MEDICAL POLICY

POLICY TITLE	WIRELESS CAPSULE ENDOSCOPY FOR GASTROINTESTINAL (GI) DISORDERS
POLICY NUMBER	MP-5.033

Effective Date:	1/1/2024

I. POLICY

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 endoscopic studies performed during the current episode of illness
- Persistent or unexplained iron deficiency anemia suspected to be due to gastrointestinal bleeding when etiology remains unknown despite prior upper and lower gastrointestinal endoscopic studies
- Initial diagnosis in individuals with suspected Crohn's disease without evidence of disease on conventional diagnostic tests such as small bowel follow-through and upper and lower endoscopy.
- In individual with an established diagnosis of Crohn's 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 gastrointestinal (GI) polyposis syndromes, including familial adenomatous polyposis and Peutz-Jeghers syndrome
- In individuals with an established diagnosis of Celiac disease who continue to have symptoms despite treatment
- In individuals with suspected small bowel tumors when radiographic imaging and/or other forms of endoscopy fail to reveal a suspected primary lesion

Wireless capsule endoscopy may be considered **not medically necessary** for the following indications:

- Evaluation of the extent of involvement of known Crohn's disease or ulcerative colitis

- Evaluation of the esophagus, in individuals with gastroesophageal reflux (GERD) or other esophageal pathologies
- Evaluation of the colon including, but not limited to, detection of colonic polyps or colon cancer
- Evaluation of individuals with evidence of lower GI bleeding and major risks for colonoscopy or moderate sedation
- Evaluation of individuals following incomplete colonoscopy
- Diagnosis of portal hypertensive enteropathy

All other indications of wireless capsule endoscopy are considered **investigational**, including but not limited to:

- Evaluation of irritable bowel syndrome, Lynch syndrome, and unexplained chronic abdominal pain
- Initial evaluation of individuals with acute upper GI bleeding

The patency capsule is considered **medically necessary** to evaluate the patency of the gastrointestinal tract before wireless capsule endoscopy in individuals with a history of strictures. All other indications are considered **investigational** as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Magnetic capsule endoscopy is considered **investigational** for the evaluation of individuals with unexplained upper abdominal complaints and all other indications. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

The National Comprehensive Cancer Network (NCCN) is a nonprofit alliance of cancer centers throughout the United States. NCCN develops the Clinical Practice Guidelines in Oncology which are recommendations aimed to help health care professionals diagnose, treat and manage patients with cancer. Guidelines evolve continuously as new treatments and diagnostics emerge and may be used by Capital BlueCross when determining medical necessity according to this policy.

POLICY GUIDELINES

When upper or lower endoscopy is contraindicated or the individual declines endoscopy, wireless capsule endoscopy may be used as a first line treatment.

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital BlueCross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies

III. DESCRIPTION/BACKGROUND

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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 some 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.

Regulatory Status

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

Code used: NEZ

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

Device	Manufacturer	Date Cleared	510(k) No.	Indication
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	IntroMedic Co. Ltd.	11/8/2018	K180732	May be used as a tool in the detection of

System				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 PilCam Desktop Software 9.0	Given Imaging Ltd.	9/1/2017	K170210	For visualization of the small intestine mucosa.
RAPID Web	Given Imaging Ltd.	5/26/2017	K170839	Intended for visualization of the small bowel mucosa.
AdvanCE capsule endoscope delivery device	United States Endoscopy Group Inc.	3/10/2017	K163495	Intended for visualization of the small bowel mucosa.
OLYMPUS SMALL INTESTINAL CAPSULE ENDOSCOPE SYSTEM	OLYMPUS MEDICAL SYSTEMS CORP.	1/19/2017	K163069	Intended for visualization of the small bowel mucosa.
CapsoCam Plus (SV-3) Capsule Endoscope System	CapsoVision Inc	10/21/2016	K161773	Intended for visualization of the small bowel mucosa.
CapsoCam (SV-	CapsoVision	2/9/2016	K151635	For use in

1)	Inc.			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	OLYMPUS MEDICAL SYSTEMS CORP.	2/8/2015	K142680	Intended for visualization of the small bowel mucosa.

LIGHT				

GI: gastrointestinal.

