# Capsule Endoscopy

**ACG: A-0134 (AC)**
**Link to Codes**

**MCG Health**
Ambulatory Care
30th Edition

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## Clinical Indications

- Capsule endoscopy may be indicated when **ALL** of the following are present(1)(2)(3)(4)(5)(6):
  - GI condition, as indicated by **1 or more** of the following:
    - Celiac disease, known or suspected, as indicated by **1 or more** of the following(44)(45)(46)(47):N
      - Celiac disease, suspected, based on clinical presentation and serologic testing, and esophagogastroduodenoscopy and mucosal biopsy unable to be performed[A][B](49)
      - Celiac disease with persistent or recurrent symptoms after 12 months of gluten-free diet(50)(55)(56)(57)
    - Constitutional mismatch repair deficiency(58)(59)(60)(61)(62)N
    - Crohn disease, known or suspected, when there is no clinical suspicion or radiologic evidence of significant stricture(64)(65)(66)(67)(68)N
    - Esophageal varices, suspected, as indicated by **ALL** of the following(76)(77):N
      - Cirrhosis diagnosis confirmed
      - Esophagogastroduodenoscopy unable to be performed on patient

- GI polyposis syndrome, known or suspected (eg, familial adenomatous polyposis, Peutz-Jeghers syndrome)(82)(83)(84)(85)(86)N
- Iron deficiency anemia, and endoscopic studies (eg, esophagogastroduodenoscopy, colonoscopy) negative for source of bleeding(92)(93)(94)(95)(96)N
- Suspected small bowel bleeding, and endoscopic studies (eg, esophagogastroduodenoscopy, colonoscopy) negative for source of bleeding(71)(98)(99)(100)(101)(102)(103)N

- No clinical or x-ray evidence of small bowel or other GI obstruction(12)(104)(112)(113)(114)
- No history of GI fistula, stricture or stenosis, or Zenker (esophageal) diverticulum(112)(115)(116)(117)
- No known extensive intestinal diverticulosis(112)(114)(118)
- No NSAIDs for 1 month prior to capsule endoscopy(6)
- No swallowing disorder, or swallowing disorder with capsule inserted endoscopically(112)(113)(114)
- Patient not pregnant(112)(113)(114)

# Alternatives

- Alternatives include:
  - Colonoscopy. See Colonoscopy AC for further information.(1)
  - Contrast enema. See Contrast Enema: Single-Contrast, Double-Contrast, or Therapeutic AC for further information.
  - CT angiography. See Abdominal/Pelvic CT Angiography (CTA) AC for further information.(119)
  - CT or MR enterography(119)(120)(121)(122)(123)(124)
  - Device-assisted enteroscopy (eg, small bowel endoscopy)[C](10)(107)(116)(125)(126)
  - Esophagogastroduodenoscopy. See Esophagogastroduodenoscopy (EGD), UGI Endoscopy AC for further information.(48)
  - Nuclear medicine GI blood loss study(119)
  - UGI contrast studies. See UGI Contrast Studies: Esophagography, UGI Study, Small Bowel Follow-Through, and Swallowing Evaluation AC for further information.

# Evidence Summary

## Background

Capsule endoscopy, also called video capsule endoscopy or wireless capsule endoscopy, can provide visualization of the mucosa of the esophagus, the small bowel, and the large bowel.(7)(8)(9)(10) **(EG 2)** After an overnight fast, and possibly a purgative bowel preparation, the patient swallows a capsule that sends images to a computer-aided viewing system.(1)(11) **(EG 2)** The capsule is disposable and is excreted with stool; capsule retention rates, when used to investigate cases of occult GI bleeding and Crohn disease, have been estimated to be 1.2% and 4.6%, respectively, with an overall retention rate of approximately 2%.(6)(12)(13) **(EG 2)** To avoid capsule retention and the need for subsequent endoscopic or surgical intervention, a dissolvable sham capsule (patency capsule) is utilized for at-risk patients to assess GI patency prior to capsule endoscopy. Conditions associated with increased risk of capsule retention include a history of small bowel obstruction or abdominal radiation, recent abdominal surgery, suspected small bowel tumor or stricture, use of NSAIDs, or established small bowel Crohn disease.(14)(15)(16) **(EG 2)**

Capsule enhancements have been developed that include faster image capture speed, wide angle optics, variations in light source, adaptive frame technology that adjusts to capsule speed, cameras at both ends, and 4 cameras that allow for a 360-degree view.(7)(17) **(EG 2)** Safety and successful imaging have been demonstrated in children as young as 8 months of age, although endoscopic delivery may be required in patients unable to swallow the capsule.(3) **(EG 2)**

# Criteria

The evidence for the clinical indications found in this guideline includes 100 published peer reviewed articles, 15 specialty society or other evidence-based guidelines, and 1 Cochrane systematic review.

