

Wireless Capsule Endoscopy Clinical Coverage Criteria

Overview

Wireless capsule endoscopy, also called capsule endoscopy, is a noninvasive endoscopic procedure which allows visualization of the small intestine, which is also called the small bowel, without sedation or anesthesia. As the name implies, capsule endoscopy makes use of a swallowable capsule that contains a miniature video camera. It has been demonstrated that capsule endoscopy is superior to traditional radiological techniques (small-bowel follow through and small bowel enteroclysis) and push enteroscopy in the diagnosis of obscure gastrointestinal bleeding.

Capsule endoscopy is not without limitations however. Capsule endoscopy has no therapeutic capabilities therefore it does not obviate the need for other tests or procedures in some cases, and it is contraindicated in patients with small bowel strictures or swallowing disorders. Patients with established small bowel Crohn's disease, chronic usage of non-steroidal anti-inflammatory drugs and abdominal radiation injury are at high risk of capsule retention. Patients should be fully informed about the risk of capsule retention before consent for capsule endoscopy is given. Patients should be advised that further intervention, including surgery, may be required if passage of the capsule is impeded.

Policy

This Policy applies to the following Fallon Health products:

- □ Commercial

- NaviCare
- **⊠ PACE**

Fallon Health follows guidance from the Centers for Medicare and Medicaid Services (CMS) for organization (coverage) determinations for Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and guidance in the Medicare manuals are the basis for coverage determinations. When there is no NCD, LCD, LCA or manual guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations.

Medicare does not have an NCD for capsule endoscopy. National Government Services, Inc. is the Part A/B Medicare Administrative Contractor (MAC) with jurisdiction in our service area. National Government Services, Inc. does not have an LCD or LCA for wireless capsule endoscopy (MCD search 02-08-2022).

National Government Services, Inc. has an LCD for Colon Capsule Endoscopy (CCE) (L38571) and an LCA Billing and Coding: Colon Capsule Endoscopy (CCE) (A58294) (MCD search 02-08-2022).

For plan members enrolled in NaviCare, Fallon Health follows Medicare guidance for coverage determinations. In the event that there is no Medicare guidance or if the plan member does not

meet medical necessity criteria in Medicare guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations for NaviCare members.

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Fallon Health requires prior authorization for wireless capsule endoscopy. Medical records from the primary care physician and other providers who have diagnosed or treated the symptoms prompting this request are also required.

Fallon Health Clinical Coverage Criteria

Fallon Health considers wireless capsule endoscopy (CPT 91110) medically necessary for evaluation of the small bowel, when ordered by a gastroenterologist or surgeon for plan members with:

- 1. Obscure GI bleeding or unexplained iron deficiency anemia, when EGD and colonoscopy are negative or non-diagnostic, and if no contraindications exist.
- Suspected Crohn's disease and or known Crohn's disease (outside of the small bowel) with suspected small bowel involvement or a suspected recurrence, undetected by colonoscopy or ileocolonoscopy. It is recommended that these patients have radiological imaging to exclude strictures prior to capsule endoscopy.
- Suspected small bowel neoplasm, when the diagnosis has not been previously confirmed by other studies. The patient must be symptomatic for a neoplasm (e.g., partial bowel obstruction, GI bleeding), and other diagnostic testing to assess these symptoms (i.e., EGD and colonoscopy) must have been performed.

Note: For MassHealth members, wireless capsule endoscopy (CPT 91110) is covered for the identification of previously undocumented lesions in polyposis syndromes.

A patency capsule is used to verify an unobstructed small bowel prior to capsule endoscopy. The use of a patency capsule requires additional authorization as part of the request.

Medicare

Fallon Health covers colon capsule endoscopy (CPT 0355T) for Medicare members including Medicare Advantage, NaviCare and PACE plan members in accordance with National Government Services, Inc. LCD for Colon Capsule Endoscopy (CCE) (L38571) and an LCA Billing and Coding: Colon Capsule Endoscopy (CCE) (A58294).

