

EFFECTIVE DATE: 06|01|2022

POLICY LAST UPDATED: 01|04|2023

OVERVIEW

The magnetic capsule endoscopy (CE) 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. The capsule is collected after being excreted and images interpreted. There are two types of capsules, wireless and magnetic.

This policy is for the magnetic capsule only.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Medicare Advantage Plans

Magnetic capsule endoscopy is not covered for the evaluation of individuals with unexplained upper abdominal complaints and all other indications. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome

Commercial Products

Magnetic capsule endoscopy is considered not medically necessary for the evaluation of individuals with unexplained upper abdominal complaints and all other indications. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage

BACKGROUND

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.

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 <22 years of age, and those with a body mass index ≥ 38 .

CODING

The following code(s) are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

0651T Magnetically controlled capsule endoscopy, esophagus through stomach, including intraprocedural positioning of capsule, with interpretation and report

RELATED POLICIES

Not applicable

PUBLISHED

Provider Update, March 2023

Provider Update, March 2022

REFERENCES

1. 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
2. Cross A, Szoka N. SAGES NaviCam stomach capsule system. March 10, 2021. <https://www.sages.org/publications/tavac/navicam-stomach-capsule-system/>. Accessed November 8, 2022.
3. 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
4. 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
5. 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
6. 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
7. 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
8. 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
9. 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
10. 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
11. 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

12. 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
13. 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
14. Annese V, Daperno M, Rutter MD, et al. European evidence based consensus for endoscopy in inflammatory bowel disease. *J Crohns Colitis.* Dec 2013; 7(12): 982-1018. PMID 24184171
15. 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
16. 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
17. 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
18. 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
19. 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
20. 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
21. 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
22. 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
23. 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
24. 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
25. 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
26. 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
27. 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
28. 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
29. 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
30. 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
31. 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

32. 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
33. 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
34. 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
35. 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
36. 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
37. 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
38. 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
39. 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
40. 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

[CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS](#)

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice. Blue Cross & Blue Shield of Rhode Island is an independent licensee of the Blue Cross and Blue Shield Association.

