

NO. 91476

CAPSULE ENDOSCOPY AND WIRELESS ESOPHAGEAL PH MONITORING

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Policy scope: This medical policy addresses capsule endoscopy and wireless esophageal pH monitoring.

Related policies:

- Colorectal Cancer Screening No. 91547

I. MEDICAL NECESSITY CRITERIA

A. Capsule endoscopy is considered medically necessary when all of the following criteria are met:

1. The capsule is FDA approved.
2. The service is performed by physicians trained in endoscopy or in independent diagnostic testing facilities under the general supervision of a physician trained in endoscopy procedures.
3. One of the clinical indications below applies:
 - a. Occult gastrointestinal bleeding: Capsule endoscopy is indicated for the diagnosis of occult gastrointestinal bleeding in the anemic patient when:
 - i. The site of bleeding has not previously been identified by upper gastrointestinal endoscopy, colonoscopy, push endoscopy or other radiologic procedure, OR

- ii. An abnormal x-ray of the small intestine is documented without an identified site of bleeding by endoscopic means, OR
- iii. The diagnosis of angiodysplasias of the GI tract is suspected.

If and only if both of the following have been met:

- iv. Patients have undergone upper GI endoscopy and colonoscopy within the same episode of illness that have failed to reveal a source of bleeding.
 - v. Patients have documented continuing GI blood loss and anemia secondary to bleeding.
- b. For evaluation of locoregional carcinoid tumors of the small bowel in persons with carcinoid syndrome.
 - c. For surveillance of small intestinal tumors in persons with Lynch syndrome, Peutz-Jeghers syndrome and other polyposis syndromes affecting the small bowel.
 - d. Crohn's Disease if one of the following is met:
 - i. The diagnosis of Crohn's disease is suspected but not diagnosed; and the patient has undergone upper GI endoscopy, colonoscopy and either push enteroscopy or small bowel radiologic study within the same period of illness which have failed to reveal a focus of disease, OR
 - ii. The diagnosis of Crohn's disease is known but it is necessary to determine whether there is involvement of the small bowel as well.
 - iii. The diagnosis of Crohn's disease is known and there is suspected recurrence.
 - e. For evaluation of persons with celiac disease with one of the following:
 - i. a positive serology and negative biopsy; OR
 - ii. who remain symptomatic despite treatment and there is no suspected or confirmed gastrointestinal obstruction, stricture, or fistulae
- B. Capsule endoscopy is considered experimental and investigational and therefore considered not medically necessary for all other indications, including, but not limited to the following:
1. Colorectal cancer screening
 2. As an initial test in diagnosing gastrointestinal bleeding
 3. To confirm pathology identified by other diagnostic means
 4. For patients with GI bleeding of suspected small bowel origin who have not previously undergone standard endoscopic and imaging evaluations
 5. Screening of asymptomatic patients for GI disease
- C. Wireless esophageal pH monitoring (e.g., Bravo™ pH Monitoring System [Medtronic, Inc., Shoreview, MN]) is medically necessary for ANY of the following:
1. To document abnormal esophageal acid exposure in an endoscopy-negative individual being considered for surgical antireflux repair
 2. To evaluate endoscopy-negative individuals with typical reflux symptoms that are refractory to proton pump inhibitor (PPI) therapy

3. To document adequacy of PPI therapy in esophageal acid control in individuals with complications of reflux disease that include Barrett’s esophagus
 4. To evaluate endoscopy-negative individuals with atypical reflux symptoms that are refractory to twice per day PPI therapy
 5. To evaluate individuals after anti-reflux surgery who are suspected to have ongoing abnormal reflux and have not responded to empiric trials of PPI therapy
- D. Wireless esophageal pH monitoring is considered experimental, investigational or unproven for these indications:
1. To detect or verify reflux esophagitis
 2. To evaluate for “alkaline reflux”

II. CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) COVERAGE DETERMINATION

Any applicable federal or state mandates will take precedence over this medical coverage policy.

Medicare: Refer to the [CMS Online Manual System \(IOMs\)](#) and Transmittals.

For the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA) refer to [CMS Medicare Coverage Database](#).

The information below is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. MAC jurisdiction for purposes of local coverage determinations is governed by the geographic service area where the Medicare Advantage plan is contracted to provide the service. Please refer to the Medicare [Coverage Database website](#) for the most current applicable NCD, LCD, LCA, and CMS Online Manual System/Transmittals.

