Wireless Capsule Endoscopy for Gastrointestinal (GI) Disorders

Policy # 00137
Original Effective Date: 01/27/2003
Current Effective Date: 03/11/2024

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider wireless capsule endoscopy (CE) of the small bowel to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for wireless capsule endoscopy (CE) of the small bowel will be considered when ANY of the following criteria are met:

- Suspected small bowel bleeding, as evidenced by prior inconclusive upper and lower gastrointestinal (GI) endoscopic studies performed during the current episode of illness; OR
- Initial diagnosis in individuals with suspected Crohn disease (CD) without evidence of disease on conventional diagnostic tests such as small bowel follow-through (SBFT) and upper and lower endoscopy; OR
- In individuals with an established diagnosis of Crohn disease (CD), 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; OR
- For surveillance of the small bowel in individuals with hereditary gastrointestinal (GI) polyposis syndromes, including familial adenomatous polyposis and Peutz-Jeghers syndrome.

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When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

The use of wireless capsule endoscopy (CE) of the small bowel when patient selection criteria are not met is considered to be **investigational.***

Based on review of available data, the Company considers other indications of wireless capsule endoscopy (CE), including but not limited to the following, to be **investigational*:**

- Evaluation of the extent of involvement of known Crohn disease (CD) or ulcerative colitis; or
- Evaluation of the esophagus, in individuals with gastroesophageal reflux (GERD) or other esophageal pathologies; or
- Evaluation of other gastrointestinal (GI) diseases and conditions not presenting with gastrointestinal (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; or
- Evaluation of the colon, including but not limited to, detection of colonic polyps or colon cancer; or
- Initial evaluation of individuals with acute upper gastrointestinal (GI) bleeding; or
- Evaluation of individuals with evidence of lower GI bleeding and major risks for colonoscopy or moderate sedation; or
- Evaluation of individuals following incomplete colonoscopy.

Based on review of available data, the Company considers the patency capsule, including use to evaluate patency of the gastrointestinal (GI) tract before wireless capsule endoscopy (CE), to be **investigational.***

Based on review of available data, the Company considers magnetic capsule endoscopy for the evaluation of individuals with unexplained upper abdominal complaints and all other indications, to be **investigational.***

Wireless Capsule Endoscopy for Gastrointestinal (GI) Disorders

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Background/Overview

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. 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. 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. 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. 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.

FDA or Other Governmental Regulatory Approval

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

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
Pillcam SB 3 Capsule Endoscopy System, Pillcam Software 9.0e	Given Imaging Ltd.	8/27/2021	K211684	For visualization of the small bowel mucosa. It may be used in the visualization and monitoring of: lesions that may indicate Crohn's disease not detected by upper and lower endoscopy; lesions that may be a source of obscure bleeding not detected by upper and lower endoscopy; lesions that may be potential causes of iron deficiency anemia not detected by upper and lower endoscopy.
NaviCam Stomach Capsule System	AnX Robotica, Inc.	5/22/2020	K203192	For visualization of the stomach of adults (≥22 years) with a body mass index <38. The system can be used in clinics and hospitals, including emergency room settings.
CapsoCam Plus (SV-3)	CapsoVision Inc.	4/19/2019	K183192	For visualization of the small bowel mucosa in adults. It may be used as a tool in the detection of abnormalities of the small bowel.
Olympus Small Intestinal Capsule Endoscope System	Olympus Medical Systems Corp.	3/5/2019	K183053	For visualization of the small intestine mucosa.
MiroCam Capsule Endoscope System	IntroMedic Co. Ltd.	11/8/2018	K180732	May be used as a tool in the detection of abnormalities of the small bowel and this device is

				indicated for adults and children from 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.
MiroCam Capsule Endoscope System	IntroMedic Co. Ltd.	1/30/2018	K170438	For visualization of the small intestine mucosa.
PillCam SBC capsule endoscopy system	Given Imaging Ltd.	9/1/2017	K170210	For visualization of the small intestine mucosa.

PilCam Desktop Software 9.0				
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/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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 GI 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 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.

Supplemental Information

Practice Guidelines and Position Statements
Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Gastroenterology
In 2013, the American College of Gastroenterology (ACG) issued guidelines on the diagnosis and management of celiac disease. The guidelines recommended that capsule endoscopy (CE) not be used for initial diagnosis, except for patients with positive celiac-specific serology who are unwilling or unable to undergo upper endoscopy with biopsy (strong recommendation, moderate level of evidence). These guidelines were updated in 2023, with no mention of CE.

In 2018, the ACG updated its guidelines on the management of Crohn Disease (CD) in adults. 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 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%."

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). As of November 2023, a guideline update is in progress. The 2015 guidelines made the following statements related to video CE (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.

