MEDICAL POLICY

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

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☐ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**10/1/2024**

I. POLICY

Wireless capsule endoscopy (CE) 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.
- In individuals with an established diagnosis of Celiac disease who continue to have symptoms despite treatment.
- 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 suspected small bowel tumors or a family history of small bowel cancer, and visualization of the small bowel is not feasible or is inconclusive with radiographic imaging and/or other forms of endoscopy.

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, 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

TOP

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

TOP

The wireless capsule endoscopy 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.

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 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	Given Imaging Ltd.	8/27/2021	K211684	For visualization of the small bowel mucosa.

System, Pillcam Software 9.0e				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 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	OLYMPUS	1/19/2017	K163069	Intended for

SMALL INTESTINAL CAPSULE ENDOSCOPE SYSTEM	MEDICAL SYSTEMS CORP.			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.

IV. RATIONALE

TOP

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 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 (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. However, wireless CE may play a role in surveillance for small bowel cancer. Many major practice guidelines offer the option for wireless CE if there is a family history of small bowel cancer and Lynch syndrome is confirmed.

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 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 randomized controlled trials (RCTs) and several cohort studies. Relevant outcomes are test validity, and other test performance measures, symptoms, hospitalizations, and resource utilization. The use of CE in the emergency department setting for suspected upper GI bleeding is intended to avoid unnecessary hospitalization or immediate endoscopy. Controlled studies are needed to assess further the impact of CE on health outcomes compared with standard management. The evidence is insufficient to determine that the technology results in an improvement in the net health 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, 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 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 1.2024) 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. The evidence is sufficient 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

TOP

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

TOP

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

TOP

Capital Blue Cross' 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

TOP

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
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

ICD-10-CM Diagnosis Codes	Description
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
K90.0	Celiac Disease
K92.0	Hematemesis
K92.1	Melena
K92.2	Gastrointestinal hemorrhage, unspecified
Q85.8	Other phakomatoses, not elsewhere classified
Z15.09	Genetic susceptibility to other malignant neoplasm
Z83.72	Family history of familial adenomatous polyposis
Z86.0100	Personal history of colon polyps, unspecified
Z86.0101	Personal history of adenomatous and serrated colon polyps
Z86.0102	Personal history of hyperplastic colon polyps
Z86.0109	Personal history of other colon polyps

IX. REFERENCES

TOP

1. *Joseph DA, King JB, Dowling NF, et al. Vital Signs: Colorectal Cancer Screening Test Use - United States, 2018. MMWR Morb Mortal Wkly Rep. Mar 13 2020; 69(10): 253-259. PMID 32163384*
2. *Siegel RL, Miller KD, Goding Sauer A, et al. Colorectal cancer statistics, 2020. CA Cancer J Clin. May 2020; 70(3): 145-164. PMID 32133645*
3. *Bourreille A, Ignjatovic A, Aabakken L, et al. Role of small-bowel endoscopy in the management of patients with inflammatory bowel disease: an international OMED-ECCO consensus. Endoscopy. Jul 2009; 41(7): 618-37. PMID 19588292*
4. *Cross A, Szoka N. SAGES NaviCam stomach capsule system. March 10, 2021*
5. *Koulaouzidis A, Rondonotti E, Giannakou A, et al. Diagnostic yield of small-bowel capsule endoscopy in patients with iron-deficiency anemia: a systematic review. Gastrointest Endosc. Nov 2012; 76(5): 983-92. PMID 23078923*