IV. RATIONALE

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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 non-diagnostic standard workup and a randomized control 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 (e.g., determining the extent of CD), direct evidence of improved outcomes or a strong indirect chain of evidence to improved outcomes or a strong indirect chain of evidence to improved outcomes is lacking. The American Gastroenterology Association published clinical practice guidelines for the use of video capsule endoscopy in 2017. While one consensus recommendation stated "In patients with inflammatory bowel disease (IBD), we recommend against substituting colon capsule for colonoscopy to assess the extent and severity of disease", there were three other recommendations that advised use of capsule endoscopy in the case where ileocolonoscopy and imaging studies are negative or do not provide explanation of symptoms. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have unexplained chronic abdominal pain who receive wireless CE, the evidence includes case series and diagnostic accuracy studies. Relevant outcomes are test 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 (e.g., 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 GI 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 (i.e., <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. However, studies have shown that wireless CE may be used in patients unwilling to undergo esophagogastroduodenscopy (EGD). An assessment by the American Society for Gastrointestinal Endoscopy found limited published data on wireless capsule endoscopy of the esophagus, however preliminary data in cases of certain esophageal pathologies show outstanding diagnostic yield.

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, 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. However, an article published as recently as 2015 in the World Journal of Hepatology suggests that "video capsule endoscopy and/or deep endoscopy are the current preferred modalities for establishing the diagnosis" of portal hypertensive enteropathy. 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 a randomized controlled trial 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 the effects of the technology on health outcomes.

Colon Cancer Screening

For individuals who are screened for colon cancer who receive wireless CE, the evidence includes diagnostic accuracy studies and systematic reviews. Relevant outcomes are overall survival, disease-specific survival, test 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. In 2021, the American College of Gastroenterology published clinical guidelines outlining recommendations for colon cancer screening. It was recommended that primary colorectal cancer screening modalities should be colonoscopy and fecal immunochemical tests (FIT). However, while the recommendation notes

evidence was very low-quality, the guideline also stated that "for individuals unable or unwilling to undergo colonoscopy or FIT: flexible sigmoidoscopy, multitarget stool DNA test, CT colonography or colon capsule" should be considered for screening tests. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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 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 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 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.

Suspected Small Bowel Tumors
Current National Comprehensive Cancer Network guidelines for Small Bowel Adenocarcinoma (V 1.2023) provide the following recommendations: "Capsule endoscopy: Consider when radiographic imaging and other forms of endoscopy fail to reveal a suspected primary lesion. This is not the preferred primary method for diagnostic workup due to inability to obtain tissue for diagnosis. Contraindicated where small bowel obstruction or strictures exist".

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. 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.

V. DEFINITIONS

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ANEMIA is a reduction in the amount of circulating red blood cells. Generally, a person is considered anemic when their hemoglobin levels are more than two standard deviations below the mean level of the laboratory. Various factors, such as bleeding, vitamin or mineral deficiencies or a decrease in red blood cell production can cause anemia.

ENDOSCOPY refers to inspection of body organs or cavities by use of an endoscope.

510 (K) is a premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA). Applicants must compare their 510(k) device to one or more similar devices currently on the U.S. market and make and support their substantial equivalency claims.

PERISTALSIS refers to the progressive wavelike movement that occurs involuntarily in hollow tubes of the body, especially the alimentary canal.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational; therefore, not covered:

Procedure Codes								
0651T								

Codes considered Not Medically Necessary:

Procedure Codes								
91111	91113							

Covered when medically necessary (91299 when used for patency capsule):

Procedure Codes								
91110	91299							

ICD-10-CM Diagnosis Codes	Description
D13.91	Familial adenomatous polyposis
D50.0	Iron deficiency anemia secondary to blood loss (chronic)
D50.8	Other iron deficiency 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

ICD-10-CM Diagnosis Codes	Description
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
K50.10	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
K50.80	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
K92.0	Hematemesis
K90.0	Celiac Disease
K92.1	Melena
K92.2	Gastrointestinal hemorrhage, unspecified
Q85.8	Other phakomatoses, not elsewhere classified

IX. REFERENCES

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77. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 6.01.33, Wireless Capsule Endoscopy to Diagnose Disorders of the Small Bowel, Esophagus, and Colon. January 2023*

