass index ≥ 38 .

KEY POINTS:

The most recent literature review was updated through November 10, 2021.

Summary of Evidence

Patients With Suspected GI Disorders

For individuals who have suspected small bowel bleeding (previously referred to as obscure GI bleeding) who receive wireless CE, the evidence includes numerous case series evaluating patients with a nondiagnostic standard workup and a randomized control trial (RCT). The relevant outcomes are test validity, other test performance measures, symptoms, and change in disease status. The evidence has demonstrated that CE can identify a bleeding source in a substantial number of patients who cannot be diagnosed by other methods, with a low incidence of adverse events. Because there are few other options for diagnosing obscure small bowel bleeding in patients with negative upper and lower endoscopy, this technique will likely improve health outcomes by directing specific treatment when a bleeding source is identified. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have suspected small bowel CD who receive wireless CE, the evidence includes case series. The relevant outcomes are test validity, other test performance measures, symptoms, and change in disease status. Although the test performance characteristics and diagnostic yields of the capsule for these indications are uncertain, the diagnostic yields are as good as or better than other diagnostic options, and these data are likely to improve health outcomes by identifying some cases of CD and directing specific treatment. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have suspected celiac disease who receive wireless CE, the evidence includes case series and diagnostic accuracy studies. The relevant outcomes are test validity, other test performance measures, symptoms, and change in disease status. The diagnostic characteristics of CE are inadequate to substitute for other modalities or to triage patients to other modalities. For other conditions (eg, determining the extent of CD), direct evidence of improved outcomes or a strong indirect chain of evidence to improved outcomes is lacking. The evidence is insufficient to determine the effects of technology on net health outcomes.

For individuals who have unexplained chronic abdominal pain who receive wireless CE, the evidence includes case series and diagnostic accuracy studies. The relevant outcomes are test validity, other test performance measures, symptoms, and change in disease status. The diagnostic characteristics of CE are inadequate to substitute for other modalities or to triage patients to other modalities. For other conditions (e.g., determining the extent of CD), direct evidence of improved outcomes or a strong chain of evidence to improved outcomes is lacking. The evidence is insufficient to determine the effects of technology on net health outcomes.

Patients With Confirmed GI Disorders

For individuals who have an established diagnosis of CD who receive wireless CE, the evidence includes diagnostic accuracy studies and a systematic review. The relevant outcomes are test validity, other test performance measures, symptoms, and change in disease status. A 2017 systematic review of 11 studies in patients with established CD found a similar diagnostic yield with CE compared with radiography. Because there is evidence that the diagnostic yields are as good as or better than other diagnostic options, there is indirect evidence that CE is likely to improve health outcomes by identifying some cases of CD and directing specific treatment. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have ulcerative colitis who receive wireless CE, the evidence includes case series and diagnostic accuracy studies. The relevant outcomes are test validity, other test performance measures, symptoms, and change in disease status. Several diagnostic accuracy studies have compared CE with colonoscopy to assess disease activity in patients with ulcerative colitis. Two of the 3 studies were small (i.e., <50 patients) and thus data on diagnostic accuracy are limited. Direct evidence of improved outcomes or a strong chain of evidence to improved outcomes is lacking. The evidence is insufficient to determine the effects of technology on net health outcomes.

For individuals who have esophageal disorders who receive wireless CE, the evidence includes case series and diagnostic accuracy studies. The relevant outcomes are test validity, other test performance measures, symptoms, and change in disease status. Other available modalities are superior to CE. The diagnostic characteristics of CE are inadequate to substitute for other modalities or to triage patients to other modalities. The evidence is insufficient to determine the effects of technology on net health outcomes.

For individuals who have hereditary GI polyposis syndromes who receive wireless CE, the evidence includes case series and diagnostic accuracy studies. The relevant outcomes are test validity, other test performance measures, symptoms, and change in disease status. The data are insufficient to determine whether evaluation with CE would improve patient outcomes. Further information on the prevalence and natural history of small bowel polyps in Lynch syndrome patients is necessary. At present, surveillance of the small bowel is not generally recommended as a routine intervention for patients with Lynch syndrome. The evidence is insufficient to determine the effects of technology on net health outcomes.

