

Cohere Medical Policy - Capsule Endoscopy

Clinical Guidelines for Medical Necessity Review

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Guideline Information:

Specialty Area: Gastroenterology

Guideline Name: Cohere Medical Policy - Capsule Endoscopy

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Type: $[\underline{\mathbf{X}}]$ Adult (18+ yo) | $[\underline{\mathbf{X}}]$ Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Capsule Endoscopy

Recommended Clinical Approach

Capsule endoscopy (CE) involves a patient swallowing a small disposable capsule containing a wireless camera (generally after an overnight fast). It takes images as it passes through the digestive tract and transmits the data to an external recorder. CE is a non-invasive diagnostic technique that allows real-time video imaging of the entire gastrointestinal (GI) mucosa (pan-enteric CE), reducing the need for individual invasive tests to assess the esophagus, stomach, ileum, and colon. CE is used to detect occult GI bleeding mucosal abnormalities and inflammatory bowel disease (IBD), such as Crohn's disease, polyps, tumors, etc., with sensitivity and accuracy comparable to optical endoscopy and colonoscopy. However, its major limitations are the standardization of scoring systems, poor specificity, and the lack of transmural and histological assessments.¹⁻⁴

Wireless capsule endoscopy of the small bowel may be requested when a previous upper GI endoscopy and a lower GI colonoscopy do not confirm a source of bleeding. A second capsule endoscopy is typically requested when the initial capsule does not penetrate the pylorus. Capsule endoscopy is not recommended in patients with a GI blockage, narrowing, or motility disorder.²⁻³

Medical Necessity Criteria

Indications

- → Capsule endoscopy is considered appropriate if ANY of the following are TRUE⁴⁻⁸:
 - Evaluation of a patient with an established diagnosis of celiac disease and symptoms that are persistent or recurrent following a gluten-free diet for at least 6 months^{5,9-12}; OR
 - ◆ Evaluation of Crohn's disease if **ANY** of the following is **TRUE**^{2,9-10,13-15}:
 - Suspected Crohn's Disease; OR

- No evidence of Crohn's disease is found by conventional diagnostic tests (including, but not limited to, small bowel follow-through (SBFT), abdominal computed tomography (CT) / CT enterography, magnetic resonance enterography (MRE), or EGD and ileocolonoscopy) but suspicion of the disease remains; OR
- Re-evaluation of established Crohn's disease when ANY of the following is TRUE:
 - Despite treatment, symptoms persist and are unexplained by ileocolonoscopy or conventional diagnostic tests; OR
 - Assessment of mucosal healing when disease distribution has been beyond the extent of ileocolonoscopy (i.e., jejunal or ileal, beyond terminal ileum); OR
 - When disease recurrence is suspected after bowel resection and is not sufficiently characterized by ileocolonoscopy and imaging studies; OR
- For screening or surveillance of esophageal varices in patients with known cirrhosis or portal hypertension when EGD and sedation are prohibited due to medical risk^{2,10,16,25}; OR
- For surveillance of small bowel neoplasia in patients with a GI polyposis syndrome (e.g., familial adenomatous polyposis, Peutz-Jeghers syndrome, Lynch syndrome) (0,17,30); OR
- ◆ Evaluation of GI bleeding with **ANY** of the following^{3,18,20,22,23,27}:
 - Documented overt GI bleeding (melena or hematochezia, but not hematemesis) that is unexplained by EGD and colonoscopy performed following adequate preparation;
 OR
 - Repeated overt GI bleeding in a patient with prior negative capsule endoscopy, EGD, and colonoscopy; OR
 - Suspected obscure GI bleeding presenting as severe iron deficiency anemia (hemoglobin less than 10 gm/dL or requiring intravenous [IV] blood or iron transfusion) that is unexplained by EGD and colonoscopy; OR
 - Suspected obscure GI bleeding presenting as mild, moderate, or severe iron deficiency anemia that is persistent or recurrent despite adequate iron replacement therapy and remains unexplained by EGD and colonoscopy;
 OR

- For localization of overt or obscure chronic GI bleeding when intraoperative enteroscopy is being considered; OR
- ◆ Evaluation of locoregional non-metastatic carcinoid tumors of the small bowel in persons with carcinoid syndrome when **ALL** of the following are **TRUE**¹⁰:
 - Persistent clinical symptoms (e.g., abdominal pain, anemia, gastrointestinal bleeding, unexplained weight loss); AND
 - Failure to determine the etiology of symptoms within 12 months from the onset of symptoms using standard diagnostic testing (including, but not limited to, EGD, colonoscopy, CT, MRE, dotatate PET [postiron emission tomography] scan); OR
- Evaluation of gastric lesions when ALL of the following are TRUE 24.26.
 - Standard diagnostic EGD and sedation are contraindicated;
 AND
 - Magnetically-controlled video capsule device is available and utilized for indication; AND
 - Gastric ulcer, polyp, or erosion is suspected; OR
- ◆ Evaluation of the colon when **ANY** of the following is **TRUE**^{5,25}:
 - When a prior colonoscopy was unable to reach the cecum after adequate preparation; OR
 - When colonoscopy is contraindicated due to excessive risk from conscious or deep sedation as documented by a qualified practitioner (anesthetist, gastroenterologist, surgeon, or other adequately trained endoscopist) and ANY of the following:
 - The procedure is for surveillance of cancer/polyps; OR
 - Positive stool-based screening test (multitarget stool DNA [mt-sDNA], fecal occult blood test [FOBT], or fecal immunohistochemical test [FIT]); OR
 - Other evidence of lower GI bleeding in a hemodynamically stable patient; OR
- ◆ For surveillance of graft versus host disease when conventional imaging or endoscopy are insufficient or not tolerated by the patient.²⁰

