

Cigna Medical Coverage Policies – Gastrointestinal Endoscopic Procedure Capsule Endoscopy

Effective January 1, 2020



Instructions for use

The following coverage policy applies to health benefit plans administered by Cigna. Coverage policies are intended to provide guidance in interpreting certain standard Cigna benefit plans and are used by medical directors and other health care professionals in making medical necessity and other coverage determinations. Please note the terms of a customer's particular benefit plan document may differ significantly from the standard benefit plans upon which these coverage policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a coverage policy.

In the event of a conflict, a customer's benefit plan document always supersedes the information in the coverage policy. In the absence of federal or state coverage mandates, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of:

1. The terms of the applicable benefit plan document in effect on the date of service
2. Any applicable laws and regulations
3. Any relevant collateral source materials including coverage policies
4. The specific facts of the particular situation

Coverage policies relate exclusively to the administration of health benefit plans. Coverage policies are not recommendations for treatment and should never be used as treatment guidelines.

This evidence-based medical coverage policy has been developed by eviCore, Inc. Some information in this coverage policy may not apply to all benefit plans administered by Cigna.

These guidelines include procedures eviCore does not review for Cigna. Please refer to the Cigna CPT code list for the current list of high-tech imaging procedures that eviCore reviews for Cigna.

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Capsule Endoscopy

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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 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
 - ◆ 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 persons with:
 - ◆ Chronic abdominal pain or diarrhea (> 30 days) as their only symptoms, and no evidence of biomarkers associated with Crohn's Disease
 - Biomarkers include ESR, CRP, or fecal calprotectin

CAPEND-2: Celiac Disease

- Celiac Disease
 - ◆ 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

- GI Bleeding
 - ◆ 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
 - ◆ Prior negative CE who have repeated obscure bleeding, CE can be repeated.
 - ◆ Suspected obscure bleeding or UNEXPLAINED iron deficiency anemia (negative EGD and colonoscopy).
 - ◆ For Screening in Genetic Syndromes: See **Screening Endoscopy in Genetic Syndromes**

CAPEND-4: Small Bowel Tumors

- Small Bowel Tumors
 - ◆ For the evaluation of known or suspected small bowel tumors

CAPEND-5: Genetic Syndromes

- Juvenile Polyposis Syndrome
 - ◆ Video capsule endoscopy can be performed periodically. Time interval not established.
- Peutz-Jehgers Syndrome
 - ◆ Video capsule endoscopy at age 8 years. If no polyps, repeat at age 18 years, then every 3 years, or earlier if any symptoms occur.
- BMMRD (Biallelic Mismatch Repair Deficiency)
 - ◆ Video capsule endoscopy annually, beginning at age 8 years.

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
 - ◆ At this time, the use of colon capsule endoscopy is considered investigational/experimental.

CAPEND-8: Esophageal Capsule Endoscopy

- Esophageal Capsule Endoscopy can be approved in cases in which endoscopic procedures may be inappropriate or contraindicated, such as individuals with non-reversible coagulopathy, recent MI, or for the 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 patients 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, Dornitz 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.