Cohere Medicare Advantage Policy - Capsule Endoscopy

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Guideline Information:

Specialty Area: Gastroenterology
Guideline Name: Cohere Medicare Advantage Policy - Capsule Endoscopy

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Medical Necessity Criteria

Service: Capsule Endoscopy

Benefit Category

Not applicable.

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.[2-3,10,18,25,31-34,36]

Related CMS Documents

Please refer to the CMS Medicare Coverage Database for the most current applicable CMS National Coverage.[2-3,10,18,25,31-34,36]

- Local Coverage Determination (LCD). Colon Capsule Endoscopy (CCE) (L38777)
- Billing and Coding. Colon Capsule Endoscopy (CCE) (A58362)
- Local Coverage Determination (LCD). Wireless Capsule Endoscopy (L33774)
- Billing and Coding. Wireless Capsule Endoscopy (A56704)
- Local Coverage Determination (LCD). Wireless Capsule Endoscopy (L35089)
- Billing and Coding. Wireless Capsule Endoscopy (A57753)
- Local Coverage Determination (LCD). Endoscopy by capsule (L34081)
- Billing and Coding. Endoscopy by Capsule (A56461)
- Local Coverage Determination (LCD). Wireless Capsule Endoscopy (L36427)
- Billing and Coding. Wireless Capsule Endoscopy (A56727)

Recommended Clinical Approach

Capsule endoscopy (CE) involves a patient swallowing a small disposable capsule containing a wireless camera (generally after an overnight fast) that 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 that is 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]

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of capsule endoscopy. This process helps prevent incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Adverse events in patients undergoing capsule endoscopy are rare but may include technical problems (e.g., gaps in recordings, short duration of capsule batteries, and failure of downloading data) and clinical problems (e.g., difficulty/inability to swallow the capsule and incomplete small-bowel examination).[4]
- Due to abnormalities in gastrointestinal (GI) motility or narrowing of the GI tract, an endoscopic capsule may get stuck in the GI tract instead of passing out of the body with normal bowel movements. In such cases, endoscopic or surgical intervention may be required to retrieve the capsule.[21]
- While standard bowel preparation protocols effectively clear the small bowel in preparation for capsule endoscopy, adequate colonic cleansing remains a challenge.[26,29]

- Delays in diagnosis due to the lengthy reading times hinder the broader implementation of CE, a drawback that could be overcome through the integration of artificial intelligence (AI) models.[35]
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- Capsule endoscopy (CE) provides a comprehensive, non-invasive, and painless technique for diagnosing abnormalities throughout the gastrointestinal (GI) tract.[1]
- Studies show a high degree of diagnostic accuracy, sensitivity, and specificity of pan-enteric capsule endoscopy (PCE) compared with conventional endoscopy, intestinal ultrasound, and magnetic enterography (MRE). PCE also shows a trend toward improved diagnostic yield in Crohn's disease and ulcerative colitis.[1]
- CE has increased the diagnostic yield because it can visualize nearly the entire GI tract. Due to the length and tortuosity of the GI tract, identifying localized lesions or sources of bleeding has been elusive using standard techniques.[21]
- CE avoids insufflation or sedation and its associated risks.
- Periodic small bowel inspection with CE is beneficial in detecting intestinal polyps in patients with GI polyposis syndromes, such as patients with Peutz-Jeghers syndrome.[30]
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials and ensure that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with minimizing potential harms, providing numerous clinical benefits, and helping avoid unnecessary complications from inappropriate care.

In addition, using these criteria will likely decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

- ➔ **Capsule endoscopy** is considered appropriate if **ANY** of the following is **TRUE**[4-8]:
  - ◆ 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 are **TRUE**[2,9-10,13-15,19]:
    - Suspected Crohn's disease; **AND**
    - 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)[10,17,30]; **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 for medical reasons; **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.[27]

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[2,10,25,30]; **OR**
        - Current pregnancy[10]; **OR**
        - Dysphagia or swallowing disorders[3,25]; **OR**
        - GI obstruction, stenosis, stricture, or fistulas based on the clinical picture or pre-procedure testing[2-3,25]; **OR**
        - Extensive small intestinal diverticulosis[20-21]; **OR**
        - Zenker (hypopharyngeal) diverticulum[21-22]; **OR**
        - Allergy to any medication or preparation agent used before or during the procedure[25]; **OR**
    - The procedure is **ANY** of the following[9]:
        - 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 normally 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:
    - Duodenal lymphocytosis; **OR**
    - Suspected irritable bowel syndrome (IBS)[28]; **OR**
- For routine small bowel investigation in patients with sporadic and nonsporadic duodenal adenomas[30]; **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
0651T	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

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

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 esophagogastroduodenoscopy and colonoscopy. Select patients may benefit from capsule endoscopy, including those with unexplained chronic anemia or small bowel cancer.[5]

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Clinical Guideline Revision History/Information

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