



CLINICAL GUIDELINES

Capsule Endoscopy

Version 2.0

Effective July 1, 2021



eviCore healthcare Clinical Decision Support Tool Diagnostic Strategies: This tool addresses common symptoms and symptom complexes. Imaging requests for individuals with atypical symptoms or clinical presentations that are not specifically addressed will require physician review. Consultation with the referring physician, specialist and/or individual's Primary Care Physician (PCP) may provide additional insight.

CPT® (Current Procedural Terminology) is a registered trademark of the American Medical Association (AMA). CPT® five digit codes, nomenclature and other data are copyright 2019 American Medical Association. All Rights Reserved. No fee schedules, basic units, relative values or related listings are included in the CPT® book. AMA does not directly or indirectly practice medicine or dispense medical services. AMA assumes no liability for the data contained herein or not contained herein.

Capsule Endoscopy	
CAPEND-0: General Guidelines	3
CAPEND-1: Crohn's Disease	3
CAPEND-2: Celiac Disease	3
CAPEND-3: Gastrointestinal Bleeding	3
CAPEND-4: Small Bowel Tumors	4
CAPEND-5: Genetic Syndromes	4
CAPEND-6: Patency Capsule	4
CAPEND-7: Colon Capsule Endoscopy	4
CAPEND-8: Esophageal Capsule Endoscopy	5
Background and Supporting Information	5

CAPEND-0: General Guidelines

- These guidelines are for initial procedures unless otherwise stated; requests for follow-up should be forwarded for Medical Director Review

CAPEND-1: Crohn's Disease

- Capsule endoscopy (CPT® 91110) is indicated for the evaluation of known or suspected Crohn's Disease in the following clinical scenarios:
 - ◆ Clinical features consistent with Crohn's Disease (e.g. chronic diarrhea, abdominal pain, weight loss, +GI bleeding, with associated fatigue), negative ileocolonoscopy, and imaging studies (CT abdomen, CT abdomen/pelvis, or MRI abdomen) OR
 - ◆ To assess for the possibility of small bowel disease (i.e. Crohn's) in the presence of an indeterminate colitis OR
 - ◆ Known Crohn's Disease and ANY of the following:
 - Clinical features unexplained by ileocolonoscopy or imaging studies (CT abdomen, CT abdomen/pelvis, or MRI abdomen).
 - When assessment of small bowel mucosal healing beyond the reach of ileocolonoscopy is needed.
 - Suspected small bowel recurrence after colectomy, with negative or inconclusive ileocolonoscopy, CT, or MRI.
 - ◆ See: **Background and Supporting Information: Crohn's Disease**
- Capsule endoscopy is not indicated in individuals with:
 - ◆ Chronic abdominal pain or diarrhea (> 30 days) as their only symptoms, and no evidence of elevated biomarkers associated with Crohn's Disease.
 - Biomarkers include ESR, CRP, fecal calprotectin, or lactoferrin

CAPEND-2: Celiac Disease

- Capsule endoscopy (CPT® 91110) is indicated for the evaluation of Celiac Disease in the following clinical scenario:
 - ◆ Known celiac disease and unexplained symptoms (e.g. bloating, diarrhea, abdominal pain, weight loss, distension, evidence of malabsorption) despite treatment (refractory disease defined as persistent or recurrent symptoms despite 6 months of a gluten-free diet).
 - ◆ See: **Background and Supporting Information: Celiac Disease**
- Capsule endoscopy is not indicated for individuals with suspected celiac disease in whom endoscopy with biopsy is negative, even if serology is positive.

CAPEND-3: Gastrointestinal Bleeding

- Capsule endoscopy (CPT® 91110) is indicated for the evaluation of GI Bleeding in the following clinical scenarios:
 - ◆ Documented overt GI bleeding (observed blood per rectum, melena, or black stool excluding hematemesis) and negative findings on EGD and colonoscopy, CE is the next appropriate diagnostic step OR
 - ◆ Prior negative CE who have repeated obscure bleeding, CE can be repeated OR
 - ◆ Suspected obscure bleeding or UNEXPLAINED iron deficiency anemia (negative EGD and colonoscopy)

CAPEND-4: Small Bowel Tumors

- Capsule endoscopy (CPT® 91110) is indicated for the evaluation of small bowel tumors in the following clinical scenario:
 - ◆ For the evaluation of known or suspected small bowel tumors

CAPEND-5: Genetic Syndromes

- Capsule endoscopy (CPT® 91110) is indicated for the evaluation of Juvenile Polyposis Syndrome in the following clinical scenario:
 - ◆ Video capsule endoscopy can be performed periodically. Time interval not established.
- Capsule endoscopy (CPT® 91110) is indicated for the evaluation of Peutz-Jehgers Syndrome in the following clinical scenario:
 - ◆ Video capsule endoscopy at age 8. If no polyps, repeat at age 18, then every 3 years, or earlier if any symptoms occur.
- Capsule endoscopy (CPT® 91110) is indicated for the evaluation of BMMRD (Biallelic Mismatch Repair Deficiency) in the following clinical scenario:
 - ◆ Video capsule endoscopy annually, beginning at age 8.

