



---

## FEP Medical Policy Manual

---

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

---

**Effective Policy Date: April 1, 2021**

**Related Policies:**

**Original Policy Date: December 2011**

None

---

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

### Description

The wireless capsule endoscopy (CE) uses a noninvasive 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 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 2 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.

---

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.

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.<sup>1</sup> 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.

## OBJECTIVE

The objective of this evidence review is to determine whether the use of wireless capsule endoscopy improves the net health outcome for patients with suspected or established gastrointestinal disorders.

## POLICY STATEMENT

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

- Suspected small bowel bleeding, as evidenced by prior inconclusive upper and lower gastrointestinal (GI) endoscopic studies performed during the current episode of illness.
- 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.
- 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 (risk for hereditary nonpolyposis colorectal cancer), 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.
- Evaluation of patients with evidence of lower GI bleeding and major risks for colonoscopy or moderate sedation.
- Evaluation of patients following incomplete colonoscopy.

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

---

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.

## POLICY GUIDELINES

None

## BENEFIT APPLICATION

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

## FDA REGULATORY STATUS

Table 1 summarizes various wireless CE devices with clearance by the U.S. Food and Drug Administration.

Code used: NEZ

**Table 1. Wireless Capsule Endoscopy Devices Cleared by the U.S. Food and Drug Administration**

Device	Manufacturer	Date Cleared	510(k) No.	Indication
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 2 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.

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.

MiroCam Capsule Endoscope System	IntroMedic Co. Ltd.	1/30/2018	K170438	For visualization of the small intestine mucosa.
PillCam SBC capsule endoscopy system PillCam 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 Inc.	2/9/2016	K151635	For use in diagnosing disorders of the small bowel, esophagus, and colon.
PillCam COLON2	Given Imaging	1/14/2016	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.

## 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 capsule endoscopy (CE), the evidence includes numerous case series evaluating patients with a nondiagnostic standard workup. 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

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.

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 an improvement in the net health outcomes.

For individuals who have suspected small bowel Crohn disease (CD) who receive wireless CE, the evidence includes case series. 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 this indication 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 an improvement in the net health outcomes.

For individuals who have suspected celiac disease 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. 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 that the technology results in an improvement in the net 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 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 that the technology results in an improvement in the 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. 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 and 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 an improvement in the net health outcomes.

For individuals who have ulcerative colitis 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. 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 and a strong chain of evidence to improved outcomes are lacking. The evidence is insufficient to determine that the technology results in an improvement in the net 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 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 that the technology results in an improvement in the net health outcomes.

For individuals who have hereditary gastrointestinal (GI) polyposis syndromes 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. 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 that the technology results in an improvement in the 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, and other test performance measures, symptoms, and change in disease status. Systematic reviews of studies of CE's diagnostic performance for this indicated 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 outcomes.

---

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.

## Acute Upper GI Bleeding

For individuals who have acute upper GI tract bleeding who receive wireless CE, the evidence includes a randomized controlled trial (RCT) and several cohort studies. Relevant outcomes are test validity, and other test performance measures, symptoms, hospitalizations, 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 that the technology results in an improvement in the 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, 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. 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 that the technology results in an improvement in the 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 overall survival, disease-specific survival, resource utilization, test validity, and other test performance measures. 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 that the technology results in an improvement in the 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 overall survival, disease-specific survival, resource utilization, test validity, and other test performance measures. 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 that the technology results in an improvement in the 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. 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 that the technology results in an improvement in the net health outcomes.

---

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.

## SUPPLEMENTAL INFORMATION

### Practice Guidelines and Position Statements

#### American College of Gastroenterology

In 2013, the American College of Gastroenterology (ACG) issued guidelines on the diagnosis and management of celiac disease.<sup>52</sup> 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).