X. POLICY HISTORY

TOP

MP 5.033	CAC 5/27/03
	CAC 6/24/03

POLICY TITLE	WIRELESS CAPSULE ENDOSCOPY FOR GASTROINTESTINAL (GI) DISORDERS
POLICY NUMBER	MP-5.033

	CAC 9/28/04
	CAC 9/27/05
	CAC 11/28/06
	CAC 5/27/08
	CAC 9/29/09 Requirements for small bowel follow through as a pre-requisite removed from the policy. Information added to the description regarding the Given AGILE patency system and new PillCam models.
	CAC 11/30/10 Consensus review
	CAC 4/24/12 Title changed to match BCBSA. (Formerly Wireless Capsule Endoscopy. Wording changes do not alter coverage criteria. Added definition of obscure GI bleeding as a note. Patency capsule remains investigational
	CAC 6/4/13 Consensus review. No code changes.
	CAC 9/24/13 Minor review. Added evaluation of extent of known ulcerative colitis, evaluation of Lynch syndrome, and initial evaluation of initial episode of acute upper GI bleeding as investigational indications. Added the statement "performed during the current episode of illness" to the second medically necessary bullet "Obscure gastrointestinal (GI) bleeding suspected of being of small bowel origin, as evidenced by prior inconclusive upper and lower gastrointestinal endoscopic studies". Added rationale section and FEP variation referencing the FEP manual. Administrative code review complete.
	CAC 3/25/14 Consensus review. No change to policy statements. References reviewed.
	3/27/14 New LCD for Novitas in effect
	CAC 3/24/15 Minor revision. Added portal hypertensive enteropathy and unexplained chronic abdominal pain to the investigational policy statement. Also added a new medically necessary policy statement in patients with established Crohn's disease for unexpected change(s) in course of disease or response to treatment suggesting the initial diagnosis may be incorrect and re-examination may be indicated. Background, references, and rationale updated. Coding reviewed.
	11/2/15 Administrative update. LCD number changed from L34342 to L35089 due to Novitas update to ICD-10.
	CAC 3/29/16 Consensus review. No change to policy statements. Regulatory Status, Rationale, and References updated. Coding reviewed.
	Admin Update 1/1/17 Variation reformatting.
	CAC 3/28/17 Consensus review. Title changed to "Wireless Capsule Endoscopy to Diagnose Disorders of the Small Bowel, Esophagus, and Colon." Verbiage change to the 3rd bullet of the 1st policy statement, "Obscure gastrointestinal bleeding" changed to "Suspected small bowel bleeding." No change to the intent of the policy statement. Description/Background, Regulatory Status, Rationale, and Reference sections updated. Coding reviewed.
	1/1/18 Admin update: Medicare variations removed from Commercial

POLICY TITLE	WIRELESS CAPSULE ENDOSCOPY FOR GASTROINTESTINAL (GI) DISORDERS
POLICY NUMBER	MP-5.033

	Policies.
	3/9/18 Consensus review. No change to policy statements. References, rationale, and background updated.
	2/27/19 Consensus review. No changes to the policy statements. References and rationale updated.
	2/26/20 Consensus review. Policy updated with literature review, references added. Policy statements unchanged.
	2/24/21 Major review. Added to the list of medically necessary indications: in patients with an established diagnosis of celiac disease who continue to have symptoms despite treatment AND in patients with suspected small bowel tumors. Expanded list of investigational indications. Revised position on the patency capsule from investigational to medically necessary with criteria. Added table one, updated references.
	12/1/21 Admin update. New code update: replaced 0355T with 91113; effective 1/1/22.
	3/16/2022 Minor review. Changed several INV statements to NMN. Added policy statement for magnetic capsule endoscopy as INV. FEP, rationale, and references updated. 91113 is now NMN. No other coding changes.
	02/13/2023 Minor review. Title changed to Wireless Capsule Endoscopy for Gastrointestinal Disorders. Added iron deficiency anemia as medically necessary with criteria for wireless capsule endoscopy of the small bowel. Clarified diagnostic testing requirements for criteria speaking to initial diagnosis with suspected Crohn's disease. Evaluation of the esophagus in patients with GERD and other esophageal pathologies moved from E/I to not medically necessary. NCCN language added. Policy Guidelines added. Background and Rationale updated. References updated.
	09/15/2023 Administrative Update. New ICD10 code D13.91 added. Removed Z83.71. Effective 10/1/2023

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