CAPEND-6: Patency Capsule

- Patency Capsule
 - ◆ At this time, the use of a patency capsule for the pre-evaluation of the small intestine for capsule endoscopy is considered investigational/experimental

CAPEND-7: Colon Capsule Endoscopy

- Colon Capsule Endoscopy (CPT® 0355T) is indicated in the following clinical scenarios:
 - ◆ As a primary procedure in individuals with major risk for standard optical colonoscopy or moderate sedation as indicated from an evaluation by a board-certified or board-eligible gastroenterologist, a surgeon trained in endoscopy, or a physician with equivalent endoscopic training AND one of the following:
 - Fecal occult blood test positive OR
 - Multitarget Stool DNA (sDNA) Test positive OR
 - Other evidence of lower GI bleeding in hemodynamically stable individuals
 - ◆ As a secondary procedure:
 - For the detection or surveillance of colon polyp(s) if the diagnostic optical colonoscopy was incomplete OR
 - When an incomplete diagnostic optical colonoscopy was performed for either:
 - Multitarget Stool DNA (sDNA) Test Positive OR
 - Other evidence of lower GI bleeding in hemodynamically stable individuals
- Colorectal Cancer Screening
 - ◆ Colon Capsule Endoscopy is considered investigational/experimental for Colorectal Cancer Screening and as such is not approvable for this indication.

CAPEND-8: Esophageal Capsule Endoscopy

- Esophageal Capsule Endoscopy (CPT® 91111) is indicated in the following clinical scenario:
 - ◆ When endoscopic procedures may be inappropriate or contraindicated, such as:
 - Individuals with non-reversible coagulopathy OR
 - Recent MI OR
 - Evaluation of esophageal varices in cirrhotic individuals who are unable to tolerate or undergo EGD

Background and Supporting Information

- Crohn's Disease
 - ◆ In a study, in individuals with both abdominal pain and diarrhea with positive inflammatory markers, the diagnostic yield of CE was 90.1% vs. 0% in those with negative inflammatory markers.
 - ◆ The consensus group of the Canadian Association of Gastroenterology concluded "CE is not warranted in most individuals who present with chronic abdominal pain the absence of positive tests for inflammatory markers or abnormal findings on endoscopy or imaging.
- Celiac Disease
 - ◆ In 2 studies, despite positive serology, no individuals with negative endoscopy and histology showed mucosal changes compatible with celiac disease on CE. CE performed after endoscopy is unlikely to detect any additional individuals with celiac disease that had been missed on duodenal biopsy.
- Patency Capsule
 - ◆ While the American Gastroenterologic Association provides a recommendation for a patency capsule in individuals with known or suspected strictures of the small bowel, this is a conditional recommendation with very low quality of evidence for efficacy and low quality evidence for safety. The AGA notes:
"Therefore, the consensus group suggested that in patients with obstructive symptomatology, imaging should be performed before CE. In patients with negative imaging, most investigators will not use a patency capsule. In patients with abnormalities, suggesting a high risk of capsule retention, patency capsules can be considered although some recent data have questioned their benefit."
 - ◆ In addition, it has been reported that the positive predictive value of a patency capsule was relatively low at 44%.