For individuals who have portal hypertensive enteropathy who receive wireless CE, the evidence includes case series and diagnostic accuracy studies. Relevant outcomes are test validity, other test performance measures, symptoms, and change in disease status. Systematic reviews of studies of CE's diagnostic performance for this indication have reported limited sensitivity and specificity. Due to insufficient data on diagnostic accuracy, a chain of evidence on clinical utility cannot be constructed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Acute Upper GI Bleeding

For individuals who have acute upper GI tract bleeding who receive wireless CE, the evidence includes a RCT and several cohort studies. Relevant outcomes are test validity, other test performance measures, symptoms, change in disease status, and resource utilization. The use of CE in the emergency department setting for suspected upper GI bleeding is intended to avoid unnecessary hospitalization or immediate endoscopy. Controlled studies are needed to assess further the impact of CE on health outcomes compared with standard management. The evidence is insufficient to determine the effects of technology on net health outcomes.

Colon Cancer Screening

For individuals who are screened for colon cancer who receive wireless CE, the evidence includes diagnostic accuracy studies and systematic reviews. Relevant outcomes are overall survival, disease-specific survival, test validity, test accuracy, and other test performance measures. Studies of CE in screening populations are necessary to determine the diagnostic characteristics of the test in this setting. Studies of diagnostic characteristics alone are insufficient evidence to determine the efficacy of CE for colon cancer screening. Because diagnostic performance is worse than standard colonoscopy, CE would need to be performed more frequently than standard colonoscopy to have comparable efficacy potentially. Without direct evidence of efficacy in a clinical trial of colon cancer screening using CE, modeling studies using established mathematical models of colon precursor incidence and progression to cancer could provide estimates of efficacy in preventing colon cancer mortality. The evidence is insufficient to determine the effects of technology on net health outcomes.

Lower GI Tract Bleeding and Major Risks for Colonoscopy or Moderate Sedation

For individuals who are screened for colon polyps with evidence of lower GI tract bleeding and major risks for colonoscopy or moderate sedation who receive wireless CE, the evidence includes diagnostic accuracy studies. Relevant outcomes are test accuracy, test validity, other test performance measures, symptoms, change in disease status, and resource utilization. Studies of CE in the intended use population are necessary to determine the diagnostic characteristics of the test in the triage setting. Studies of diagnostic characteristics alone are insufficient evidence to determine the clinical utility of CE in this population, and no studies adequately assess the impact of findings on specific health outcomes or patient adherence. The evidence is insufficient to determine the effects of the technology on net health outcomes.

Incomplete Colonoscopy

For individuals who are screened for colon polyps following an incomplete colonoscopy with adequate preparation who receive wireless CE, the evidence includes case series. Relevant outcomes are test accuracy, test validity, other test performance measures, symptoms, change in disease status, and resource utilization. Studies of CE compared to standard management with repeat colonoscopy in the intended use population are necessary to determine the diagnostic characteristics of the test in the triage setting. Studies of diagnostic characteristics alone are insufficient evidence to determine the clinical utility of CE in this population, and no studies adequately assess the impact of findings on specific health outcomes or patient adherence. The evidence is insufficient to determine the effects of the technology on net health outcomes.

Patency Capsule for Patients with Bowel Stricture

For individuals who are scheduled to undergo CE for known or suspected small bowel stricture who receive a patency capsule, the evidence includes case series. The relevant outcomes are test validity, symptoms, change in disease status, and treatment-related morbidity. The available studies have reported that CE following a successful patency capsule test results in high rates of success with low rates of adverse events. The capsule is also associated with adverse events. Because of the lack of comparative data to other diagnostic strategies, it is not possible to determine whether the use of the patency capsule improves the net health outcome. The evidence is insufficient to determine the effects of technology on net health outcomes.

