

Capsule Endoscopy



INDEPENDENT CARE HEALTH PLAN

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Medical Coverage Policy

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Disclaimer

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Related Medical/Pharmacy Coverage Policies

None

Related Documents

Please refer to [CMS website](#) for the most current applicable National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA)/CMS Online Manual System/Transmittals.

Type	Title	ID Number	Jurisdiction Medicare	Applicable States/Territories
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			Administrative Contractors (MACs)	
LCD (and pertinent LCA)	Colon Capsule Endoscopy (CCE)	L38837 A58471	J5 - Wisconsin Physicians Service Insurance Corporation	IA, KS, MO, NE, IN, MI
LCD (and pertinent LCA)	Colon Capsule Endoscopy (CCE)	L38777 A58362	J15 - CGS Administrators, LLC (Part A/B MAC)	KY, OH
LCD (and pertinent LCA)	Endoscopy by Capsule	L34081 A56461	J15 - CGS Administrators, LLC (Part A/B MAC)	KY, OH
LCD (and pertinent LCA)	Colon Capsule Endoscopy (CCE)	L38824 A58436	JE - Noridian Healthcare Solutions, LLC	CA, HI, NV, American Samoa, Guam, Northern Mariana Islands
LCD (and pertinent LCA)	Colon Capsule Endoscopy (CCE)	L38826 A58438	JF - Noridian Healthcare Solutions, LLC	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
LCD (and pertinent LCA)	Colon Capsule Endoscopy (CCE)	L38807 A58414	JH - Novitas Solutions, Inc. (Part A/B MAC)	AR, CO, NM, OK, TX, LA, MS
LCD (and pertinent LCA)	Wireless Capsule Endoscopy (CCE)	L35089 A57753	JH - Novitas Solutions, Inc. (Part A/B MAC)	AR, CO, NM, OK, TX, LA, MS
LCD (and pertinent LCA)	Colon Capsule Endoscopy (CCE)	L38755 A58321	JJ – JM Palmetto GBA (Part A/B MAC)	AL, GA, TN, SC, VA, WV, NC
LCD (and pertinent LCA)	Wireless Capsule Endoscopy	L36427 A56727	JJ – JM Palmetto GBA (Part A/B MAC)	AL, GA, TN, SC, VA, WV, NC
LCD (and pertinent LCA)	Colon Capsule Endoscopy (CCE)	L38571 A58294	J6 – JK - National Government Services, Inc. (Part A/B MAC)	IL, MN, WI, CT, NY, ME, MA, NH, RI, VT
LCD (and pertinent LCA)	Wireless Capsule Endoscopy	L35089 A57753	JL - Novitas Solutions, Inc. (Part A/B MAC)	DE, DC, MD, NJ, PA
LCD (and pertinent LCA)	Colon Capsule Endoscopy (CCE)	L38805 A58410	JN - First Coast Service Options, Inc. (Part A/B MAC)	FL, PR, U.S. VI
LCD (and pertinent LCA)	Wireless Capsule Endoscopy	L33774 A56704	JN - First Coast Service Options, Inc. (Part A/B MAC)	FL, PR, U.S. VI

Description

Capsule endoscopy (CE), also known as wireless capsule endoscopy or video capsule endoscopy, is a noninvasive diagnostic procedure that is designed to visualize the esophagus, stomach, small bowel or colon. To perform this procedure, a small digestible capsule (approximately the size of a large vitamin) containing a video camera and a light source is swallowed. The camera takes multiple pictures per second and sends electronic signals wirelessly to a data recorder worn around the individual's waist. The data is then downloaded into a computer program that captures the images to be analyzed by a physician. The body typically excretes the capsule naturally within 8 to 72 hours after ingestion.

Currently, CE is only utilized for diagnostic purposes; individuals who require a biopsy or therapeutic intervention must undergo a conventional endoscopic procedure.