National Coverage Determinations (NCDs)	
Endoscopy 100.2	
Colorectal Cancer Screening Tests 210.3	
Local Coverage Determinations (LCDs)	
CGS Administrators, LLC	Endoscopy by Capsule L34081 A56461
First Coast Service Options, Inc.	Wireless Capsule Endoscopy L33774 A56704 Colon Capsule Endoscopy (CCE) L38805 A58410
National Government Services, Inc.	Colon Capsule Endoscopy (CCE) L38571 A58294
Noridian Healthcare Solutions	Colon Capsule Endoscopy (CCE) L38824 A58436
Novitas Solutions, Inc.	Wireless Capsule Endoscopy L35089 A57753 Colon Capsule Endoscopy (CCE) L38807 A58414
Palmetto GBA	Wireless Capsule Endoscopy L36427 A56727 Colon Capsule Endoscopy L38755 A58321
WPS Insurance Corporation	Colon Capsule Endoscopy (CCE) L38837 A58471

III. BACKGROUND

Wireless capsule endoscopy (WCE) is a noninvasive procedure in which a swallowable, multivitamin-sized capsule containing a miniaturized video camera, light, transmitter, and batteries takes a video recording of the mucosal lining of the small bowel as it moves through the gastrointestinal (GI) tract. The video images are transmitted to sensors taped to the body and stored on a portable recorder. The strength of the signal is used to calculate the position of the capsule as it passes through the GI tract. Video images are stored on a portable recorder and later downloaded to computer, from which they may be viewed. The capsule passes naturally from the body with the stool, and since it is disposable, is not recovered.

A procedure known as wireless capsule endoscopy (WCE) or capsule endoscopy has been developed for the noninvasive visualization of suspected small-bowel abnormalities. For this test, a specially designed, ingestible capsule captures and records images as it travels through the GI tract. Before swallowing the capsule, the patient is fitted with the belt holding the data recorder and the battery pack, and a sensor array is attached to the abdomen. During imaging, the patient is able to leave the clinic and resume normal activities. After 6 to 8 hours, or in noticing that the capsule has been excreted, the patient returns the belt and data recorder to the clinic or office for processing and evaluation. The test is intended for patients with chronic or recurrent GI bleeding of unknown etiology and other GI symptoms who have negative findings on upper GI endoscopy, colonoscopy, and other tests. WCE was initially approved by the Food and Drug Administration (FDA) in August 2001 for use as an adjunct to standard procedures for diagnosing suspected abnormalities of the small bowel. In July 2003, the device was cleared for use as a first-line tool in diagnosing small-bowel disease.

In August 2001, the FDA cleared for marketing a swallowable capsule containing a small camera that snaps pictures twice a second as it passes through the small intestine. The FDA classified the capsule, called the Given Diagnostic Imaging System (Given Imaging Ltd., Yoqneam, Israel), as a Class II device that is subject only to general regulatory controls. The capsule has a clear end that allows the camera to view the lining of the small intestine. In addition to the camera, the wireless capsule, about the size of a grape, contains a lighting system and a transmitter that will send images from inside the intestine to video monitors, allowing doctors to detect sources of bleeding in the small intestine. FDA cleared the device for use along with, not as a replacement for, other endoscopic and radiological evaluations of the small intestine. The capsule was not studied in the large intestine.

When swallowed, the device travels down the digestive tract at about the same speed as food, propelled by peristalsis, and takes two to three hours to pass through. Once the device reaches the colon, things slow down, and the disposable device is eliminated like any solid waste within a few days.

The downside to this technology is that the images may not match fiber-optic endoscopes for detail, and concerns have been raised that the camera's view may be obscured by bubbly saliva or green bile. The capsule cannot be stopped or steered to collect close-up details of the small intestine's millions of interior wrinkles where ailments often occur. Nor is it fitted with surgical tools like a conventional endoscope to take biopsies or treat bleeding lesions or remove polyps. If a lesion requiring invasive therapy is found on capsule endoscopy, then the patient will need to undergo surgery with intraoperative endoscopy. In addition, if an abnormality is seen on capsule endoscopy, there is no good way to define its location within the small intestine.