Magnetic Capsule Endoscopy for Patients with Suspected Gastrointestinal Disorders

For individuals who have unexplained upper abdominal complaints who receive magnetic CE, the evidence includes diagnostic accuracy studies. Relevant outcomes are test validity, symptoms, change in disease status, and treatment-related morbidity. Studies evaluating the diagnostic characteristics of magnetic CE as compared to conventional gastroscopy in the target population have generally demonstrated similar accuracy, sensitivity, and specificity, with increases in patient preference and an acceptable safety profile with the magnetic CE approach. However, the diagnostic characteristics of magnetic CE are inadequate to substitute for other modalities or to triage patients to other modalities based on the current literature. Direct evidence of improved outcomes or a strong chain of evidence to improved outcomes is lacking. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

American College of Gastroenterology

The ACG (2013) issued guidelines on the diagnosis and management of celiac disease. The guidelines recommended that capsule endoscopy (CE) not be used for initial diagnosis, except for patients with positive celiac-specific serology who are unwilling or unable to undergo upper endoscopy with biopsy (strong recommendation, moderate level of evidence).

CE should be considered for the evaluation of small bowel mucosa in patients with complicated Crohn disease (CD; strong recommendation, moderate level of evidence).

The ACG (2018) updated its guidelines on the management of CD in adults. It makes two recommendations specific to video capsule endoscopy:

“Video capsule endoscopy (VCE) is a useful adjunct in the diagnosis of patients with small bowel Crohn’s disease in patients in whom there is a high index of suspicion of disease.”

“Patients with obstructive symptoms should have small bowel imaging and/or patency capsule evaluation before VCE to decrease risk of capsule retention.”

These recommendations are based on multiple studies. Capsule endoscopy was found to be “superior to small bowel barium studies, computed tomography enterography (CTE) and ileocolonoscopy in patients with suspected CD, with incremental yield of diagnosis of 32%, 47%, and 22%, respectively....Capsule endoscopy has a high negative predictive value of 96%.”

“However, some studies have questioned the specificity of capsule endoscopy findings for CD, and to date there is no consensus as to exactly which capsule endoscopy findings constitute a diagnosis of CD.”

The ACG (2015) issued guidelines on the diagnosis and management of small bowel bleeding (including using “small bowel bleeding” to replace “obscure GI [gastrointestinal] bleeding,” which should be reserved for patients in whom a source of bleeding cannot be identified anywhere in the GI tract). These guidelines made the following statements related to video CE (see Table 15).

Table 15. Recommendations on Diagnosis and Management of Small Bowel Bleeding

Recommendation	SOR	LOE
“... VCE should be considered as a first-line procedure for SB evaluation after upper and lower GI sources have been excluded, including second-look endoscopy when indicated”	Strong	Moderate
“VCE should be performed before deep enteroscopy to increase diagnostic yield. Initial deep enteroscopy can be considered in cases of massive hemorrhage or when VCE is contraindicated”	Strong	High

GI: gastrointestinal; LOE: level of evidence; SB: small bowel; SOR: strength of recommendation; VCE: video capsule endoscopy.

American Society of Gastrointestinal Endoscopy

The American Society of Gastrointestinal Endoscopy (2016) published guidelines for the use of endoscopy in the management of suspected small bowel bleeding. These guidelines made the following recommendations on capsule endoscopy (VCE) (see Table 16).

Table 16. Recommendations on Use of Endoscopy to Manage Suspected Small Bowel Bleeding

Recommendation	QOE
We suggest VCE as the initial test for patients with overt or occult small-bowel bleeding. Positive VCE results should be followed with push enteroscopy if within reach or DAE.”	Moderate
“We suggest DAE or push enteroscopy if VCE is unavailable or nondiagnostic in patients with overt small bowel bleeding.”	Moderate

DAE: device-assisted enteroscopy; QOE: quality of evidence; VCE: video capsule endoscopy.