6. *Leung WK, Ho SS, Suen BY, et al. Capsule endoscopy or angiography in patients with acute overt obscure gastrointestinal bleeding: a prospective randomized study with long-term follow-up. Am J Gastroenterol. Sep 2012; 107(9): 1370-6. PMID 22825363*
7. *Hartmann D, Schmidt H, Bolz G, et al. A prospective two-center study comparing wireless capsule endoscopy with intraoperative enteroscopy in patients with obscure GI bleeding. Gastrointest Endosc. Jun 2005; 61(7): 826-32. PMID 15933683*
8. *Pennazio M, Santucci R, Rondonotti E, et al. Outcome of patients with obscure gastrointestinal bleeding after capsule endoscopy: report of 100 consecutive cases. Gastroenterology. Mar 2004; 126(3): 643-53. PMID 14988816*
9. *Choi M, Lim S, Choi MG, et al. Effectiveness of Capsule Endoscopy Compared with Other Diagnostic Modalities in Patients with Small Bowel Crohn's Disease: A Meta-Analysis. Gut Liver. Jan 15 2017; 11(1): 62-72. PMID 27728963*
10. *El-Matary W, Huynh H, Vandermeer B. Diagnostic characteristics of given video capsule endoscopy in diagnosis of celiac disease: a meta-analysis. J Laparoendosc Adv Surg Tech A. Dec 2009; 19(6): 815-20. PMID 19405806*
11. *Rokkas T, Niv Y. The role of video capsule endoscopy in the diagnosis of celiac disease: a meta-analysis. Eur J Gastroenterol Hepatol. Mar 2012; 24(3): 303-8. PMID 22266837*
12. *Kurien M, Evans KE, Aziz I, et al. Capsule endoscopy in adult celiac disease: a potential role in equivocal cases of celiac disease?. Gastrointest Endosc. Feb 2013; 77(2): 227-32. PMID 23200728*
13. *Culliford A, Daly J, Diamond B, et al. The value of wireless capsule endoscopy in patients with complicated celiac disease. Gastrointest Endosc. Jul 2005; 62(1): 55-61. PMID 15990820*
14. *Xue M, Chen X, Shi L, et al. Small-bowel capsule endoscopy in patients with unexplained chronic abdominal pain: a systematic review. Gastrointest Endosc. Jan 2015; 81(1): 186-93. PMID 25012561*
15. *Yang L, Chen Y, Zhang B, et al. Increased diagnostic yield of capsule endoscopy in patients with chronic abdominal pain. PLoS One. 2014; 9(1): e87396. PMID 24498097*
16. *Kopylov U, Yung DE, Engel T, et al. Diagnostic yield of capsule endoscopy versus magnetic resonance enterography and small bowel contrast ultrasound in the evaluation of small bowel Crohn's disease: Systematic review and meta-analysis. Dig Liver Dis. Aug 2017; 49(8): 854-863. PMID 28512034*
17. *Bruining DH, Oliva S, Fleisher MR, et al. Panenteric capsule endoscopy versus ileocolonoscopy plus magnetic resonance enterography in Crohn's disease: a multicentre, prospective study. BMJ Open Gastroenterol. Jun 2020; 7(1). PMID 32499275*
18. *Elosua A, Rullan M, Rubio S, et al. Does capsule endoscopy impact clinical management in established Crohn's disease?. Dig Liver Dis. Jan 2022; 54(1): 118-124. PMID 34518128*
19. *Shi HY, Chan FKL, Higashimori A, et al. A prospective study on second-generation colon capsule endoscopy to detect mucosal lesions and disease activity in ulcerative colitis (with video). Gastrointest Endosc. Dec 2017; 86(6): 1139-1146.e6. PMID 28713062*
20. *San Juan-Acosta M, Caunedo-Alvarez A, Arguelles-Arias F, et al. Colon capsule endoscopy is a safe and useful tool to assess disease parameters in patients with*

ulcerative colitis. Eur J Gastroenterol Hepatol. Aug 2014; 26(8): 894-901. PMID 24987825

