MASSACHUSETTS

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Medical Policy

Wireless Capsule Endoscopy for Gastrointestinal (GI) Disorders

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Policy Number: 185

BCBSA Reference Number: 6.01.33 (For Plan internal use only)

Related Policies

None

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

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 individuals with suspected Crohn disease without evidence of disease on conventional diagnostic tests such as small bowel follow-through and upper and lower endoscopy.
- In individuals 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 individuals with hereditary GI polyposis syndromes, including familial adenomatosis 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 individuals 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 individuals with acute upper GI bleeding.
- Evaluation of individuals with evidence of lower GI bleeding and major risks for colonoscopy or moderate sedation.
- Evaluation of individuals following incomplete colonoscopy.

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

Magnetic capsule is considered **INVESTIGATIONAL** for the evaluation of individuals with unexplained upper abdominal complaints.

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 **not required**.
Commercial PPO and Indemnity	Prior authorization is **not required**.

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
Q85.81	PTEN tumor syndrome
Q85.82	Other Cowden syndrome
Q85.83	Von Hippel-Lindau syndrome
Q85.89	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 <u>Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:</u>

CPT Codes

CPT codes:	**Code Description**

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

Health and Health Outcome Disparities in Certain Populations

Screening for colon cancer is suboptimal in the U.S., with only 68.8% of Americans age 50 to 75 years up-to-date with colorectal cancer screening as of 2018.[1,] Additionally, screening rates vary considerably by race, ethnicity, and socioeconomic status in the U.S, with highest rates of screening occurring in White Americans (71.1%) and the lowest rates of screening among Hispanic Americans (56.1%). Black Americans (70.1%), American Indian/Native Americans (62.1%), and Asian Americans/Pacific Islanders (64.8%) have lower screening rates than White Americans. These disparities seem to be associated with limited access to care, a lack of knowledge on family history, and adverse social determinants of health.

As of 2018, the mortality rate for colorectal cancer had decreased by 53% among men and by 30% in women since 1990 and 1969, respectively.[2,] However, colorectal cancer incidence and mortality rates vary between racial and ethnic groups. Between 2012 and 2016, reported incidence rates were highest in non-Hispanic Black individuals, accounting for 45.7 per 100,000 population, and lowest in Asian/Pacific Islander individuals, accounting for 30.0 per 100,000 population. The magnitude of disparity is more evident in mortality rates. Colorectal cancer death rates in non-Hispanic Black individuals (19.0 per 100,000 population) between 2013 and 2017 were nearly 40% higher than those in non-Hispanic White individuals (13.8 per 100,000) and twice that of Asian/Pacific Islander individuals (9.5 per 100,000). Disparities have been attributed to many socioeconomic and social determinants of health, including low median family income, higher prevalence of risk factors, and lower rates of screening and likelihood of timely follow-up.

Wireless Capsule Endoscopy

Wireless capsule endoscopy (CE) is performed using the PillCam Given Diagnostic Imaging System (previously called M2A), which is a disposable imaging capsule manufactured by Given Imaging. The capsule measures 11 by 30 mm and contains video imaging, self-illumination, and image transmission modules, as well as a battery supply that lasts up to 8 hours. The indwelling camera takes images at a rate of 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.

Capsule endoscopy 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.[3,] Thus it is difficult to determine the diagnostic characteristics of various tests used to diagnose the condition and difficult to determine a single comparator diagnostic test to CE.

Magnetic Capsule Endoscopy

The U.S. Food and Drug Administration (FDA) approved a novel magnetically maneuvered CE system (NaviCam™; AnX Robotica, Inc.) in May 2020.[4,] This system consists of a single-use ingestible capsule and magnet linked to a physician-operated console. The capsule contains a camera that wirelessly captures images of the desired anatomy. The console allows the operator to control the motion and direction of the capsule, ensuring visualization of the entire stomach. The system is non-invasive, does not require sedation, and has a procedural time of approximately 15 to 20 minutes. The capsule leaves the body in 24 hours on average but may take as long as 2 weeks. The device is contraindicated for use in patients with gastrointestinal obstruction, stenosis, fistula, or those with dysphagia. Other contraindications include patients with cardiac pacemakers or other implantable electronic medical

devices as well as pregnant women, those less than 22 years of age, and those with a body mass index of 38 or greater.

Summary

Description

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

Summary of Evidence

Patients With Suspected Gastrointestinal Disorders

For individuals who have suspected small bowel bleeding (previously referred to as obscure gastrointestinal [GI] bleeding) who receive wireless capsule endoscopy (CE) , the evidence includes numerous case series evaluating patients with a nondiagnostic standard workup and a randomized controlled trial (RCT). 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 outcome.

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 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 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 outcome.

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 outcome.

Patients With Confirmed Gastrointestinal Disorders

For individuals who have an established diagnosis of CD who receive wireless CE, the evidence includes diagnostic accuracy studies, a systematic review, and a retrospective cohort study. 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. A retrospective cohort study demonstrated

therapeutic management changes based on CE results. The evidence is sufficient to determine that the technology results in an 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 validity, other test performance measures, symptoms, and change in disease status. Several diagnostic accuracy studies have compared CE with colonoscopy to assess disease activity in patients with ulcerative colitis. Two of the 3 studies were small (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 outcome.

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 outcome.

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

Acute Upper Gastrointestinal Bleeding
For individuals who have acute upper GI tract bleeding who receive wireless CE, the evidence includes RCTs and several cohort studies. Relevant outcomes are test validity, 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 outcome.

Colon Cancer Screening
For individuals who are screened for colon cancer who receive wireless CE, the evidence includes diagnostic accuracy studies and systematic reviews. Relevant outcomes are overall survival, disease-specific survival, test validity, test accuracy, and other test performance measures. Studies of CE in screening populations are necessary to determine the diagnostic characteristics of the test in this setting. Studies of diagnostic characteristics alone are insufficient evidence to determine the efficacy of CE for colon cancer screening. Because diagnostic performance is worse than standard colonoscopy, CE would need to be performed more frequently than standard colonoscopy to have comparable efficacy. 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 outcome.

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

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

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 outcome.

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

Policy History

Date	Action
1/2024	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
2/2023	Annual policy review. Minor editorial refinements to policy statements; intent unchanged.
10/2022	Clarified coding information.
5/2022	Annual policy review. Magnetic capsule endoscopy (NaviCam) added to policy with new indication and investigational policy statement. Title changed to "Wireless Capsule Endoscopy for Gastrointestinal (GI) Disorders." Effective 5/1/2022.
1/2022	Clarified coding information.

7/2021	Clarified coding information.
5/2021	Annual 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	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2019	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2018	Annual policy review. New references added.
1/2017	Annual policy review. New references added.
1/2017	Annual 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	Annual policy review. New references added.
2/2015	Annual 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	Annual 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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