American Gastroenterological Association Institute

The American Gastroenterological Institute (AGA)(2017) issued guidelines on the use of capsule endoscopy. Table 17. summarizes the most relevant recommendations (not all recommendations are included).

Table 17. AGA 2017 Capsule Endoscopy Recommendations

Stmnt No.	Recommendation	Grade	QOE
-----------	----------------	-------	-----

Recommendations Supporting the Use of Capsule Endoscopy (CE)

1	For suspected Crohn’s disease (CD), with negative ileocolonoscopy and imaging studies (CE of small bowel)	Strong	Very low
2	For CD and clinical features unexplained by ileocolonoscopy or imaging studies	Strong	Very low
3	For CD, when assessment of small-bowel mucosal healing (beyond reach of ileocolonoscopy) is needed	Conditional	Very low
4	For suspected small-bowel recurrence of CD after colectomy, undiagnosed by ileocolonoscopy or imaging studies	Strong	Very low

7	For celiac disease with unexplained symptoms despite treatment and appropriate investigations	Strong	Very low (efficacy) Low (safety)
8	For documented overt gastrointestinal (GI) bleeding (excluding hemoatemesis) and negative findings on high-quality esophagogastroduodenoscopy (EGD) and colonoscopy	Strong	Very low
9	For overt, obscure bleeding episode, as soon as possible	Strong	Very low
10	With prior negative CE with repeated obscure bleeding, repeated studies (endoscopy, colonoscopy and/or CE)	Strong	Very low
11	For suspected obscure bleeding and unexplained mild chronic iron-deficiency anemia, in selected cases	Strong	Very low
12	For polyposis syndromes, which require small bowel studies, for ongoing surveillance	Conditional	Very low (efficacy) Low (safety)

Recommendations Against Use of CE

5	For diagnosing CD when chronic abdominal pain or diarrhea are only symptoms, and with no evidence of
6	For diagnosing celiac disease
13	For routine substitution of colonoscopy
14	For inflammatory bowel disease (IBD), as substitute for colonoscopy to assess extent and severity of disease

QOE: quality of evidence; Stmt: statement.

U.S. Multi-Society Task Force

The U.S. Multi-Society Task Force (2017) issued recommendations for colorectal cancer screening with representation from the American College of Gastroenterology, the American Gastroenterological Association, and The American Society for Gastrointestinal Endoscopy. Capsule endoscopy every 5 years received a tier 3 ranking with the following recommendation: "We suggest that capsule colonoscopy (if available) is an appropriate screening test when patients decline colonoscopy, FIT, FIT-fecal DNA, CT colonography, and flexible sigmoidoscopy (weak recommendation, low-quality evidence)."

U.S. Preventive Services Task Force Recommendations

The U.S. Preventive Services Task Force published its most recent recommendations for colorectal cancer screening in 2021. Colorectal cancer screening was recommended starting at age 50 years and continuing until age 75 years (A recommendation) and in adults aged 45 to 49 years (B recommendation). The USPSTF recommendation for screening for colorectal cancer does not include serum tests, urine tests, or CE for colorectal cancer screening because of the limited available evidence on these tests and because other effective tests are available. The U.S. Preventive Services Task Force is in the process of updating its recommendations for colorectal cancer screening. The proposed analytic framework in the Draft Research Plan includes the evaluation of CE as a triage test for colonoscopy.

KEY WORDS:

Wireless capsule endoscopy, Given® Imaging System, camera endoscopy, ingestible video capsule, PillCam ESO, PillCam SB, Given® AGILE Patency System, patency capsule, CapsoCam Plus, Olympus Small Intestinal Capsule Endoscope System, MiroCam Capsule Endoscope System, NaviCam, Magnetic Capsule Endoscopy

APPROVED BY GOVERNING BODIES:

Table 18 summarizes various wireless CE devices with clearance by the U.S. Food and Drug Administration.

