

FEP 6.01.33 Wireless Capsule Endoscopy to Diagnose Disorders of the Small Bowel, Esophagus, and Colon

Effective Date: April 15, 2018

Related Policies: None

Wireless Capsule Endoscopy to Diagnose Disorders of the Small Bowel, Esophagus, and Colon

Description

The wireless capsule endoscopy (CE) uses a device to visualize portions of the bowel that are not accessible via upper or lower endoscopy, primarily the small bowel. 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.

FDA REGULATORY STATUS

In August 2001, the PillCam™ Given® Diagnostic Imaging System (Given Imaging) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. FDA clearance provides for the capsule's use "along with – not as a replacement for – other endoscopic and radiologic evaluations of the small bowel." FDA clarified that the "capsule was not studied in the large intestine." In 2003, after a supplemental 510(k) premarket notification, the labeled indications were modified by removing the "adjunctive" use qualification: "the Given® Diagnostic System is intended for visualization of the small bowel mucosa. It may be used as a tool in the detection of abnormalities of the small bowel."

In 2004, the device received FDA clearance for the following labeled indication: "the Given® Diagnostic System with the PillCam™ ESO Capsule is intended for the visualization of esophageal mucosa." A new model (PillCam™ ESO2 Capsule) was cleared by FDA in June 2007. In September 2007, the Olympus Capsule Endoscope System was cleared for marketing by FDA through the 510(k) process for "visualization of the small intestine mucosa." More recent versions of both systems also incorporate a blood indicator feature to assist with rapid screening of intestinal lesions with bleeding potential.

In 2006, the Given AGILE™ patency system was cleared by FDA through the 510(k) process. This system is an accessory to the PillCam™ video capsule and, according to FDA, is intended to verify adequate patency of the GI tract before administration of the PillCam™ into patients with known or suspected strictures. This capsule is of similar size to the endoscopy capsule but made of lactose and barium and dissolves within 30 to 100 hours of entering the GI tract. It carries a tracer material that can be detected by a scanning device. Excretion of the intact capsule without symptoms (abdominal pain or obstruction) is reported to predict the uncomplicated passage of the wireless capsule.

In 2014, PillCam™ COLON was cleared for marketing by FDA through a de novo 510(k) classification. The new classification applies to devices with low-to-moderate risk that have no predicate on the market.

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PillCam™ COLON is intended to visualize the colon in patients who have had an incomplete colonoscopy due to a technical impossibility and not incomplete evacuation.

In 2016, the PillCam™ COLON 2 Capsule Endoscopy System was cleared by FDA through the 510(k) process for the detection of colon polyps in patients after an incomplete colonoscopy with adequate preparation, 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 in patients with major risks for colonoscopy or moderate sedation, but who could tolerate a colonoscopy and moderate sedation in the event that a clinically significant colon abnormality was identified on capsule endoscopy.

FDA product code: NEZ.

POLICY STATEMENT

Wireless capsule endoscopy of the small bowel may be considered **medically necessary** for the following indications:

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

Other indications for wireless capsule endoscopy are considered **investigational**, including but not limited to:

- Evaluation of the extent of involvement of known Crohn disease or ulcerative colitis.
- Evaluation of the esophagus, in patients with gastroesophageal reflux or other esophageal pathologies.
- Evaluation of other GI diseases and conditions not presenting with GI bleeding, including but not limited to, celiac sprue, irritable bowel syndrome, Lynch syndrome, portal hypertensive enteropathy, small bowel neoplasm, and unexplained chronic abdominal pain.
- Evaluation of the colon, including but not limited to, detection of colonic polyps or colon cancer.
- Initial evaluation of patients with acute upper GI bleeding.

The patency capsule is considered **investigational**, including use to evaluate patency of the GI tract before wireless capsule endoscopy.