Examples of commercially available capsule endoscopy systems include, but may not be limited to:

- CapsoCam Plus (SV-3) capsule endoscope system is intended for visualization and detection of abnormalities of the small bowel mucosa in adults.
- Capsule delivery devices reportedly introduce the capsule, endoscopically, into the small bowel in an individual who cannot swallow the capsule, who have gastroparesis or some other impediment that may prevent passage of the capsule into the small bowel in a reasonable time.^{72,73,81} Examples of these devices include, but may not be limited to, the AdvanCE endoscopy delivery system and the PillCam Express.
- Magnetically maneuvered capsule endoscopy systems consist of an ingestible capsule and a magnetic controller. The capsule reportedly provides visualization of the stomach and duodenum and captures pictures images of the mucosa. The location and viewing direction are controlled outside the individual's body by a magnetic controller. An example of this type of device includes, but may not be limited to, is the NaviCam capsule endoscope system.⁸⁵
- MiroCam capsule endoscope system is intended for visualization of the small bowel mucosa. It may be used as a tool in the detection of abnormalities of the small bowel in adults and children from 2 years of age or older.⁷⁷
- Patency capsule systems (eg, Agile Patency Capsule, PillCam Patency Capsule) are intended to verify adequate patency of the gastrointestinal tract prior to administration of the PillCam video capsule in an individual with known or suspected strictures.^{64,82}
- PillCam COLON 2 is intended for visualization of the colon and detection of colon polyps ONLY in an individual who had an incomplete optical colonoscopy with adequate preparation and a complete evaluation of the colon was not technically possible. The device is also indicated for the detection of colon polyps in an individual with evidence of gastrointestinal (GI) bleeding of lower GI origin. This only applies to an individual with major risks for colonoscopy or moderate sedation but who could tolerate colonoscopy and moderate sedation in the event a clinically significant colon abnormality was identified on capsule endoscopy.⁷⁹

- PillCam Crohn's Capsule is intended to visualize both the small bowel and the colon in an individual with Crohn's disease via a capsule that has two camera heads. It is designed to provide a broader view of the intestinal mucosa.
- PillCam ESO is intended for the visualization of the esophageal mucosa to detect abnormalities such as gastroesophageal reflux disease (GERD), Barrett's esophagus or varices.
- PillCam UGI capsule endoscopy system is intended for visualization of the upper GI tract (esophagus, stomach, duodenum) in a hemodynamically stable individual who is 18 years of age or older.⁸⁴
- Pill Cam SB 3 and the Olympus small intestinal capsule endoscope system (eg, Endocapsule EC-10) are intended for the visualization of the small intestinal mucosa.

An ingestible gastrointestinal blood detection capsule is also being investigated. This capsule (eg, Pill Sense System) utilizes an optical sensor that purportedly measures the presence of blood by measuring the absorption of wavelengths of light. The data gathered is transmitted to an external receiver where an algorithm is used to process the presence of blood or no blood. No images are sent from the capsule.

Coverage Determination

iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

Please refer to the above Medicare guidance for **capsule endoscopy (esophageal, small bowel and colon)**.

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the following criteria:

Capsule endoscopy of the small bowel will be considered medically reasonable and necessary when the following requirements are met:

- Aid in the diagnosis of celiac disease in an individual with positive celiac-specific serology who is unable to undergo esophagogastroduodenoscopy (EGD) with biopsy (eg, medically unstable, presence of known or suspected perforated viscus) or the biopsy was negative and clinical suspicion for celiac disease remains; **OR**
- Evaluation of an individual with suspicion of obscure (hidden or indistinct) GI bleeding in the small bowel with the following:
 - EGD and colonoscopy that failed to identify bleeding source; **OR**