Table 18. Wireless Capsule Endoscopy Devices Cleared by the Food and Drug Administration

Device	Manufacturer	Date Cleared	510(k) No.	Indication
Pillcam SB 3 Capsule Endoscopy System, Pillcam Software 9.0e	Given Imaging Ltd.	8/27/2021	K211684	For visualization of the small bowel mucosa. It may be used in the visualization and monitoring of: lesions that may indicate Crohn's disease not detected by upper and lower endoscopy; lesions that may be a source of obscure bleeding not detected by upper and lower endoscopy; lesions that may be potential causes of iron deficiency anemia not detected by upper and lower endoscopy.

NaviCam Stomach Capsule System	AnX Robotica, Inc.	5/22/2020	K203192	For visualization of the stomach of adults (≥ 22 years) with a body mass index < 38 . The system can be used in clinics and hospitals, including emergency room settings.
CapsoCam Plus (SV-3)	CapsoVision Inc.	4/19/2019	K183192	For visualization of the small bowel mucosa in adults. It may be used as a tool in the detection of abnormalities of the small bowel.
Olympus Small Intestinal Capsule Endoscope System	Olympus Medical Systems Corp	3/5/2019	K183053	For visualization of the small intestine mucosa.
MiroCam Capsule Endoscope System	IntroMedic Co. Ltd.	11/8/2018	K180732	May be used as a tool in the detection of abnormalities of the small bowel and this device is indicated for adults and children from two years of age.
Olympus Small Intestinal Capsule Endoscope System	Olympus Medical Systems Corp.	3/13/2018	K173459	May be used in the visualization and monitoring of lesions that may indicate Crohn's disease not detected by upper and lower endoscopy. - It may be used in the visualization and monitoring of lesions that may be a source of obscure bleeding (either overt or occult) not detected by upper and lower endoscopy. It may be used in the visualization and monitoring of lesions that may be potential causes of iron deficiency anemia (IDA) not detected by upper and lower

				endoscopy. The Red Color Detection Function is intended to mark frames of the video suspected of containing blood or red areas.
PillCam Patency System	Given Imaging Ltd.	3/8/2018	K180171	Intended to verify adequate patency of the gastrointestinal tract prior to administration of the PillCam video capsule in patients with known or suspected strictures.
MiroCam Capsule Endoscope System	IntroMedic Co. Ltd.	1/30/2018	K170438	For visualization of the small intestine mucosa.
PillCam SBC capsule endoscopy system PilCam Desktop Software 9.0	Given Imaging Ltd.	9/1/2017	K170210	For visualization of the small intestine mucosa.
RAPID Web	Given Imaging Ltd.	5/26/2017	K170839	Intended for visualization of the small bowel mucosa.
AdvanCE capsule endoscope delivery device	United States Endoscopy Group Inc.	3/10/2017	K163495	Intended for visualization of the small bowel mucosa.
OLYMPUS SMALL INTESTINAL CAPSULE ENDOSCOPE SYSTEM	OLYMPUS MEDICAL SYSTEMS CORP.	1/19/2017	K163069	Intended for visualization of the small bowel mucosa.
CapsoCam Plus (SV-3) Capsule Endoscope System	CapsoVision Inc	10/21/2016	K161773	Intended for visualization of the small bowel mucosa.
CapsoCam (SV-1)	CapsoVision	2/9/2016	K151635	For use in diagnosing

	Inc.			disorders of the small bowel, esophagus, and colon.
PillCam TM COLON 2	Given® Imaging	01/14/2016	K153466	Detection of colon polyps in patients after an incomplete colonoscopy and a complete evaluation of the colon was not technically possible, and for detection of colon polyps in patients with evidence of GI bleeding of lower GI origin with major risks for colonoscopy or moderate sedation, but who could tolerate colonoscopy or moderate sedation in the event a clinically significant colon abnormality was identified on capsule endoscopy.
MiroCam Capsule Endoscope System	INTROMEDIC CO. LTD	3/17/2015	K143663	Intended for visualization of the small bowel mucosa.
ENDOCAPSULE SOFTWARE 10; ENDOCAPSULE SOFTWARE 10 LIGHT	OLYMPUS MEDICAL SYSTEMS CORP.	2/8/2015	K142680	Intended for visualization of the small bowel mucosa.