In 2018, the ACG updated its guidelines on the management of CD in adults.<sup>53</sup> It makes 2 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."<sup>53</sup>

In 2015, the 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).<sup>54</sup> 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

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

#### American Society of Gastrointestinal Endoscopy

In 2017, the American Society of Gastrointestinal Endoscopy released guidelines for the use of endoscopy in the management of suspected small bowel bleeding.<sup>55</sup> These guidelines made the following recommendations on capsule endoscopy (see Table 3).

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.



**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 Institute

In 2017, the American Gastroenterological Association Institute issued guidelines on the use of capsule endoscopy.<sup>56</sup> Table 4 summarizes the most relevant recommendations (not all recommendations are included).

**Table 4. AGA 2017 Capsule Endoscopy Recommendations**

Stmt No.	Recommendation	Grade	QOE
<b>Recommendations Supporting the Use of Capsule Endoscopy (CE)</b>			
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 hematoemesis) 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)
<b>Recommendations Against Use of CE</b>			
5	For diagnosing CD when chronic abdominal pain or diarrhea are only symptoms, and with no evidence of biomarkers associated with CD	Conditional	Low
6	For diagnosing celiac disease	Strong	Very low (efficacy) Low (safety)
13	For routine substitution of colonoscopy	Strong	Very low

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.



14	For inflammatory bowel disease (IBD), as substitute for colonoscopy to assess extent and severity of disease	Strong	Very low (efficacy) Low (safety)
----	--	--------	-------------------------------------

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.<sup>57</sup> 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 2016.<sup>58</sup> Colorectal cancer screening was recommended starting at age 50 years and continuing until age 75 years (A recommendation). Studies evaluating CE were not included in the evidence reviews in this report.

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.<sup>59</sup>

## Medicare National Coverage

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

## REFERENCES

1. Bourreille A, Ignjatovic A, Aabakken L, et al. Role of small-bowel endoscopy in the management of patients with inflammatory bowel disease: an international OMED-ECCO consensus. *Endoscopy*. Jul 2009; 41(7): 618-37. PMID 19588292
2. 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*. Nov 2012; 76(5): 983-92. PMID 23078923
3. 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*. Sep 2012; 107(9): 1370-6. PMID 22825363
4. 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*. Jun 2005; 61(7): 826-32. PMID 15933683
5. Pennazio M, Santucci R, Rondonotti E, et al. Outcome of patients with obscure gastrointestinal bleeding after capsule endoscopy: report of 100 consecutive cases. *Gastroenterology*. Mar 2004; 126(3): 643-53. PMID 14988816
6. 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. PMID 27728963
7. El-Matary W, Huynh H, Vandermeer B. Diagnostic characteristics of given video capsule endoscopy in diagnosis of celiac disease: a meta-analysis. *J Laparoendosc Adv Surg Tech A*. Dec 2009; 19(6): 815-20. PMID 19405806
8. Rokkas T, Niv Y. The role of video capsule endoscopy in the diagnosis of celiac disease: a meta-analysis. *Eur J Gastroenterol Hepatol*. Mar 2012; 24(3): 303-8. PMID 22266837
9. 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*. Feb 2013; 77(2): 227-32. PMID 23200728
10. Culliford A, Daly J, Diamond B, et al. The value of wireless capsule endoscopy in patients with complicated celiac disease. *Gastrointest Endosc*. Jul 2005; 62(1): 55-61. PMID 15990820

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.