21. *Oliva S, Di Nardo G, Hassan C, et al. Second-generation colon capsule endoscopy vs. colonoscopy in pediatric ulcerative colitis: a pilot study. Endoscopy. Jun 2014; 46(6): 485-92. PMID 24777427*
22. *Sung J, Ho KY, Chiu HM, et al. The use of Pillcam Colon in assessing mucosal inflammation in ulcerative colitis: a multicenter study. Endoscopy. Aug 2012; 44(8): 754-8. PMID 22696193*
23. *Guturu P, Sagi SV, Ahn D, et al. Capsule endoscopy with PILLCAM ESO for detecting esophageal varices: a meta-analysis. Minerva Gastroenterol Dietol. Mar 2011; 57(1): 1-11. PMID 21372764*
24. *Bhardwaj A, Hollenbeak CS, Pooran N, et al. A meta-analysis of the diagnostic accuracy of esophageal capsule endoscopy for Barrett's esophagus in patients with gastroesophageal reflux disease. Am J Gastroenterol. Jun 2009; 104(6): 1533-9. PMID 19491867*
25. *Urquhart P, Grimpen F, Lim GJ, et al. Capsule endoscopy versus magnetic resonance enterography for the detection of small bowel polyps in Peutz-Jeghers syndrome. Fam Cancer. Jun 2014; 13(2): 249-55. PMID 24509884*
26. *Brown G, Fraser C, Schofield G, et al. Video capsule endoscopy in peutz-jeghers syndrome: a blinded comparison with barium follow-through for detection of small-bowel polyps. Endoscopy. Apr 2006; 38(4): 385-90. PMID 16680639*
27. *Mata A, Llach J, Castells A, et al. A prospective trial comparing wireless capsule endoscopy and barium contrast series for small-bowel surveillance in hereditary GI polyposis syndromes. Gastrointest Endosc. May 2005; 61(6): 721-5. PMID 15855978*
28. *Haanstra JF, Al-Toma A, Dekker E, et al. Prevalence of small-bowel neoplasia in Lynch syndrome assessed by video capsule endoscopy. Gut. Oct 2015; 64(10): 1578-83. PMID 25209657*
29. *Saurin JC, Pilleul F, Soussan EB, et al. Small-bowel capsule endoscopy diagnoses early and advanced neoplasms in asymptomatic patients with Lynch syndrome. Endoscopy. Dec 2010; 42(12): 1057-62. PMID 20821360*
30. *McCarty TR, Afinogenova Y, Njei B. Use of Wireless Capsule Endoscopy for the Diagnosis and Grading of Esophageal Varices in Patients With Portal Hypertension: A Systematic Review and Meta-Analysis. J Clin Gastroenterol. Feb 2017; 51(2): 174-182. PMID 27548729*
31. *Colli A, Gana JC, Turner D, et al. Capsule endoscopy for the diagnosis of oesophageal varices in people with chronic liver disease or portal vein thrombosis. Cochrane Database Syst Rev. Oct 01 2014; (10): CD008760. PMID 25271409*
32. *Sung JJ, Tang RS, Ching JY, et al. Use of capsule endoscopy in the emergency department as a triage of patients with GI bleeding. Gastrointest Endosc. Dec 2016; 84(6): 907-913. PMID 27156655*
33. *Gutkin E, Shalomov A, Hussain SA, et al. Pillcam ESO((R)) is more accurate than clinical scoring systems in risk stratifying emergency room patients with acute upper gastrointestinal bleeding. Therap Adv Gastroenterol. May 2013; 6(3): 193-8. PMID 23634183*