Capsule endoscopy has not been proven to be of value in detecting conditions in the esophagus or colon. The esophageal transit time of the capsule is brief (less than 5 seconds) when patients ingest the capsule with water in the upright position. The transit time may be lengthened by having the patient ingest the capsule lying horizontally.

The colon is not well visualized with capsule endoscopy because stool obscures the visualization of the colonic mucosa. Visualization of the colon is more difficult than the small intestine because of its slower transit time and larger diameter; it is possible for the camera to miss suspicious areas of the colon simply by being pointed in the wrong direction. An American Cancer Society position statement (Levin, et al., 2003) has concluded that there is no evidence to support the use of capsule endoscopy for detecting colorectal polyps or cancers.

Capsule endoscopy is contraindicated in patients with obstruction of the gastrointestinal tract. The available literature indicates that an upper gastrointestinal series should be performed prior to capsule endoscopy if the patient is suspected of having intestinal obstruction.

There is some evidence from several comparative clinical trials and case series that WCE can provide useful diagnostic information in carefully selected patients with documented, chronic occult or obscure GI bleeding of suspected small-bowel origin or for patients with other chronic GI symptoms suggestive of small-bowel disease who have negative or indeterminate findings on standard tests. Moreover, some studies have reported that patients who are treated based on WCE results demonstrate clinical improvement, although long-term health outcomes are unknown due to inadequate follow-up times. Therefore, WCE has the potential to improve the health outcomes of selected patients whose diagnoses remain unknown or indeterminate following standard endoscopic and imaging evaluations. However, despite these promising findings, definitive conclusions regarding the appropriate clinical role for WCE cannot be made due to limitations in study design and execution. There is a need for additional larger, well-designed trials that compare the findings of WCE with an adequate reference standard of diagnosis so that the diagnostic accuracy of this technology can be determined. The effect of WCE on clinical decision-making requires systematic evaluation in order to determine its optimal clinical role in the general healthcare setting and to identify which patients would benefit from this procedure.

Wireless esophageal pH monitoring involves the temporary attachment of a small, capsular device to the distal esophagus. This capsule contains a miniaturized pH electrode and broadcasting system that enables measurement of esophageal pH and wireless transmission of pH data to an external data recorder. Records of esophageal pH are subsequently downloaded to a computer for analysis. The goal of this procedure is to assess esophageal exposure to gastric acid and determine if the patient has gastroesophageal reflux disease (GERD) or a related disorder.

IV. GUIDELINES / POSITION STATEMENTS

Medical/Professional Society	Guideline
American College of Gastroenterology	Guideline for the Diagnosis and Management of Gastroesophageal Reflux Disease (2022) (Katz PO et al., 2022)

	ACG Clinical Guidelines: Clinical use of Esophageal Physiologic Testing (Gyawali CP et al., 2020) ACG Clinical Guideline: Management of Crohn's Disease in Adults (Lichtenstein GR et al., 2018)
American Gastrological Association	AGA Clinical Practice update on the Personalized Approach to the Evaluation and Management of GERD: Expert Review (Yadlapati R et al., 2022)
Scottish Health Technologies Group (SHTG)	Colon capsule endoscopy (CCE-2) for the detection of colorectal polyps and cancer in adults (2020)
The Japanese Society of Gastroenterology (JSGE)	Evidence-Based Clinical Practice Guidelines for Inflammatory Bowel Disease 2020 (Nakase H et al., 2021)
National Institute for Health and Care Excellence	Gastro-oesophageal Reflux Disease in Children and Young People: Diagnosis and Management [NG1] (2019) Catheterless Oesophageal pH Monitoring. Interventional Procedures Guidance [IPG187] (2006)
German Guideline Program in Oncology (GGPO)	Evidenced-based Guideline for Colorectal Cancer (2019)
North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN) and European Society for Pediatric Gastroenterology Hepatology, and Nutrition (ESPGHAN)	Pediatric Gastroesophageal Reflux Clinical Practice Guidelines: Joint Recommendations of the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition and the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition (Rosen R et al., 2018)
Lyon Consensus	Modern Diagnosis of GERD: the Lyon Consensus (Gyawali CP et al., 2018)
U.S. Multi-Society Task Force on Colorectal Cancer	Colorectal Cancer Screening: Recommendations for Physicians and Patients From the U.S. Multi-Society Task Force on Colorectal Cancer (Rex DK et al., 2017)
International Working Group for Disorders of Gastrointestinal Motility and Function	Expert Consensus Document: Advances in the Physiological Assessment and Diagnosis of GERD (Savarino E et al., 2017)
Canadian Association of Gastroenterology (CAG)	Clinical Practice Guidelines for the Use of Video Capsule Endoscopy (Enns RA, et al., 2017)
European Crohn and Colitis Organisation (ECCO)	3rd European Evidence-based Consensus on the Diagnosis and