References

1. Wang A, Banerjee S, Barth BA, et al. Wireless capsule endoscopy. *Gastrointest Endosc.* 2013;78(6):805-815. doi:10.1016/j.gie.2013.06.026
2. Shergill AK, Lightdale JR, Bruining DH, et al. The role of endoscopy in inflammatory bowel disease. *Gastrointest Endosc.* 2015;81(5). doi:10.1016/j.gie.2014.10.030
3. Katsinelos P, Fasoulas K, Beltsis A, et al. Diagnostic yield and clinical impact of wireless capsule endoscopy in patients with chronic abdominal pain with or without diarrhea: A Greek multicenter study. *European Journal of Internal Medicine.* 2011;22(5). doi:10.1016/j.ejim.2011.06.012
4. Enns RA, Hookey L, Armstrong D, et al. Clinical Practice Guidelines for the Use of Video Capsule Endoscopy. *Gastroenterology.* 2017;152(3):497-514. doi:10.1053/j.gastro.2016.12.032
5. Lidums I, Cummins AG, Teo E. The role of capsule endoscopy in suspected celiac disease patients with positive celiac serology. *Digestive Diseases and Sciences.* 2010;56(2):499-505. doi:10.1007/s10620-010-1290-6
6. Rondonotti E, Spada C, Cave D, et al. Video capsule enteroscopy in the diagnosis of celiac disease: a multicenter study. *Am J Gastro.* 2007;102(8):1624-1631. doi:10.1111/j.1572-0241.2007.01238.x
7. Noujaim MG, Green J, Min M, et al. Carcinoids and capsules: a case series highlighting the utility of capsule endoscopy in patients with small bowel carcinoids. *Gastroenterol Res.* 2017;10(6):347-351. doi: 10.14740/gr937w
8. Hakim FA, Alexander JA, Huprich JE, Grover M, Enders FT. CT-Enterography may identify small bowel tumors not detected by capsule endoscopy: eight years experience at mayo clinic rochester. *Digestive Diseases and Sciences.* 2011;56(10):2914-2919. doi:10.1007/s10620-011-1773-0
9. Syngal S, Brand RE, Church JM, Giardiello FM, Hampel HL, Burt RW. ACG clinical guideline: genetic testing and management of hereditary gastrointestinal cancer syndromes. *Am J Gastro.* 2015;110(2):223-262. doi:10.1038/ajg.2014.435.
10. Durno C, Boland CR, Cohen S, et al. Recommendations on surveillance and management of Biallelic Mismatch Repair Deficiency (BMMRD) Syndrome: A consensus statement by the US Multi-Society Task Force on colorectal cancer. *Gastroenterology.* 2017;152(6):1605-1614. doi:10.1053/j.gastro.2017.02.011.
11. Yaday A, Heigh RI, Hara AK, et. al. Performance of the patency capsule compared with nonenteroclysis radiologic examinations in patients with known or suspected intestinal strictures. *Gastrointest Endosc.* 2011;74:834-839. doi:10.1016/j.gie.2011.05.038.
12. Bond A, Collins P. PTH-010 outcomes after use of patency capsules after video capsule endoscopy. *Gut.* 2016;65:A222. doi:10.1136/gutjnl-2016-312388.415.
13. Sawada T, Nakamura M, Watanabe O, et al. Clinical factors related to false-positive rates of patency capsule examination. *Therap Adv Gastroenterol.* 2017;10(8):589-598. doi:10.1177/1756283X17722744.
14. Nemeth A, Kopylov U, Koulaouzidis A, et.al. Use of patency capsule in patients with established Crohn's disease. *Endoscopy.* 2016;48:373-379. doi:10.1055/s-0034-1393560.
15. 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. *Am J Gastro.* July 2017;112(7):1016-1030. doi:10.1038/ajg.2017.174.
16. Han YM, Im JP. Colon capsule endoscopy: where are we and where are we going. *Clin Endosc.* 2016;49(5):449-453. doi:10.5946/ce.2016.095.
17. Rex DK, Adler SN, Aisenberg J, et. al. Accuracy of capsule colonoscopy in detecting colorectal polyps in a screening population. *Gastroenterology.* 2015;148(5):948-957. doi:10.1053/j.gastro.2015.01.025.
18. Sacher-Huvelin S, Coron E, Gaudric M, et.al. Colon capsule endoscopy vs. colonoscopy in patients at average or increased risk of colorectal cancer. *Aliment Pharmacol Ther.* 2010;32(9):1145-53. doi:10.1111/j.1365-2036.2010.04458.x.
19. Pasha SF. Applications of colon capsule endoscopy. *Curr Gastroenterol Rep.* 2018;20(5):22. doi: 10.1007/s11894-018-0628-7.
20. Morgan DR, Malik PR, Romeo DP, Rex DK. Initial US evaluation of second generation capsule colonoscopy for detecting polyps. *BMJ Open Gastroenterol.* 2016;3(1):e000089. doi:10.1136/bmjgast-2016-00089.

21. 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*. 2016;14(11):1533-1543. doi:10.1016/j.cgh.2016.04.038.
22. Spada C, Hassan C, Barbaro B et. al. Colon capsule versus CT colonography in patients with incomplete colonoscopy: A prospective, comparative trial. *Gut*. 2015;64(2):272-281.
23. Novitas Solutions, Inc. Future Local Coverage Determination (LCD): Colon Capsule Endoscopy (CCE) (L38807). <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?lcdid=38807&ver=7&bc=CAAAAAAAAAAAAA>
24. U.S. Preventative Services Task Force. Colorectal cancer: screening. Draft recommendation statement. October 27, 2020. <https://uspreventiveservicestaskforce.org/uspstf/draft-recommendation/colorectal-cancer-screening3#fullrecommendationstart>