In 2021, the ACG issued guidelines on colorectal cancer screening. They "suggest consideration of the following screening tests for individuals unable or unwilling to undergo a colonoscopy or FIT [fecal immunochemical testing]: flexible sigmoidoscopy, multitarget stool DNA test, CT [computed tomography] colongraphy, or colon capsule [capsule endoscopy]" (conditional recommendation, very low quality of evidence).

American Gastroenterological Association Institute

In 2017, the American Gastroenterological Association Institute issued guidelines on the use of CE. Table 3 summarizes the most relevant recommendations (not all recommendations are included).

Table 3. AGA 2017 Capsule Endoscopy Recommendations

Statement number	Recommendation	Grade	QOE
Recommendations supporting the use of CE			
1	For suspected 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 GI bleeding (excluding hematoemesis) and negative findings on high-quality EGD and colonoscopy	Strong	Very low
9	For overt, obscure bleeding episode, as soon as possible	Strong	Very low
10	With prior negative CE with repeated obscure bleeding, repeated studies (endoscopy, colonoscopy and/or CE)	Strong	Very low

11	For suspected obscure bleeding and unexplained mild chronic iron-deficiency anemia, in selected cases	Strong	Very low
12	For polyposis syndromes, which require small bowel studies, for ongoing surveillance	Conditional	Very low (efficacy) Low (safety)
Recommendations against the use of CE			
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
14	For IBD, as substitute for colonoscopy to assess extent and severity of disease	Strong	Very low (efficacy) Low (safety)

AGA: American Gastroenterological Association; CD: Crohn disease; CE: capsule endoscopy; EGD: esophagogastroduodenoscopy; GI: gastrointestinal; IBD: inflammatory bowel disease; QOE: quality of evidence.

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. These guidelines made the following recommendations on capsule endoscopy (Table 4).

Table 4. 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.

U.S. Multi-Society Task Force
The U.S. Multi-Society Task Force (2017) issued recommendations for colorectal cancer screening with representation from the ACG, the American Gastroenterological Association, and the American Society for Gastrointestinal Endoscopy. Capsule endoscopy every 5 years received a tier 3 ranking with the following recommendation:

- "We suggest that capsule colonoscopy (if available) is an appropriate screening test when patients decline colonoscopy, FIT, FIT-fecal DNA, CT colonography, and flexible sigmoidoscopy (weak recommendation, low-quality evidence)."

In tandem with the U.S. Preventative Services Task Force (USPSTF) 2021 recommendations, the Multi-Society Task Force released a focused update to these guidelines in 2021, however, no changes were made regarding CE.

U.S. Preventive Services Task Force Recommendations
The USPSTF published its most recent recommendations for colorectal cancer screening in 2021. Colorectal cancer screening was recommended starting at age 50 years and continuing until age 75 years (A recommendation) and in adults aged 45 to 49 years (B recommendation). The USPSTF recommendation for screening for colorectal cancer does not include serum tests, urine tests, or CE for colorectal cancer screening because of the limited available evidence on these tests and because other effective tests are available.

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.

Ongoing and Unpublished Clinical Trials
Some currently ongoing and unpublished trials that might influence this review are listed in Table 5.

Table 5. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04472364	Impact of Blood Detection Capsule "HemoPill Acute" on the Time to Emergency Endoscopy in Case of Suspected Nonvariceal Upper Gastrointestinal Bleeding	72	Dec 2024
NCT02738359	Efficacy of Colonoscopy, Colon Capsule and Fecal Immunological Test for Colorectal Cancer Screening, in First Degree Relatives of Patients With Colorectal Neoplasia: a Prospective Randomized Study	3250	Nov 2023
NCT04307901	Safety of Colorectal Assessment and Tumor Evaluation by Colon Capsule Endoscopy (SOCRATEC)	600	Dec 2030
NCT05108844	A Randomized Controlled Trial Evaluating the Efficacy of Early Videocapsule Endoscopy Following Negative Gastroscopy in Patients Presenting With Suspected Upper Gastrointestinal Bleeding	70	Oct 2023
NCT03616041	Video Capsule Endoscopy for Lesion Localization and Diagnosis in Patients With Severe Hematochezia	50	Jul 2023
Unpublished			
NCT03458000[a]	Capsule Endoscopy for Hemorrhage in the ER	24	Sep 2020

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

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Policy History

Original Effective Date: 01/27/2003
Current Effective Date: 03/11/2024
03/21/2002 Medical Policy Committee review
03/25/2002 Managed Care Advisory Council approval
06/24/2002 Format revision. No substance change to policy.
11/21/2002 Medical Policy Committee review. Format revision. No substance change to policy.
01/27/2003 Managed Care Advisory Council approval

