



MASSACHUSETTS

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

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### Policy Number: 185

BCBSA Reference Number: 6.01.33

NCD/LCD: N/A

### Related Policies

None

### Policy

#### Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue<sup>SM</sup> and Medicare PPO Blue<sup>SM</sup> Members

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 re-examination 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, 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 the use to evaluate patency of the GI tract before wireless capsule endoscopy.

## Prior Authorization Information

### Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

### Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is <b>not required</b> .
Commercial PPO and Indemnity	Prior authorization is <b>not required</b> .
Medicare HMO Blue <sup>SM</sup>	Prior authorization is <b>not required</b> .
Medicare PPO Blue <sup>SM</sup>	Prior authorization is <b>not required</b> .

## CPT Codes / HCPCS Codes / ICD Codes

*Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.*

*Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.*

*The following codes are included below for informational purposes only; this is not an all-inclusive list.*

The above **medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO; Indemnity, Medicare HMO Blue, and Medicare PPO Blue:**

### CPT Codes

CPT codes:	Code Description
91110	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), esophagus through ileum, with physician interpretation and report

The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT codes above if **medical necessity criteria** are met:

### ICD-10 Diagnosis Codes

ICD-10-CM Diagnosis codes:	Code Description
D12.6	Benign neoplasm of colon, unspecified** Polyposis (hereditary) of colon
D13.2	Benign neoplasm of duodenum** adenomatosis polyposis
D13.30	Benign neoplasm of unspecified part of small intestine
D13.39	Benign neoplasm of other parts of small intestine
D46.1	Refractory anemia with ring sideroblasts
D46.2	Refractory anemia with excess of blasts [RAEB]

D46.20	Refractory anemia with excess of blasts, unspecified
D46.4	Refractory anemia, unspecified
D50.0	Iron deficiency anemia secondary to blood loss (chronic)
D50.8	Other iron deficiency anemias
D50.9	Iron deficiency anemia, unspecified
D52.0	Dietary folate deficiency anemia
D52.9	Folate deficiency anemia, unspecified
D53.0	Protein deficiency anemia
D53.9	Nutritional anemia, unspecified
D64.89	Other specified anemias
K50.00	Crohn's disease of small intestine without complications
K50.011	Crohn's disease of small intestine with rectal bleeding
K50.012	Crohn's disease of small intestine with intestinal obstruction
K50.013	Crohn's disease of small intestine with fistula
K50.014	Crohn's disease of small intestine with abscess
K50.018	Crohn's disease of small intestine with other complication
K50.019	Crohn's disease of small intestine with unspecified complications
K50.10	Crohn's disease of large intestine without complications
K50.111	Crohn's disease of large intestine with rectal bleeding
K50.112	Crohn's disease of large intestine with intestinal obstruction
K50.113	Crohn's disease of large intestine with fistula
K50.114	Crohn's disease of large intestine with abscess
K50.118	Crohn's disease of large intestine with other complication
K50.119	Crohn's disease of large intestine with unspecified complications
K50.80	Crohn's disease of both small and large intestine without complications
K50.811	Crohn's disease of both small and large intestine with rectal bleeding
K50.812	Crohn's disease of both small and large intestine with intestinal obstruction
K50.813	Crohn's disease of both small and large intestine with fistula
K50.814	Crohn's disease of both small and large intestine with abscess
K50.818	Crohn's disease of both small and large intestine with other complication
K50.819	Crohn's disease of both small and large intestine with unspecified complications
K50.90	Crohn's disease, unspecified, without complications
K50.911	Crohn's disease, unspecified, with rectal bleeding
K50.912	Crohn's disease, unspecified, with intestinal obstruction
K50.913	Crohn's disease, unspecified, with fistula
K50.914	Crohn's disease, unspecified, with abscess
K50.918	Crohn's disease, unspecified, with other complication
K92.0	Hematemesis
K92.1	Melena
K92.2	Gastrointestinal hemorrhage, unspecified
Q85.8	Other phakomatoses, not elsewhere classified
R19.7	Diarrhea, unspecified
R93.3	Abnormal findings on diagnostic imaging of other parts of digestive tract

**The following CPT code is considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:**

**CPT Codes**

CPT codes:	Code Description
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91111	Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus with physician interpretation and report
91113	Gastrointestinal tract imaging, intraluminal colon
0651T	Magnetically controlled capsule endoscopy, esophagus through stomach, including intraprocedural positioning of capsule, with interpretation and report

## Description

### Wireless Capsule Endoscopy

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.

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.

## Summary

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.

### 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 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 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 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.

#### **Acute Upper GI Bleeding**

For individuals who have acute upper GI tract bleeding who receive wireless CE, the evidence includes an 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.

## **Policy History**

Date	Action
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1/2022	Clarified coding information.
7/2021	Clarified coding information.
5/2021	BCBSA National medical policy review. Added lower GI bleeding and major risks for colonoscopy or moderate sedation and incomplete colonoscopy to investigational policy statement. Effective 5/1/2021.
12/2019	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
1/2019	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
1/2018	New references added from BCBSA National medical policy.
1/2017	New references added from BCBSA National medical policy.
1/2017	BCBSA National medical policy review. Policy statement clarified: "Obscure gastrointestinal bleeding" to "Suspected small bowel bleeding." Title changed to "Wireless Capsule Endoscopy to Diagnose Disorders of the Small Bowel, Esophagus, and Colon." New references added. 1/1/2017
11/2015	New references added from BCBSA National medical policy.
2/2015	BCBSA National medical policy review. New medically necessary and investigational indications described. Clarified coding information. Effective 2/1/2015.
7/2014	Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.
2/2014	BCBSA National medical policy review. New investigational indications described. Effective 2/1/2014. Removed CPT code 91112 as it does not meet the intent. Removed ICD-9 diagnosis codes as they are not in the LCD (L22531) 280.9, 456.0, 456.2, 537.83, 555.1, 555.2, 555.9, and added 569.86 as this is in the :LCD.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
10/2011	Reviewed - Medical Policy Group - Gastroenterology, Nutrition, Organ Transplantation. No changes to policy statements.
11/2010	Reviewed - Medical Policy Group - Gastroenterology, Nutrition, Organ Transplantation. No changes to policy statements.
5/1/2010	Medical Policy 185 effective 5/1/2010 describing covered and non-covered indications.
11/2008	Reviewed - Medical Policy Group - Gastroenterology, Nutrition, Organ Transplantation. No changes to policy statements.
11/2007	Reviewed - Medical Policy Group - Gastroenterology, Nutrition, Organ Transplantation. No changes to policy statements.
1/2007	National policy reviewed 1/2007. Revisions to policy statements.
11/2006	Reviewed - Medical Policy Group - Gastroenterology, Nutrition, Organ Transplantation. No changes to policy statements.

## Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

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