Policy References:

LCD link: Colon Capsule Endoscopy (CCE) (L38571)

LCA link: Billing and Coding: Colon Capsule Endoscopy (CCE) (A58294)

Diagnostic and/or surveillance* colon capsule endoscopy (CCE) is considered medically necessary for the detection of colon polyps when either of the following criteria are met:

- Secondary procedure after an incomplete diagnostic optical colonoscopy (OC) with adequate preparation, and a complete evaluation of the colon was not technically possible when either of the following criteria are met
 - a. Detection or surveillance of colon polyp(s) OR
 - b. Diagnostic procedure when any of the following criteria are met (3):
 - i. Fecal Occult Blood Test (FOBT) positive (guaiac or immunochemical) OR
 - ii. Multitarget Stool DNA (sDNA) Test positive OR
 - iii. Other evidence of lower GI bleed in hemodynamically stable patients

- 2. Primary procedure in patients with major risks for 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 when either of the following criteria are met:
 - a. Surveillance of colon polyp(s) in previously diagnosed patients OR
 - b. Diagnostic procedure when ANY of the following criteria are met (3):
 - i. Fecal Occult Blood Test (FOBT) positive (guaiac or immunochemical) OR
 - ii. Multitarget Stool DNA (sDNA) Test positive OR
 - iii. Other evidence of lower GI bleed in hemodynamically stable patients
- * Diagnostic strategies refer to the measures taken to investigate persons with symptoms suspicious for malignancy or as a result of positive screening tests. Surveillance refers to the interval utilization of diagnostic strategies in people with previously detected cancerous or precancerous lesions. Screening strategies refer to those measures taken to diagnose cancerous and pre-cancerous lesions in asymptomatic people with no previous history of such.

Exclusion Criteria (NONE of the below are allowed)

- Known or suspected gastrointestinal obstruction, stricture, or fistula
- Cardiac pacemaker or another implanted electro-medical device if the CCE device is contraindicated due to emission of a radiofrequency or other interfering signal
- Swallowing disorder
- Known contraindication or allergy to any medication or preparation agent used before or during the procedure
- May not be done in conjunction with CT Colonography (CTC)
- CCE is not a Medicare Benefit for colorectal cancer screening, regardless of family history or other risk factors for the development of colonic disease.

Exclusions

- Wireless capsule endoscopy for other small bowel indications, including but not limited to colorectal screening, suspected celiac disease, polyposis syndromes, etc.
- Wireless capsule endoscopy is not covered for the investigation of pathologies of the gastrointestinal tract within the reach of conventional EGD or colonoscopy.
- Wireless capsule endoscopy of the esophagus (e.g., PillCAM™ ESO) (CPT 91111) is experimental/investigational and will deny vendor liable.

Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

The ingestion of the capsule is part of the test and an Evaluation & Management (E&M) Service may not be billed for this purpose.

CPT code 91299 should be reported for patency capsule testing,

Code	Description
91110	Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy); esophagus through ileum, with physician interpretation and report
91299	Unlisted diagnostic gastroenterology procedure

Colon Capsule Endoscopy

Colon capsule endoscopy is covered for Medicare members only. ICD-10 codes Z53.09 or Z53.8 must be reported with K63.5, K92.1, K92.2, or R19.5. ICD-10-CM code Z53.8 indicates that the instrument colonoscopy has been attempted and was incomplete and Z53.09 indicates the procedure is contraindicated when a board certified or board eligible gastroenterologist, a surgeon trained in endoscopy, or a physician with equivalent endoscopic training determined from

an evaluation of the patient that optical colonoscopy cannot be safely attempted (National Government Services, Inc. LCA: Billing and Coding: Colon Capsule Endoscopy (A58294)...

Code	Description
91113	Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy),
	colon, with interpretation and report