02/01/2005	Medical Director review
02/15/2005	Medical Policy Committee review. Format revision
03/07/2005	Managed Care Advisory Council approval
07/13/2005	Medical Director review
07/19/2005	Medical Policy Committee review
08/24/2005	Managed Care Advisory Council approval
03/09/2006	Medical Director review
03/15/2006	Medical Policy Committee approval. Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
06/13/2007	Medical Director review
06/20/2007	Medical Policy Committee approval. Wireless capsule endoscopy for surveillance of the small bowel in individuals with hereditary GI polyposis syndromes, including familial adenomatous polyposis and Peutz-Jeghers syndrome are now eligible for coverage. Rationale updated.
09/09/2008	Medical Director review
09/17/2008	Medical Policy Committee approval. Added bullets to investigational statement as follows: • Evaluation of the extent of involvement of known Crohn's disease; or • Evaluation of the esophagus, in individuals with gastroesophageal reflux (GERD) or other esophageal pathologies. Added that the patency capsule, including use to evaluate patency of the gastrointestinal tract before wireless capsule endoscopy is considered to be investigational.
09/03/2009	Medical Policy Committee approval.
09/16/2009	Medical Policy Implementation Committee approval. Added "and Colon" to the end of the current title to read, "Wireless Capsule Endoscopy as a Diagnostic Technique in Disorders of the Small Bowel, Esophagus and Colon". Removed both sets of patient selection criteria from the When Services May be Eligible for Coverage section and added a new set of patient selection criteria to this section. Added a fourth criteria bullet to the When Services Are Considered Investigational. Updated the entire policy.
09/09/2010	Medical Policy Committee review
09/15/2010	Medical Policy Implementation Committee. Coverage eligibility unchanged.

09/01/2011	Medical Policy Committee review
09/14/2011	Medical Policy Implementation Committee. Coverage eligibility unchanged.
09/06/2012	Medical Policy Committee review
09/19/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/05/2013	Medical Policy Committee review
09/18/2013	Medical Policy Implementation Committee approval. Added ulcerative colitis, Lynch syndrome, and acute GI bleeding to investigational statements.
10/02/2014	Medical Policy Committee review
10/15/2014	Medical Policy Implementation Committee approval. Added portal hypertensive enteropathy and unexplained chronic abdominal pain to the investigational policy statement; Added a statement indicating wireless capsule endoscopy may be eligible for coverage, in individuals with an established diagnosis of Crohn disease, for 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.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
12/03/2015	Medical Policy Committee review
12/16/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/01/2016	Coding update
12/01/2016	Medical Policy Committee review
12/21/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
12/07/2017	Medical Policy Committee review
12/20/2017	Medical Policy Implementation Committee approval. Title changed from “Wireless Capsule Endoscopy as a Diagnostic Technique in Disorders of the Small Bowel, Esophagus, and Colon” to “Wireless Capsule Endoscopy to Diagnose Disorders of the Small Bowel, Esophagus, and Colon”. Coverage criteria changed from “Obscure gastrointestinal bleeding” to “Suspected small bowel bleeding”. Policy statements otherwise unchanged.
12/06/2018	Medical Policy Committee review

Wireless Capsule Endoscopy for Gastrointestinal (GI) Disorders

Policy # 00137
Original Effective Date: 01/27/2003
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12/19/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/05/2019	Medical Policy Committee review
12/11/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/03/2020	Medical Policy Committee review
12/09/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/04/2021	Medical Policy Committee review
02/10/2021	Medical Policy Implementation Committee approval. Added "(risk for hereditary nonpolyposis colorectal cancer)" after Lynch syndrome in the investigational indications. Added lower GI bleeding and major risks for colonoscopy or moderate sedation and incomplete colonoscopy to investigational indications.
12/17/2021	Coding Update
02/03/2022	Medical Policy Committee review
02/09/2022	Medical Policy Implementation Committee approval. Title changed from "Wireless Capsule Endoscopy to Diagnose Disorders of the Small Bowel, Esophagus and Colon" to "Wireless Capsule Endoscopy for Gastrointestinal (GI) Disorders". Added an investigation statement for magnetic capsule endoscopy for the evaluation of individuals with unexplained upper abdominal complaints and all other indications.
2/09/2022	Coding Update
02/02/2023	Medical Policy Committee review
02/08/2023	Medical Policy Implementation Committee approval. No change to coverage. Minor editorial refinements to policy statements; intent unchanged.
05/29/2023	Coding update
02/01/2024	Medical Policy Committee review
02/14/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 02/2025

Wireless Capsule Endoscopy for Gastrointestinal (GI) Disorders

Policy # 00137
Original Effective Date: 01/27/2003
Current Effective Date: 03/11/2024

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2023 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0651T, 91110, 91111, 91113, 91299 Delete code effective 07/01/2023: 91112
HCPCS	No codes
ICD-10 Diagnosis	All related Diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into

standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.