- Evaluation of suspected disease related to the small bowel (such as protein-losing gastroenteropathy and malabsorption) and standard diagnostic tests (eg, laboratory tests, EGD, colonoscopy and imaging) failed to provide a diagnosis.
- Initial diagnosis of suspected Crohn's disease when there is no evidence of the disease found via standard diagnostic tests such as upper and lower endoscopy (EGD and colonoscopy), computed tomography (CT) enterography, magnetic resonance (MR) enterography or small bowel follow-through (SBFT); **OR**
- Re-evaluate known celiac or Crohn's disease in an individual remaining symptomatic despite adherence to prescribed therapy; **OR**
- Surveillance of small intestinal tumors in an individual with Lynch syndrome, Peutz-Jeghers syndrome, or other polyposis syndromes affecting the small bowel. Suspected small bowel tumors with the following:
 - Persistent clinical symptoms (eg, abdominal pain, anemia, gastrointestinal bleeding, unexplained weight loss); **AND**
 - Standard diagnostic testing has failed to determine the etiology of symptoms (testing includes, but may not be limited to, upper and lower endoscopy [EGD and colonoscopy], upper gastrointestinal series, advanced imaging [eg, CT scan/MRI enteroscopy])

Colon capsule endoscopy will be considered medically reasonable and necessary when the following requirements are met:

- Primary procedure in patients with major risks for Optical Colonoscopy (OC) or moderate sedation as indicated from an evaluation of the patient by a board certified or board eligible gastroenterologist, a surgeon trained in endoscopy, or a physician with equivalent endoscopic training and **EITHER** of the following criteria are met:
 - Fecal Occult Blood Test (FOBT) positive (guaiac or immunochemical) **OR**
 - Multitarget Stool DNA (sDNA) Test positive **OR**
 - Other evidence of lower GI bleeding in hemodynamically stable patients
- Secondary procedure:
 - For the detection or surveillance of colon polyp(s) if the diagnostic OC was incomplete **OR**
 - When an incomplete diagnostic OC was performed for either:
 - Fecal Occult Blood Test (FOBT) positive (guaiac or immunochemical) **OR**
 - Multitarget Stool DNA (sDNA) Test positive **OR**
 - Other evidence of lower GI bleeding in hemodynamically stable patients²⁹

Esophageal capsule endoscopy will be considered medically reasonable and necessary in the evaluation of esophageal varices in an individual with portal hypertension, as an alternative to upper GI endoscopy.³²

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

[US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage](#)

Capsule endoscopy will not be considered medically reasonable and necessary for the following indications:

- Evaluation the colon, for colorectal screening or for the confirmation of lesions of pathology normally within reach of the upper and lower endoscopes (lesions proximal to the ligament of Treitz or distal to the ileum³⁰; **OR**
- Individual with a known or suspected GI obstruction, strictures or fistulas based on the clinical picture or pre-procedure testing and profile; **OR**
- Use of patency capsule³⁰

A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

Summary of Evidence

The review of the current medical literature concludes that the use of the colon capsule for colorectal cancer screening remains uncertain. The capsule does not allow for biopsy or polyp removal; therefore, if lesions are detected with the capsule, a subsequent colonoscopy would be required. Studies comparing colon capsule endoscopy with standard colonoscopy have had variable results with most studies reporting sensitivities between 70-88%.^{30,72}

Currently, GI obstructions, strictures or fistulas are known contraindications on the manufacturer labeling.⁷²

The review of the current medical literature demonstrates a lack of evidence or an unclear utility of the use of a patency capsule. The studies were retrospective and were considered to be of poor or very poor quality. Three of the 4 studies did not have comparison groups and only compared pre and posttest measures. There were no systematic reviews identified for its use.^{30,38}

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
91110	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), esophagus through ileum, with interpretation and report	
91111	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), esophagus with interpretation and report	
91113	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), colon, with interpretation and report	
91299	Unlisted diagnostic gastroenterology procedure	
CPT® Category III Code(s)	Description	Comments
0651T	Magnetically controlled capsule endoscopy, esophagus through stomach, including intraprocedural positioning of capsule, with interpretation and report	
HCPCS Code(s)	Description	Comments
No code(s) identified		

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Change Summary

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