GI: gastrointestinal

BENEFIT APPLICATION:

Coverage is subject to member’s specific benefits, group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes:

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
91113	Gastrointestinal tract imaging, intraluminal colon (Effective 01/01/2022)

PREVIOUS CODING:

0355T	Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), colon, with interpretation and report (Deleted 12/31/2021)
-------	---

REFERENCES:

1. American College of Gastroenterology (ACG). Guidelines: Diagnosis and management of Celiac disease. 2013; //gi.org/guideline/diagnosis-and-management-of-celiac-disease/.
2. Annese V, Daperno M, Rutter MD, et al. European evidence based consensus for endoscopy in inflammatory bowel disease. J Crohns Colitis. Dec 15 2013; 7(12):982-1018.
3. Appleyard, M., et al. Wireless-capsule diagnostic endoscopy for recurrent small bowel bleeding, The New England Journal of Medicine, Vol. 344:232-233, January 18, 2001.
4. ASGE Standards of Practice Committee, Gurudu SR, Bruining DH, et al. The role of endoscopy in the management of suspected smallbowel bleeding. Gastrointest Endosc. Jan 2017;85(1):22-31.
5. Bibbins-Domingo K, Grossman DC, et al. Screening for Colorectal Cancer: US Preventive Services Task Force Recommendation Statement. JAMA. Jun 21 2016;315(23):2564- 2575.
6. 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. Jun 2020; 7(1).
7. 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. Nov 2021; 70(11): 2115-2122.
8. Chandran S, Testro A, Urquhart P et al. Risk stratification of upper GI bleeding with an esophageal capsule. Gastrointest Endosc 2013; 77(6):891-8.
9. Choi M, Lim S, Choi MG, et al. Effectiveness of Capsule Endoscopy Compared with Other Diagnostic Modalities in Patients with Small Bowel Crohn's Disease: A Meta-Analysis. Gut Liver. Oct 13 2016.
10. Choi M, Lim S, Choi MG, et al. Effectiveness of capsule endoscopy compared with other diagnostic modalities in patients with small bowel Crohn's disease: a meta-analysis. Gut Liver. Jan 15 2017;11(1):62-72