11. Xue M, Chen X, Shi L, et al. Small-bowel capsule endoscopy in patients with unexplained chronic abdominal pain: a systematic review. *Gastrointest Endosc.* Jan 2015; 81(1): 186-93. PMID 25012561
12. 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. PMID 24498097
13. Annese V, Daperno M, Rutter MD, et al. European evidence based consensus for endoscopy in inflammatory bowel disease. *J Crohns Colitis.* Dec 2013; 7(12): 982-1018. PMID 24184171
14. 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. PMID 28512034
15. 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). PMID 32499275
16. 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.e6. PMID 28713062
17. 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. PMID 24987825
18. 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): 485-92. PMID 24777427
19. Sung J, Ho KY, Chiu HM, et al. The use of Pillcam Colon in assessing mucosal inflammation in ulcerative colitis: a multicenter study. *Endoscopy.* Aug 2012; 44(8): 754-8. PMID 22696193
20. Guturu P, Sagi SV, Ahn D, et al. Capsule endoscopy with PILLCAM ESO for detecting esophageal varices: a meta-analysis. *Minerva Gastroenterol Dietol.* Mar 2011; 57(1): 1-11. PMID 21372764
21. Bhardwaj A, Hollenbeak CS, Pooran N, et al. A meta-analysis of the diagnostic accuracy of esophageal capsule endoscopy for Barrett's esophagus in patients with gastroesophageal reflux disease. *Am J Gastroenterol.* Jun 2009; 104(6): 1533-9. PMID 19491867
22. 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): 249-55. PMID 24509884
23. Brown G, Fraser C, Schofield G, et al. Video capsule endoscopy in peutz-jeghers syndrome: a blinded comparison with barium follow-through for detection of small-bowel polyps. *Endoscopy.* Apr 2006; 38(4): 385-90. PMID 16680639
24. 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.* May 2005; 61(6): 721-5. PMID 15855978
25. Haanstra JF, Al-Toma A, Dekker E, et al. Prevalence of small-bowel neoplasia in Lynch syndrome assessed by video capsule endoscopy. *Gut.* Oct 2015; 64(10): 1578-83. PMID 25209657
26. Saurin JC, Pilleul F, Soussan EB, et al. Small-bowel capsule endoscopy diagnoses early and advanced neoplasms in asymptomatic patients with Lynch syndrome. *Endoscopy.* Dec 2010; 42(12): 1057-62. PMID 20821360
27. 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. PMID 27548729
28. 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.* Oct 01 2014; (10): CD008760. PMID 25271409
29. 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.* Dec 2016; 84(6): 907-913. PMID 27156655
30. 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.* May 2013; 6(3): 193-8. PMID 23634183
31. Chandran S, Testro A, Urquhart P, et al. Risk stratification of upper GI bleeding with an esophageal capsule. *Gastrointest Endosc.* Jun 2013; 77(6): 891-8. PMID 23453185
32. 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. PMID 23254402
33. 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.* Nov 2016; 14(11): 1533-1543.e8. PMID 27165469
34. 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. PMID 32858753
35. 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): 861-9. PMID 25936450

---

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.