	<p>Management of Crohn's Disease 2016: Part 1: Diagnosis and Medical Management (Gomollon et al., 2017)</p> <p>3rd European Evidence-based Consensus on the Diagnosis and Management of Crohn's Disease 2016: Part 2: Surgical Management and Special Situations (Gionchetti et al., 2017)</p>
American Society for Gastrointestinal Endoscopy (ASGE)	<p>The Role of Endoscopy in Inflammatory Bowel Disease (2015) (Shergill AK et al., 2015)</p> <p>The role of endoscopy in the management of obscure GI bleeding (Fisher et al., 2010)</p> <p>ASGE Technology Status Evaluation Report: wireless capsule endoscopy (Mishkin DS et al., 2006)</p>
European Society of Gastrointestinal Endoscopy (ESGE)	<p>Small-Bowel Capsule Endoscopy and Device-Assisted Enteroscopy for Diagnosis and Treatment of Smallbowel Disorders: European Society of Gastrointestinal Endoscopy (ESGE) Clinical Guideline (2015) (Pennazio M et al., 2015)</p> <p>European Society of Gastrointestinal Endoscopy (ESGE): recommendations (2009) on clinical use of video capsule endoscopy to investigate small-bowel, esophageal and colonic diseases (Ladas et al., 2010)</p>
Ontario Health Technology Assessment Committee (OHTAC)	Colon Capsule Endoscopy for the Detection of Colorectal Polyps: OHTAC Recommendation (2015)
European Crohn's and Colitis Organisation	European Evidence Based Consensus for Endoscopy in Inflammatory Bowel Disease (2013) (Annese V et al., 2013)
World Endoscopy Organization (formerly World Organisation of Digestive Endoscopy (OMED)) and the European Crohn's and Colitis Organisation (ECCO)	Role of Small-Bowel Endoscopy in the Management of Patients with Inflammatory Bowel Disease: An International OMED–ECCO Consensus (2009) (Bourreille A et al., 2009)

V. REGULATORY (US FOOD AND DRUG ADMINISTRATION)

See [U.S. Food & Drug Administration \(FDA\) Medical Device Databases](#) for the most current information.

Device	Premarket Approval, 513(f)(2)(De Novo), or 510(k) Number	Notice date
PillSense™ GI Bleed Detection System (Cook Medical)	DEN220065	02/24/2023
PillCam SB 3 capsule endoscopy system (Given Imaging Ltd. [Medtronic])	K211684	08/27/2021
PillCam Patency System (Given Imaging Ltd.)	K180171	03/08/2018
PillCam Desktop Software 9.0	K170210	09/01/2017
RAPID Web	K170839	05/26/2017
PillCam Colon 2 Capsule Endoscopy System	K153466	01/14/2016
Bravo pH Monitoring System and Accessories (Given imaging Ltd.)	K102543	12/01/2010
SmartPill GI Monitoring System, version 2.0 (The SmartPill Corp.)	K092342	10/30/2009
Given AGILE Patency System and Given PillCam Platform with PillCam SB Capsules	K090557	09/28/2009
SmartPill GI Monitoring System	K053547	07/18/2006
Given AGILE Patency System	K053639	05/08/2006
Given Diagnostic Imaging System	DEN010002	08/01/2001
Bravo pH Monitoring System (Endonetics, Inc.)	K002028	09/29/2000

VI. CODING

See also **Priority Health Medical Policy No. 91636 Category III Current Procedural Terminology (CPT®) Codes (“T” codes)**

ICD-10 Codes that apply to this policy: *Procedures 91110 and 91113 are considered medically necessary only for the following diagnoses when criteria listed above are met.*