34. *Chandran S, Testro A, Urquhart P, et al. Risk stratification of upper GI bleeding with an esophageal capsule. Gastrointest Endosc. Jun 2013; 77(6): 891-8. PMID 23453185*
35. *Gralnek IM, Ching JY, Maza I, et al. Capsule endoscopy in acute upper gastrointestinal hemorrhage: a prospective cohort study. Endoscopy. 2013; 45(1): 12-9. PMID 23254402*
36. *Spada C, Pasha SF, Gross SA, et al. Accuracy of First- and Second-Generation Colon Capsules in Endoscopic Detection of Colorectal Polyps: A Systematic Review and Meta-analysis. Clin Gastroenterol Hepatol. Nov 2016; 14(11): 1533-1543.e8. PMID 27165469*
37. *Kjolhede T, Olholm AM, Kaalby L, et al. Diagnostic accuracy of capsule endoscopy compared with colonoscopy for polyp detection: systematic review and meta-analyses. Endoscopy. Aug 28, 2020. PMID 32858753*
38. *Saito Y, Saito S, Oka S, et al. Evaluation of the clinical efficacy of colon capsule endoscopy in the detection of lesions of the colon: prospective, multicenter, open study. Gastrointest Endosc. Nov 2015; 82(5): 861-9. PMID 25936450*
39. *Morgan DR, Malik PR, Romeo DP, et al. Initial US evaluation of second-generation capsule colonoscopy for detecting colon polyps. BMJ Open Gastroenterol. 2016; 3(1): e000089. PMID 27195129*
40. *Parodi A, Vanbiervliet G, Hassan C, et al. Colon capsule endoscopy to screen for colorectal neoplasia in those with family histories of colorectal cancer. Gastrointest Endosc. Mar 2018; 87(3): 695-704. PMID 28554656*
41. *Cash BD, Fleisher MR, Fern S, et al. Multicentre, prospective, randomised study comparing the diagnostic yield of colon capsule endoscopy versus CT colonography in a screening population (the TOPAZ study). Gut. Nov 2021; 70(11): 2115-2122. PMID 33443017*
42. *Kobaek-Larsen M, Kroijer R, Dyrvig AK, et al. Back-to-back colon capsule endoscopy and optical colonoscopy in colorectal cancer screening individuals. Colorectal Dis. Jun 2018; 20(6): 479-485. PMID 29166546*
43. *Rondonotti E, Borghi C, Mandelli G, et al. Accuracy of capsule colonoscopy and computed tomographic colonography in individuals with positive results from the fecal occult blood test. Clin Gastroenterol Hepatol. Aug 2014; 12(8): 1303-10. PMID 24398064*
44. *Eliakim R, Yassin K, Niv Y, et al. Prospective multicenter performance evaluation of the second-generation colon capsule compared with colonoscopy. Endoscopy. Dec 2009; 41(12): 1026-31. PMID 19967618*
45. *Franco DL, Leighton JA, Gurudu SR. Approach to Incomplete Colonoscopy: New Techniques and Technologies. Gastroenterol Hepatol (N Y). Aug 2017; 13(8): 476-483. PMID 28867979*
46. *Hussey M, Holleran G, Stack R, et al. Same-day colon capsule endoscopy is a viable means to assess unexplored colonic segments after incomplete colonoscopy in selected patients. United European Gastroenterol J. Dec 2018; 6(10): 1556-1562. PMID 30574326*
47. *Baltes P, Bota M, Albert J, et al. PillCamColon2 after incomplete colonoscopy - A prospective multicenter study. World J Gastroenterol. Aug 21 2018; 24(31): 3556-3566. PMID 30131662*