36. 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. PMID 27195129
37. 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*. Mar 2018; 87(3): 695-704. PMID 28554656
38. Kobaek-Larsen M, Kroijer R, Dyrvig AK, et al. Back-to-back colon capsule endoscopy and optical colonoscopy in colorectal cancer screening individuals. *Colorectal Dis*. Jun 2018; 20(6): 479-485. PMID 29166546
39. Rondonotti E, Borghi C, Mandelli G, et al. Accuracy of capsule colonoscopy and computed tomographic colonography in individuals with positive results from the fecal occult blood test. *Clin Gastroenterol Hepatol*. Aug 2014; 12(8): 1303-10. PMID 24398064
40. Eliakim R, Yassin K, Niv Y, et al. Prospective multicenter performance evaluation of the second-generation colon capsule compared with colonoscopy. *Endoscopy*. Dec 2009; 41(12): 1026-31. PMID 19967618
41. Franco DL, Leighton JA, Gurudu SR. Approach to Incomplete Colonoscopy: New Techniques and Technologies. *Gastroenterol Hepatol (N Y)*. Aug 2017; 13(8): 476-483. PMID 28867979
42. 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*. Dec 2018; 6(10): 1556-1562. PMID 30574326
43. Baltés P, Bota M, Albert J, et al. PillCamColon2 after incomplete colonoscopy - A prospective multicenter study. *World J Gastroenterol*. Aug 21 2018; 24(31): 3556-3566. PMID 30131662
44. Negreanu L, Babiuc R, Bengus A, et al. PillCam Colon 2 capsule in patients unable or unwilling to undergo colonoscopy. *World J Gastrointest Endosc*. Nov 16 2013; 5(11): 559-67. PMID 24255748
45. Pioche M, de Leusse A, Filoche B, et al. Prospective multicenter evaluation of colon capsule examination indicated by colonoscopy failure or anesthesia contraindication. *Endoscopy*. Oct 2012; 44(10): 911-6. PMID 22893133
46. Nogales O, Garcia-Lledo J, Lujan M, et al. Therapeutic impact of colon capsule endoscopy with PillCam COLON 2 after incomplete standard colonoscopy: a Spanish multicenter study. *Rev Esp Enferm Dig*. May 2017; 109(5): 322-327. PMID 28229607
47. Spada C, Shah SK, Riccioni ME, et al. Video capsule endoscopy in patients with known or suspected small bowel stricture previously tested with the dissolving patency capsule. *J Clin Gastroenterol*. Jul 2007; 41(6): 576-82. PMID 17577114
48. Delvaux M, Ben Soussan E, Laurent V, et al. Clinical evaluation of the use of the M2A patency capsule system before a capsule endoscopy procedure, in patients with known or suspected intestinal stenosis. *Endoscopy*. Sep 2005; 37(9): 801-7. PMID 16116529
49. Herrerias JM, Leighton JA, Costamagna G, et al. Agile patency system eliminates risk of capsule retention in patients with known intestinal strictures who undergo capsule endoscopy. *Gastrointest Endosc*. May 2008; 67(6): 902-9. PMID 18355824
50. Postgate AJ, Burling D, Gupta A, et al. Safety, reliability and limitations of the given patency capsule in patients at risk of capsule retention: a 3-year technical review. *Dig Dis Sci*. Oct 2008; 53(10): 2732-8. PMID 18320313
51. Banerjee R, Bhargava P, Reddy P, et al. Safety and efficacy of the M2A patency capsule for diagnosis of critical intestinal patency: results of a prospective clinical trial. *J Gastroenterol Hepatol*. Dec 2007; 22(12): 2060-3. PMID 17614957
52. 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): 656-76; quiz 677. PMID 23609613
53. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. *Am J Gastroenterol*. Apr 2018; 113(4): 481-517. PMID 29610508
54. 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): 1265-87; quiz 1288. PMID 26303132
55. Gurudu SR, Bruining DH, Acosta RD, et al. The role of endoscopy in the management of suspected small-bowel bleeding. *Gastrointest Endosc*. Jan 2017; 85(1): 22-31. PMID 27374798
56. 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. PMID 28063287
57. Rex DK, Boland CR, Dominitz JA, et al. Colorectal Cancer Screening: Recommendations for Physicians and Patients From the U.S. Multi-Society Task Force on Colorectal Cancer. *Gastroenterology*. Jul 2017; 153(1): 307-323. PMID 28600072
58. Bibbins-Domingo K, Grossman DC, Curry SJ, et al. Screening for Colorectal Cancer: US Preventive Services Task Force Recommendation Statement. *JAMA*. Jun 21 2016; 315(23): 2564-2575. PMID 27304597
59. 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.

---

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.

## POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2011	New Policy	
March 2013	Replace policy	Policy and references updated, Policy statement updated to read "performed during current episode of illness" for obscure GI bleed.
December 2013	Replace 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	Replace 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 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	Replace 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	Replace 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 510(k) status.
March 2019	Replace policy	Policy updated with literature review through September 7, 2018; references 9 and 18 added. Edits made to the Policy section; intent of policy statements unchanged.
March 2020	Replace policy	Policy updated with literature review through September 9, 2019; references added. Policy statements unchanged
March 2021	Revised policy	Policy updated with literature review through September 21, 2020; references added. Added lower GI bleeding and major risks for colonoscopy or moderate sedation and incomplete colonoscopy to investigational policy statement.

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.