Non-Indications

- → Capsule endoscopy is not considered appropriate if ANY of the following is TRUE:
 - ◆ The patient has ANY of the following:

- Implanted electrical defibrillators that emit a radiofrequency or other interfering signal^{2,10,25}; OR
- Current pregnancy¹⁰; OR
- Dysphagia or swallowing disorders 3.25; OR
- Gl obstruction, stenosis, stricture, or fistulas based on the clinical picture or pre-procedure testing^{2-3,25}; OR
- Extensive small intestinal diverticulosis²⁰⁻²¹; **OR**
- Zenker (hypopharyngeal) diverticulum²¹⁻²²; **OR**
- Allergy to any medication or preparation agent used before or during the procedure²⁵; OR
- The procedure is ANY of the following⁹:
 - A repeat procedure to verify the effectiveness of surgery, except when related to Crohn's disease; OR
 - A screening test (other than esophageal varices); OR
 - For colorectal cancer screening regardless of family history or other risk factors for the development of colonic disease^{2-3,25}; OR
 - An initial test for diagnosing GI bleeding; OR
 - For evaluation of intussusception; OR
 - For evaluation of diseases involving the esophagus (other than esophageal varices); OR
 - For confirmation of pathology that is sufficiently characterized by other diagnostic means; OR
 - For confirmation of lesions or pathology generally within the reach of upper and lower endoscopes (proximal to the ligament of Treitz, or distal to the ileum)²; OR
 - To be performed in conjunction with computed tomography colonography (CTC)²⁵; OR
 - For investigation of ANY of the following:
 - o Duodenal lymphocytosis; OR
 - Suspected irritable bowel syndrome (IBS)²⁸; OR
 - For routine small bowel investigation in patients with sporadic and nonsporadic duodenal adenomas³⁰; OR
 - For detecting gastric varices; OR
 - For detecting hookworms; OR
 - For diagnosing or evaluating mucosal inflammation in ulcerative colitis.

Level of Care Criteria

Inpatient or outpatient.

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
91110	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), esophagus through ileum, with interpretation and report
065IT	Magnetically controlled capsule endoscopy, esophagus through stomach, including intraprocedural positioning of capsule, with interpretation and report
91111	Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus with interpretation and report
91113	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), colon, with interpretation and report

Medical Evidence

Tamilarasan et al. (2022) conducted a systematic review and meta-analysis to compare the diagnostic accuracy of pan-enteric capsule endoscopy (PCE) with conventional endoscopy, intestinal ultrasound, and magnetic enterography (MRE). Analyzing 14 comparative studies, including 7 studies evaluating PCE diagnostic yield in Crohn's disease (CD) and 7 in ulcerative colitis (UC), the authors identified a trend to superiority of PCE over MRE and colonoscopy, with a pooled odds ratio of 1.25 for the detection of CD, which indicates an increased diagnostic yield of 5% and 7% for PCE compared to that of MRE and colonoscopy, respectively. Moreover, PCE showed a diagnostic sensitivity of 93.8% and a specificity of 69.8% for detecting UC. The authors concluded that PCE has a comparable diagnostic yield to colonoscopy and MRE for CD.¹

Rosa et al. (2023) conducted a systematic review and meta-analysis on 26 observational studies and 5 randomized controlled trials (RCTs) involving a total of 4,072 patients to evaluate the efficacy of bowel preparation protocols for capsule colonoscopy. By evaluating multiple steps of the cleansing protocol (viz., diet, adjunctive laxatives, purgative solutions, prokinetic agents, and boosters), the authors identified strategies associated with higher rates of adequate cleansing (ACR) and complete examinations (CR), the main quality outcomes for capsule colonoscopy and pan-intestinal capsule endoscopy. Regression analysis revealed that the highest ACR was obtained using a low-fiber diet, adjunctive laxatives, and a split dose of the purgative polyethylene glycol (PEG, less than 4 liters). The highest CR was observed using routine prokinetics before swallowing the capsule and using sodium phosphate as a booster.²⁹

Geropulos et al. (2021) conducted a systematic review and meta-analysis of 7 studies with a total of 916 patients to assess the performance of magnetically controlled capsule endoscopy and evaluate its potential in diagnosing gastric lesions. The overall sensitivity of CE was 87%, and subgroup analysis showed that its sensitivity was 82% in detecting gastric ulcers, 82% in detecting gastric polyps, and 95% in detecting gastric erosions. The authors also noted that CE was well tolerated with minimal adverse events.²⁶

Enns et al. (2017) performed a systematic review to identify 21 statements regarding the use of capsule endoscopy for patients with Crohn's disease. It is recommended for patients with unexplained symptoms of celiac disease and treatment is unsuccessful. Capsule endoscopy is also recommended when there is overt gastrointestinal bleeding with negative findings on



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Clinical Guideline Revision History/Information

Original Date: December 8, 2023		
Review History		
Version 2	1/9/2025	 Annual Review 91111 and 91113 CPT codes added Indications updated: Repeat procedure criterion Endoscopy changed to ileocolonoscopy for greater specificity; Need for magnetically controlled capsule discussed and retained; Addition of ulcerative colitis and indeterminate colitis indications discussed and discarded; Graft vs host surveillance added Dotatate PET scan added as standard diagnostics for carcinoid syndrome Non-indications updated Diagnosis of Takayasu's removed Repeat procedure clarified with exception in the case of Crohn's disease Medical evidence updated References updated