48. *Negreanu L, Babiuc R, Bengus A, et al. PillCam Colon 2 capsule in patients unable or unwilling to undergo colonoscopy. World J Gastrointest Endosc. Nov 16 2013; 5(11): 559-67. PMID 24255748*
49. *Pioche M, de Leusse A, Filoche B, et al. Prospective multicenter evaluation of colon capsule examination indicated by colonoscopy failure or anesthesia contraindication. Endoscopy. Oct 2012; 44(10): 911-6. PMID 22893133*
50. *Nogales O, Garcia-Lledo J, Lujan M, et al. Therapeutic impact of colon capsule endoscopy with PillCam COLON 2 after incomplete standard colonoscopy: a Spanish multicenter study. Rev Esp Enferm Dig. May 2017; 109(5): 322-327. PMID 28229607*
51. *Spada C, Shah SK, Riccioni ME, et al. Video capsule endoscopy in patients with known or suspected small bowel stricture previously tested with the dissolving patency capsule. J Clin Gastroenterol. Jul 2007; 41(6): 576-82. PMID 17577114*
52. *Delvaux M, Ben Soussan E, Laurent V, et al. Clinical evaluation of the use of the M2A patency capsule system before a capsule endoscopy procedure, in patients with known or suspected intestinal stenosis. Endoscopy. Sep 2005; 37(9): 801-7. PMID 16116529*
53. *Herrerias JM, Leighton JA, Costamagna G, et al. Agile patency system eliminates risk of capsule retention in patients with known intestinal strictures who undergo capsule endoscopy. Gastrointest Endosc. May 2008; 67(6): 902-9. PMID 18355824*
54. *Postgate AJ, Burling D, Gupta A, et al. Safety, reliability and limitations of the given patency capsule in patients at risk of capsule retention: a 3-year technical review. Dig Dis Sci. Oct 2008; 53(10): 2732-8. PMID 18320313*
55. *Banerjee R, Bhargav P, Reddy P, et al. Safety and efficacy of the M2A patency capsule for diagnosis of critical intestinal patency: results of a prospective clinical trial. J Gastroenterol Hepatol. Dec 2007; 22(12): 2060-3. PMID 17614957*
56. *Denzer UW, Rosch T, Hoytat B, et al. Magnetically guided capsule versus conventional gastroscopy for upper abdominal complaints: a prospective blinded study. J Clin Gastroenterol. Feb 2015; 49(2): 101-7. PMID 24618504*
57. *Liao Z, Hou X, Lin-Hu EQ, et al. Accuracy of Magnetically Controlled Capsule Endoscopy, Compared With Conventional Gastroscopy, in Detection of Gastric Diseases. Clin Gastroenterol Hepatol. Sep 2016; 14(9): 1266-1273.e1. PMID 27211503*
58. *Rubio-Tapia A, Hill ID, Kelly CP, et al. ACG clinical guidelines: diagnosis and management of celiac disease. Am J Gastroenterol. May 2013; 108(5): 656-76; quiz 677. PMID 23609613*
59. *Rubio-Tapia A, Hill ID, Semrad C, et al. American College of Gastroenterology Guidelines Update: Diagnosis and Management of Celiac Disease. Am J Gastroenterol. Jan 01 2023; 118(1): 59-76. PMID 36602836*
60. *Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. Am J Gastroenterol. Apr 2018; 113(4): 481-517. PMID 29610508*
61. *Gerson LB, Fidler JL, Cave DR, et al. ACG Clinical Guideline: Diagnosis and Management of Small Bowel Bleeding. Am J Gastroenterol. Sep 2015; 110(9): 1265-87; quiz 1288. PMID 26303132*
62. *American College of Gastroenterology Guidelines. 2023*