POLICY GUIDELINES

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

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

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RATIONALE**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. Relevant outcomes are test accuracy and 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 suspected small bowel CD who receive wireless CE, the evidence includes case series. Relevant outcomes are test accuracy and 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. Relevant outcomes are test accuracy and test validity, other test performance measures, symptoms, and change in disease status. The diagnostic characteristics of CE are inadequate enough 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 the technology on health outcomes.

For individuals who have unexplained chronic abdominal pain who receive wireless CE, the evidence includes case series and diagnostic accuracy studies. Relevant outcomes are test accuracy and 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 chain of evidence to improved outcomes is lacking. The evidence is insufficient to determine the effects of the technology on 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. Relevant outcomes are test accuracy and 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. Relevant outcomes are test accuracy and validity, other test

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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 3 studies were small (ie, <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 the technology on health outcomes.

For individuals who have esophageal disorders who receive wireless CE, the evidence includes case series and diagnostic accuracy studies. Relevant outcomes are test accuracy and 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 the technology on health outcomes.

For individuals who have hereditary polyposis syndromes who receive wireless CE, the evidence includes case series and diagnostic accuracy studies. Relevant outcomes are test accuracy and 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 the technology on 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 accuracy and validity, and other test performance measures, symptoms, and change in disease status. Systematic reviews of studies of its diagnostic performance for this purpose 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 the effects of the technology on health outcomes.

Acute Upper GI Bleeding

For individuals who have acute upper GI tract bleeding who receive wireless CE, the evidence includes a randomized controlled trial and several cohort studies. Relevant outcomes are test accuracy and validity, and 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 based on efficiency (avoiding hospitalization, avoiding immediate endoscopy). Further 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 the technology on 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 accuracy and validity, 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 the technology on health outcomes.

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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. Relevant outcomes are test accuracy and 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 the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Canadian Association of Gastroenterology

In 2017, the Canadian Association of Gastroenterology published guidelines on the use of video capsule endoscopy (CE), which included the following consensus recommendations (majority voting for recommendation) (see Table 1).⁴⁴

Table 1: Recommendations on Use of Video CE

Recommendation	QOE
Crohn disease	
Patients presenting with clinical features consistent with Crohn disease and negative ileocolonoscopy and imaging studies	Very low or low
Patients with Crohn disease and clinical features not explained by negative ileocolonoscopy and imaging studies	Very low or low
Patients with Crohn disease, when assessment of small-bowel mucosal healing is needed, and the area is beyond the reach of ileocolonoscopy	Very low or low
Patients with suspected small bowel recurrence of Crohn disease after colectomy, undiagnosed by ileocolonoscopy and imaging studies	Very low or low
Celiac disease	
Recommend against CE in patients with suspected celiac disease	Very low or low
Recommend for CE in patients with celiac disease and unexplained symptoms despite treatment and appropriate investigations	Very low or low
Gastrointestinal bleeding	
Recommend for CE in patients with documented overt gastrointestinal bleeding (excluding hematemesis) and negative colonoscopy and high-quality esophagogastroduodenoscopy	Very low or low
Recommend for CE in patients with an overt, obscure bleeding episode	Very low or low
Recommend for endoscopy, colonoscopy and/or CE in patients with prior negative CE who have repeated obscure bleeding	Very low or low

CE: capsule endoscopy; QOE: quality of evidence (all consensus based).

American College of Gastroenterology

In 2013, the American College of Gastroenterology (ACG) issued guidelines on the diagnosis and management of celiac disease.⁴⁵ The guidelines recommended that 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).

ACG issued guidelines in 2009 on the management of CD in adults.⁴⁶ The guidelines indicated that use of video CE had been assessed in a prospective blinded evaluation and was shown to be superior in its

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ability to detect small bowel pathology missed on small bowel radiographic studies and computed tomography radiographic examinations. However, because there is a risk of capsule retention in up to 13% of patients with CD, which could require surgical intervention, CE is considered to be a contraindication in patients with known small bowel strictures. It was recommended that radiographic studies such as computed tomography enterography, small bowel follow-through, or magnetic resonance imaging be done to assess for the presence of unsuspected bowel strictures before CE. A patency capsule may also be considered.