C17.0 - C17.9	Malignant neoplasm of small intestine
D37.1	Neoplasm of uncertain behavior of stomach
D37.2	Neoplasm of uncertain behavior of small intestine
D37.4	Neoplasm of uncertain behavior of colon
D37.5	Neoplasm of uncertain behavior of rectum
D50.0	Iron deficiency anemia secondary to blood loss (chronic)
D50.9	Iron deficiency anemia, unspecified

D62	Acute posthemorrhagic anemia
D64.9	Anemia, unspecified
E34.0	Carcinoid syndrome
K31.811	Angiodysplasia of stomach and duodenum with bleeding
K31.819	Angiodysplasia of stomach and duodenum without bleeding
K50.00	Crohn's disease of small intestine without complications
K50.011– K50.919	Crohn;s disease of small intestine with complications
K52.2x	Allergic and dietetic gastroenteritis and colitis
K52.89	Other specified noninfective gastroenteritis and colitis
K52.9	Noninfective gastroenteritis and colitis, unspecified
K55.20	Angiodysplasia of colon without hemorrhage
K55.21	Angiodysplasia of colon with hemorrhage
K57.01	Diverticulitis of small intestine with perforation and abscess with bleeding
K57.11	Diverticulosis of small intestine without perforation or abscess with bleeding
K57.13	Diverticulitis of small intestine without perforation or abscess with bleeding
K57.41	Diverticulitis of both small and large intestine with perforation and abscess with bleeding
K57.51	Diverticulosis of both small and large intestine without perforation or abscess with bleeding
K57.53	Diverticulitis of both small and large intestine without perforation or abscess with bleeding
K63.3	Ulcer of intestine
K63.5	Polyp of Colon
K90.0	Celiac disease
K90.1	Tropical sprue
K90.9	Intestinal malabsorption, unspecified
K92.1	Melena
K92.2	Gastrointestinal hemorrhage, unspecified
R19.5	Other fecal abnormalities
R19.7	Diarrhea, unspecified
R93.3	Abnormal findings on diagnostic imaging of other parts of digestive tract

CPT HCPCS Codes:

- 91110 Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus through ileum, with interpretation and report
- 91113 Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), colon, with interpretation and report
- 91034 Esophagus, gastroesophageal reflux test; with nasal catheter pH electrode(s) placement, recording, analysis and interpretation
- 91035 Esophagus, gastroesophageal reflux test; with mucosal attached telemetry pH electrode placement, recording, analysis and interpretation

Not Medically Necessary:

- 91111 Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus with interpretation and report
- 91112 Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report
- 0977T Upper gastrointestinal blood detection, sensor capsule, with interpretation and report

VII. MEDICAL NECESSITY REVIEW

Prior authorization for certain drugs, devices, services and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service or procedure is medically necessary. For more information, refer to the [Priority Health Provider Manual](#).

Individual case review may allow coverage for care or treatment that is investigational yet promising for the conditions described. Requests for individual consideration require prior plan approval. All determinations of coverage for experimental, investigational, or unproven treatment will be made by a Priority Health medical director or clinical pharmacist. The exclusion of coverage for experimental, investigational, or unproven treatment may be reviewed for exception if the condition is either a terminal illness, or a chronic, life threatening, severely disabling disease that is causing serious clinical deterioration.

VIII. APPLICATION TO PRODUCTS

Coverage is subject to the member's specific benefits. Group-specific policy will supersede this policy when applicable.

- **HMO/EPO:** This policy applies to insured HMO/EPO plans.
- **POS:** This policy applies to insured POS plans.
- **PPO:** This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.
- **ASO:** For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.
- **INDIVIDUAL:** For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.
- **MEDICARE:** Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.
- **MEDICAID/HEALTHY MICHIGAN PLAN:** For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the [Michigan Medicaid Fee Schedule](#). If there is a discrepancy between this policy and the [Michigan Medicaid Provider Manual](#), the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

IX. REFERENCES

Guidelines

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SUMMARY OF CHANGES

Clarifications:

- Modified policy name to better reflect policy scope.

Past committee review dates: 02/2004, 01/2005, 05/2005, 04/2006, 04/2007, 06/2007, 04/2008, 04/2009, 04/2010, 04/2011, 04/2012, 04/2013, 05/2014, 05/2015, 05/2016, 05/2017, 05/2018, 05/2019, 05/2020, 05/2022, 05/2023, 05/2024, 05/2025

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