11. 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;10:CD008760.
12. Cross A, Szoka N. SAGES NaviCam stomach capsule system. March 10, 2021. <https://www.sages.org/publications/tavac/navicam-stomach-capsule-system/>. Accessed November 10, 2021.
13. Davidson KW, Barry MJ, Mangione CM, et al. Screening for Colorectal Cancer: US Preventive Services Task Force Recommendation Statement. *JAMA.* May 18 2021; 325(19): 1965-1977.
14. D'Haens G, Lowenberg M, Samaan MA, et al. Safety and Feasibility of Using the Second-Generation Pillcam Colon Capsule to Assess Active Colonic Crohn's Disease. *Clin Gastroenterol Hepatol.* Aug 2015;13(8):1480-1486 e1483.
15. Enns RA, Hookey L, Armstrong D et al. Clinical Practice Guidelines for the Use of Video Capsule Endoscopy.. *Gastroenterology*, 2017 Jan 8;152(3).
16. Enns RA, Hookey L, Armstrong D, et al. Clinical practice guidelines for the use of video capsule endoscopy. *Gastroenterology.* Feb 2017; 152(3):497-514.
17. Force USPST, Bibbins-Domingo K, Grossman DC, et al. Screening for Colorectal Cancer: US Preventive Services Task Force Recommendation Statement. *JAMA.* Jun 21 2016;315(23):2564-2575.
18. Gerson LB, Fidler JL, Cave DR, et al. ACG Clinical Guideline: Diagnosis and Management of Small Bowel Bleeding. *Am J Gastroenterol.* Sep 2015;110(9):1265-1287; quiz 1288.
19. Gralnek IM, Ching JY, Maza I et al. Capsule endoscopy in acute upper gastrointestinal hemorrhage: a prospective cohort study. *Endoscopy* 2013; 45(1):12-9.
20. Gurudu SR, Bruining DH, Acosta RD, et al. The role of endoscopy in the management of suspected small bowel bleeding. *Gastrointest Endosc.* Jun 30 2016.
21. Gutkin E, Shalomov A, Hussain SA et al. Pillcam ESO((R)) is more accurate than clinical scoring systems in risk stratifying emergency room patients with acute upper gastrointestinal bleeding. *Therap Adv Gastroenterol* 2013; 6(3):193-8.
22. Guturu P, Sagi SV, Ahn D et al. Capsule endoscopy with PILLCAM ESO for detecting esophageal varices: a meta-analysis. *Minerva Gastroenterol Dietol* 2011; 57(1):1-11.
23. Haanstra JF, Al-Toma A, Dekker E, et al. Prevalance of small-bowel neoplasia in Lynch syndrome assessed by video capsule endoscopy. *Gut.* Oct 2015; 64(10):1578-1583.
24. Iddan, G., et al. Wireless Capsule Endoscopy, *NATURE* 2000; 405(6785); 417.
25. IOM (Institute of Medicine). 2011. *Clinical Practice Guidelines We Can Trust.* Washington, DC: The National Academies Press.
26. Jeon SR, Kim JO, Kim JB, et al. Portal hypertensive enteropathy diagnosed by capsule endoscopy in cirrhotic patients: a nationwide multicenter study. *Dig Dis Sci.* May 2014; 59(5):1036-1041.
27. 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.* Aug 28 2020.

28. 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*. Jul 2021; 53(7): 713-721.
29. Koornstra JJ. Small bowel endoscopy in familial adenomatous polyposis and Lynch syndrome. *Best Pract Res Clin Gastroenterol*. Jun 2012; 26(3):359-368.
30. 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*. Aug 2017; 49(8):854-863.
31. Koulaouzidis A, Rondonotti E, Giannakou A et al. Diagnostic yield of small-bowel capsule endoscopy in patients with iron-deficiency anemia: a systematic review. *Gastrointest Endosc* 2012; 76(5):983-92.
32. Kurien M, Evans KE, Aziz I et al. Capsule endoscopy in adult celiac disease: a potential role in equivocal cases of celiac disease? *Gastrointest Endosc* 2013; 77(2):227-32.
33. Lansdorp-Vogelaar I, von Karsa L, International Agency for Research on C. European guidelines for quality assurance in colorectal cancer screening and diagnosis. First Edition--Introduction. *Endoscopy*. Sep 2012; 44 Suppl 3:SE15-30.
34. Leung WK, Ho SS, Suen BY et al. Capsule endoscopy or angiography in patients with acute overt obscure gastrointestinal bleeding: a prospective randomized study with long-term follow-up. *Am J Gastroenterol* 2012; 107(9):1370-6.
35. Lichtenstein GR, Loftus EV, Isaacs KL et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults.. *Am. J. Gastroenterol.*, 2018 Apr 4;113(4).
36. 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*. Feb 2017; 51(2):174-182.
37. Morgan DR, Malik PR, Romeo DP et al. Initial US evaluation of second generation capsule colonoscopy for detecting colon polyps. *BMJ Open Gastroenterol*. 2016; 3(1):e000089.
38. Oliva S, Di Nardo G, Hassan C, et al. Second-generation colon capsule endoscopy vs. colonoscopy in pediatric ulcerative colitis: a pilot study. *Endoscopy*. Jun 2014; 46(6): 485-492.
39. Parodi A, Vanbiervliet G, Hassan C, et al. Colon capsule endoscopy to screen for colorectal neoplasia in those with family histories of colorectal cancer. *Gastrointest Endosc*. May 26 2017.
40. Raju GS, Gerson L, Das A et al. American Gastroenterological Association (AGA)
41. Rex DK, Adler SN, Aisenberg J, et al. Accuracy of capsule colonoscopy in detecting colorectal polyps in a screening population. *Gastroenterology*. May 2015; 148(5):948-957 e942.
42. Rokkas T, Niv Y. The role of video capsule endoscopy in the diagnosis of celiac disease: a meta-analysis. *Eur J Gastroenterol Hepatol* 2012; 24(3):303-8.
43. Rubio-Tapia A, Hill ID, Kelly CP, et al. ACG clinical guidelines: diagnosis and management of celiac disease. *AM J Gastroenterol*. May 2013; 108(5):656-676.