63. *Shaukat A, Kahi CJ, Burke CA, et al. ACG Clinical Guidelines: Colorectal Cancer Screening 2021. Am J Gastroenterol. Mar 01 2021; 116(3): 458-479. PMID 33657038*
64. *Gurudu SR, Bruining DH, Acosta RD, et al. The role of endoscopy in the management of suspected small-bowel bleeding. Gastrointest Endosc. Jan 2017; 85(1): 22-31. PMID 27374798*
65. *Enns RA, Hookey L, Armstrong D, et al. Clinical Practice Guidelines for the Use of Video Capsule Endoscopy. Gastroenterology. Feb 2017; 152(3): 497-514. PMID 28063287*
66. *Rex DK, Boland CR, Dominitz JA, et al. Colorectal Cancer Screening: Recommendations for Physicians and Patients From the U.S. Multi-Society Task Force on Colorectal Cancer. Gastroenterology. Jul 2017; 153(1): 307-323. PMID 28600072*
67. *Davidson KW, Barry MJ, Mangione CM, et al. Screening for Colorectal Cancer: US Preventive Services Task Force Recommendation Statement. JAMA. May 18 2021; 325(19): 1965-1977. PMID 34003218*
68. *Patel SG, May FP, Anderson JC, et al. Updates on Age to Start and Stop Colorectal Cancer Screening: Recommendations From the U.S. Multi-Society Task Force on Colorectal Cancer. Gastroenterology. Jan 2022; 162(1): 285-299. PMID 34794816*
69. *National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Small Bowel Adenocarcinoma. Version 1.2024*
70. *Geropoulos G, Aquilina J, Kakos C, Anestiadou E, Giannis D. Magnetically Controlled Capsule Endoscopy Versus Conventional Gastroscopy: A Systematic Review and Meta-Analysis. J Clin Gastroenterol. 2021 Aug 1; 55(7):577-585. PMID: 33883514*
71. *Mekaroonkamol, P., Cohen, R., & Chawla, S. (2015). Portal hypertensive enteropathy. World journal of hepatology, 7(2), 127–138*
72. *Sacher-Huvelin S, Calès P, Bureau C, Valla D, et al. Screening of esophageal varices by esophageal capsule endoscopy: results of a French multicenter prospective study. Endoscopy. 2015 Jun; 47(6):486-92. doi: 10.1055/s-0034-1391393. Epub 2015 Mar 2. PMID: 25730284*
73. *de Franchis R, Eisen GM, Laine L, et al. Esophageal capsule endoscopy for screening and surveillance of esophageal varices in patients with portal hypertension. Hepatology. 2008 May; 47(5):1595-603. doi: 10.1002/hep.22227. PMID: 18435461*
74. *Waterman M, Gralnek IM. Capsule endoscopy of the esophagus. J Clin Gastroenterol. 2009 Aug; 43(7):605-12. doi: 10.1097/MCG.0b013e3181aabd93. PMID: 19568182*
75. *Haanstra JF, Al-Toma A, Dekker E, Vanhoutvin SA, Nagengast FM, Mathus-Vliegen EM, van Leerdam ME, de Vos tot Nederveen Cappel WH, Sanduleanu S, Veenendaal RA, Cats A, Vasen HF, Kleibeuker JH, Koornstra JJ. Prevalence of small-bowel neoplasia in Lynch syndrome assessed by video capsule endoscopy. Gut. 2015 Oct; 64(10):1578-83. doi: 10.1136/gutjnl-2014-307348. Epub 2014 Sep 10. PMID: 25209657*
76. *Bardan E, Nadler M, Chowers Y, Fidder H, Bar-Meir S. Capsule endoscopy for the evaluation of patients with chronic abdominal pain. Endoscopy. 2003 Aug; 35(8):688-9. doi: 10.1055/s-2003-41520. PMID: 12929066*
77. *Nadler, M., & Eliakim, R. (2014). The role of capsule endoscopy in acute gastrointestinal bleeding. Therapeutic advances in gastroenterology, 7(2), 87–92*

78. *Gralnek IM, Ching JY, Maza I, et al. Capsule endoscopy in acute upper gastrointestinal hemorrhage: a prospective cohort study. Endoscopy. 2013; 45(1):12-9. doi: 10.1055/s-0032-1325933. Epub 2012 Dec 19. PMID: 23254402*
79. *Hall, M. Lynch syndrome (hereditary nonpolyposis colorectal cancer): Cancer screening and management. In: UpToDate Online Journal [serial online]. Waltham, MA: UpToDate; updated February 22, 2022. Literature review current through December 2023*
80. *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 2024*

X. POLICY HISTORY

TOP

MP 5.033	**02/26/2020 Consensus Review.** Policy updated with literature review; references added. Policy statements unchanged.
	02/24/2021 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.
	12/01/2021 Administrative Update. New code update: replaced 0355T with 91113; effective 1/1/22.
	03/16/2022 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
	01/26/2024 Minor Review. Added criteria that wireless capsule endoscopy is medically necessary in individuals with a family history of small bowel cancer and visualization of the small bowel is not feasible or is inconclusive with radiographic imaging and/or other forms of endoscopy. Removed Lynch Syndrome from list of investigational indications. Background and Rationale updated. Added ICD10 code Z15.09. References added.
	08/16/2024 Administrative Review. Added New Codes Z83.72, Z86.0100, Z86.0101, Z86.0102, Z86.0109. Effective 10/1/24.

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

TOP