References

- Mishkin DS, Chuttani R, Croffie J, Disario J, Liu J, Shah R, Somogyi L, Tierney W, Song LM, Petersen BT; Technology Assessment Committee, American Society for Gastrointestinal Endoscopy. ASGE Technology Status Evaluation Report: Wireless Capsule Endoscopy. Gastrointest Endosc. 2006 Apr;63(4):539-45. Muhammad A, Pitchumoni CS. Newly Detected Celiac Disease by Wireless Capsule Endoscopy in Older Adults with Iron Deficiency Anemia. J Cliln Gastroenterol. 2008 Oct;42(9):980-3.
- 2. Apostolopoulos P, Liatsos C, Gralnek IM et al., The Role of Wireless Capsule Endoscopy in Investigating Unexplained Iron Deficiency Anemia After Negative Endoscopic Evaluation of the Upper and Lower Gastrointestinal Tract. Endoscopy. 2006 Nov;38(11):1127-32.
- 3. Moy L, Levine J. Wireless Capsule Endoscopy in the Pediatric Age Group: Experience and Complications. J Pediatr Gastroenterol. Nutr. 2007 Apr;44(4):516-20.
- 4. Saperas E, Dot J, Videla S, et al. Capsule Endoscopy versus Computed Tomographic or Standard Angiography for the Diagnosis of Obscure Gastrointestinal Bleeding. Gastroenterol. 2007 Apr;102(4):731-7.
- 5. Saurin JC, Delvaux M, Vahedi K, et al. Clinical Impact of Capsule Endoscopy Compared to Push Enteroscopy: 1-Year Follow-up Study. Endoscopy. 2005 Apr;37(4):318-23.
- 6. Hindryckx P, Botelberge T, De Vos M et al. Clinical Impact of Capsule Endoscopy on Further Strategy and Long-Term Clinical Outcome in Patients with Obscure Bleeding. Gastrointest Endosc. 2008;68:98-104.
- 7. Van Gossum A, Navas MM, Fernandez-Urien I, et al. Capsule Endoscopy Versus Colonoscopy for the Detection of Polyps and Cancer. N Engl J Med. 2009;361(3):264-70.
- 8. Redondo-Cerezo E, Sánchez-Capilla AD, De La Torre-Rubio P, De Teresa J. Wireless capsule endoscopy: perspectives beyond gastrointestinal bleeding. World J Gastroenterol. 2014 Nov 14;20(42):15664-73.
- Neumann H, Fry LC, Nägel A, Neurath MF. Wireless capsule endoscopy of the small intestine: a review with future directions. Curr Opin Gastroenterol. 2014 Sep;30(5):463-71.
- 10. Song HJ, Shim KN. Current status and future perspectives of capsule endoscopy. Intest Res. 2016 Jan;14(1):21-9.
- 11. Choi M, Lim S, Choi MG, Shim KN, Lee SH. Effectiveness of capsule endoscopy compared with other diagnostic modalities in patients with small bowel Crohn's disease: a meta-analysis. Gut Liver. 2017;11(1):62-72.
- 12. Enns RA, Hookey L, Armstrong D, et al. Clinical practice guidelines for the use of video capsule endoscopy. Gastroenterology. 2017;152(3):497-514.
- 13. Chetcuti Zammit S, Sanders DS, Sidhu R. Capsule endoscopy for patients with coeliac disease. Expert Rev Gastroenterol Hepatol. 2018 Aug;12(8):779-790.
- 14. Sealock RJ, Thrift AP, El-Serag HB, Sellin J. Long-term follow up of patients with obscure gastrointestinal bleeding examined with video capsule endoscopy. Medicine (Baltimore). 2018 Jul;97(29):e11429.
- 15. Hosoe N, Takabayashi K, Ogata H, Kanai T. Capsule endoscopy for small-intestinal disorders: Current status. Dig Endosc. 2019 Jan 17.
- MassHealth Guidelines for Medical Necessity Determination for Capsule Endoscopy.
 Effective June 1, 2018. Available at: https://www.mass.gov/guides/masshealth-guidelines-for-medical-necessity-determination-for-capsule-endoscopy. Accessed 02-08-2022.
- National Government Services, Inc. Local Coverage Determination (LCD): Colon Capsule Endoscopy (CCE) (L38571). Original Effective Date 04/15/2021. Available at: https://www.cms.gov/medicare-coverage-database/new-search/search.aspx. Accessed 02-08-2022.

18. National Government Services, Inc. Local Coverage Article: Billing and Coding: Colon Capsule Endoscopy (CCE) (A58294). Original Effective Date 04/15/2021. Revision Effective Date: 01/01/2022. Available at: https://www.cms.gov/medicare-coverage-database/new-search/search.aspx. Accessed 02-08-2022.

Policy history

Origination date: Approval(s):

03/01/2004

Technology Assessment Subcommittee: 06/23/2009, 07/28/2009 Technology Assessment Committee: 02/23/2004, 09/30/2009, 6/25/2013, 09/24/2014 (updated criteria to have consistent across

6/25/2013, 09/24/2014 (updated criteria to have consistent across all plans and updated references, removed patency capsule exclusion) 09/23/2015 (updated references) 09/15/2016 (updated references), 09/27/2017 (updated references), 08/22/2018 (updated references), 09/10/2019 (removed definitions, updated

references).

02/08/2022 (Added clarifying language related to Medicare Advantage,

NaviCare, PACE and MassHealth under policy section).

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.