In 2015, ACG 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).⁴⁷ These guidelines made the following statements related to video CE (see Table 2).

Table 2.: 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

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

American Society of Gastrointestinal Endoscopy

In 2016, the American Society of Gastrointestinal Endoscopy published guidelines for the use of endoscopy in the management of suspected small bowel bleeding.⁴⁸ These guidelines made the following recommendations on capsule endoscopy (VCE) (see Table 3).

Table 3: 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

A 2007 position statement by American Gastroenterological Association indicated the following on obscure GI bleeding and CE¹:

“Evaluation of the patient with obscure bleeding is dependent on the extent of the bleeding and the age of the patient.

Patients with occult GI blood loss and no anemia most likely do not require evaluation beyond colonoscopy unless upper tract symptoms are present....

Patients with occult GI blood loss and iron deficiency anemia and negative workup on EGD [esophagogastroduodenoscopy] and colonoscopy need comprehensive evaluation, including capsule endoscopy to identify an intestinal bleeding lesion.”

European Crohn's and Colitis Organisation and Organisation Mondiale d'Endoscopie Digestive

In 2009, an international consensus panel published guidelines on the use of wireless capsule endoscopy for inflammatory bowel disease.⁹

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European Society of Gastrointestinal Endoscopy

In 2012, the European Society of Gastrointestinal Endoscopy published guidelines on colon CE, which made the following statements on indications for colon CE⁴⁹:

- “CCE [colon capsule endoscopy] is feasible and safe and appears to be accurate when used in average-risk individuals (Evidence level 2++, Recommendation grade C).”
- “CCE screening may be cost-effective if it increases screening uptake compared with colonoscopy (Evidence level 4, Recommendation grade D).”

European Commission

European guidelines for quality assurance in colorectal cancer screening and diagnosis, published in 2012, indicated CE is not recommended for screening for colorectal cancer.⁵⁰ These guidelines noted that studies have shown CE is inferior to colonoscopy in diagnostic performance.

U.S. Preventive Services Task Force Recommendations

The U.S. Preventive Services Task Force published its most recent recommendations for colorectal cancer screening in 2016. Colorectal cancer screening was recommended starting at age 50 years and continuing until age 75 years (A recommendation).⁵¹ Studies evaluating CE were not included in the evidence reviews in this report.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

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POLICY HISTORY

Date	Action	Description
December 2011	New Policy	
March 2013	Update Policy	Policy and references updated, Policy statement updated to read "performed during current episode of illness" for obscure GI bleed.
December 2013	Update Policy	Policy updated with literature review; added ulcerative colitis, acute GI bleeding and Lynch Syndrome to investigational policy statement. Reference numbers 7-11, 13, 17, 27 and 33 added.
March 2015	Update Policy	Policy updated with literature review; added portal hypertensive enteropathy and unexplained chronic abdominal pain to the investigational policy statement. Also added a new medically necessary

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.

FEP 6.01.33 Wireless Capsule Endoscopy to Diagnose Disorders of the Small Bowel, Esophagus, and Colon

		policy statement in patients with established Crohn disease for unexpected change(s) in course of disease or response to treatment. Reference number 27, 29-31 added.
March 2017	Update Policy	Policy updated with literature review through October 14, 2016. References 9, 14, 16, 24, and 46 added. Minor change to policy statement to change "Obscure gastrointestinal bleeding" to "Suspected small bowel bleeding;" policy statements otherwise unchanged. Title changed to "Wireless Capsule Endoscopy to Diagnose Disorders of the Small Bowel, Esophagus, and Colon".
March 2018	Update Policy	Policy updated with literature review through September 11, 2017; references 17, 30, 38, 44, 46, 49 and 51 added. Policy statements unchanged except "not medically necessary" corrected to "investigational" for patency capsule due to FDA 510k status.