44. Saito Y, Saito S, Oka S, et al. Evaluation of the clinical efficacy of colon capsule endoscopy in the detection of lesions of the colon: prospective, multicenter, open study. *Gastrointest Endosc.* Nov 2015; 82(5): 861-869.
45. San Juan-Acosta M, Caunedo-Alvarez A, Arguelles-Arias F, et al. Colon capsule endoscopy is a safe and useful tool to assess disease parameters in patients with ulcerative colitis. *Eur J Gastroenterol Hepatol.* Aug 2014; 26(8):894-901.
46. Shi HY, Chan FKL, Higashimori A, et al. A prospective study on second-generation colon capsule endoscopy to detect mucosal lesions and disease activity in ulcerative colitis (with video). *Gastrointest Endosc.* Dec 2017;86(6):1139-1146 e1136.
47. Spada C, Hassan C, Galmiche JP, et al. Colon capsule endoscopy: European Society of Gastrointestinal Endoscopy (ESGE) Guideline. *Endoscopy.* May 2012; 44(5):527-536.
48. 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.* May 7 2016.
49. Sung J, Ho KY, Chiu HM et al. The use of Pillcam Colon in assessing mucosal inflammation in ulcerative colitis: a multicenter study. *Endoscopy* 2012; 44(8):754-8.
50. Sung JJ, Tang RS, Ching JY, et al. Use of capsule endoscopy in the emergency department as a triage of patients with GI bleeding. *Gastrointest Endosc.* May 6 2016.
51. U.S. Preventive Services Task Force. Draft Research Plan: Colorectal Cancer Screening. January 13, 2019; <https://www.uspreventiveservicestaskforce.org/uspstf/document/draft-research-plan/colorectal-cancer-screening3>. Accessed November 2, 2020.
52. Urquhart P, Grimpen F, Lim GJ, et al. Capsule endoscopy versus magnetic resonance enterography for the detection of small bowel polyps in Peutz-Jeghers syndrome. *Fam Cancer.* Jun 2014; 13(2):249-255.
53. Xue M, Chen X, Shi L, et al. Small-bowel capsule endoscopy in patients with unexplained chronic abdominal pain: a systematic review. *Gastrointest Endosc.* Jul 8 2014.
54. Yang L, Chen Y, Zhang B, et al. Increased diagnostic yield of capsule endoscopy in patients with chronic abdominal pain. *PLoS One.* 2014; 9(1):e87396.

POLICY HISTORY:

Adopted for Blue Advantage, March 2005

Available for comment May 1-June 14, 2005

Medical Policy Group, December 2005

Available for comment December 27, 2005-February 9, 2006

Effective January 1, 2006: This policy was replaced with LCD L30045.

Medical Policy Group, December 2020: Reinstated policy effective March 24, 2020.

Medical Policy Group, March 2022 : Added 0355T to Previous Coding section. Effective January 1, 2022, refer to LCD 38755 for CPT 91113.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case by case basis according to the terms of the member's plan in effect as of the date

services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plans contracts.