For celiac disease, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** A meta-analysis found that video capsule endoscopy had a pooled sensitivity and specificity of 89% and 95%, respectively, for the diagnosis of celiac disease. The authors stated that, although small bowel biopsies are the gold standard for the diagnosis of celiac disease, capsule endoscopy could be a reasonable alternative in patients unwilling to undergo endoscopy.(48) **(EG 1)** A specialty society guideline recommends against small bowel capsule endoscopy for the diagnosis of celiac disease but indicates that it may be used in cases of equivocal celiac disease diagnosis or for assessment of nonresponsive or refractory celiac disease.(6) **(EG 2)** A specialty society guideline states that, although duodenal biopsy is required to establish the diagnosis of celiac disease, video capsule endoscopy may play a supportive diagnostic role for those patients with positive serology but normal mucosa or those patients who are unable or unwilling to undergo endoscopy.(49) **(EG 2)** An expert consensus guideline recommends small bowel imaging with capsule endoscopy and CT or MR enterography in patients with refractory celiac disease (ie, diagnosed celiac disease with persistent or recurrent symptoms after at least 12 months of strict adherence to a gluten-free diet, with persistent villous atrophy on duodenal biopsy) to evaluate for complications of celiac disease, including ulcerative jejunoileitis and enteropathy-associated T-cell lymphoma.(50) **(EG 2)**

For constitutional mismatch repair deficiency, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** Constitutional mismatch repair deficiency is a rare tumor predisposition caused by biallelic mutations in DNA mismatch repair genes (MLH1, MSH2, MSH6, and PMS2) that is associated with a high risk of a variety of tumors, including small bowel cancers.(61)(63) **(EG 2)** Specialty society and expert consensus guidelines recommend annual video capsule endoscopy starting between age 6 and 10 years as part of routine tumor surveillance for patients with constitutional mismatch repair deficiency.(58)(59)(60)(61) **(EG 2)**

For Crohn disease, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** A meta-analysis of 24 studies comparing the diagnostic yield of capsule endoscopy and other modalities for suspected Crohn disease found that capsule endoscopy was associated with increased diagnostic yield compared with small bowel follow-through, but no significant difference was seen compared with CT or MR enterography. For patients with established Crohn disease, there was no significant difference in diagnostic yield between capsule endoscopy, small bowel follow-through, CT or MR enterography, and ileocolonoscopy.(69) **(EG 1)** A meta-analysis that excluded patients with known strictures found that, as compared with small bowel radiography, CT enterography, and colonoscopy with ileoscopy, capsule endoscopy was associated with increased diagnostic yield for patients with suspected Crohn disease. For patients with established Crohn disease, capsule endoscopy, as compared with small bowel radiography and CT enterography, was associated with an increased diagnostic yield.(70) **(EG 1)** Meta-analyses conclude that, although capsule endoscopy is superior to barium radiography, colonoscopy with ileoscopy, and CT enterography for detecting small bowel recurrence in established Crohn disease, there is no significant difference in detection rates for patients with suspected initial presentation.(71)(72) **(EG 1)** In pediatric patients, a capsule endoscopy-derived Crohn disease severity score was predictive of the need for treatment escalation in the year following the initial test in a cohort of 59 patients age 6 to 18 years with Crohn disease.(73) **(EG 2)** A specialty society guideline recommends capsule endoscopy in patients with suspected Crohn disease and negative ileocolonoscopy findings in the absence of obstructive symptoms or known stenosis. The guideline suggests that capsule endoscopy may also have a role in monitoring response and guiding treatment in patients with established Crohn disease.(6) **(EG 2)** Another specialty society guideline recommends video capsule endoscopy for identification of small bowel Crohn disease when there is a high index of suspicion.(74) **(EG 2)** Pediatric specialty society guidelines support the use of capsule endoscopy to identify mucosal lesions in children with suspected Crohn disease in whom conventional endoscopy has been nondiagnostic or when MR enterography cannot be performed due to patient age or lack of availability.(3)(75) **(EG 2)**

For esophageal varices, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** A systematic review of 15 studies (with a total of 936 patients) evaluating the diagnostic accuracy of capsule endoscopy as a triage tool or replacement for esophagogastroduodenoscopy for the diagnosis of esophageal varices found a pooled sensitivity and specificity of 85% and 84%, respectively. The authors concluded that the accuracy of capsule endoscopy is not sufficient to replace esophagogastroduodenoscopy as the primary diagnostic tool

for suspected esophageal varices.(76) **(EG 1)** A prospective multicenter study evaluating a novel magnetically guided capsule endoscopy device for the evaluation of esophagogastric varices in 582 adults with cirrhosis reported that capsule endoscopy had a sensitivity and specificity for detection of varices of 97.5% and 97.8%, respectively, as compared with esophagogastroduodenoscopy.(78) **(EG 2)** A single-center prospective cohort study of 81 children with portal hypertension evaluated the efficacy of esophageal capsule endoscopy in detecting esophageal varices and found that the sensitivity and specificity for capsule endoscopy using the de Franchis classification for esophageal varices were 92% and 100%, respectively, as compared with the esophagogastroduodenoscopy referent gold standard. Results were limited by small study population and interrater reliability for diagnosis; further studies with larger populations and validation of the modified criteria for esophageal varices were recommended.(77) **(EG 2)** Capsule endoscopy may be an acceptable alternative in patients unable or unwilling to undergo esophagogastroduodenoscopy.(79)(80)(81) **(EG 2)**

For GI polyposis syndrome, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** Capsule endoscopy has been shown to be effective in detecting small bowel polyps, especially smaller ones.(82)(87) **(EG 2)** However, multiple studies document that capsule endoscopy can identify the ampulla of Vater only 0% to 60% of the time, calling into question its capability to detect small polyps in the proximal small bowel for surveillance of small bowel polyposis syndromes.(88) **(EG 2)** Specialty society guidelines recommend capsule endoscopy as an option for small bowel surveillance in patients with Peutz-Jeghers syndrome and for evaluation of the mid-distal small bowel in patients with familial adenomatous polyposis.(6)(89) **(EG 2)** Professional consensus guidelines support the use of capsule endoscopy for the diagnosis and surveillance of Peutz-Jeghers syndrome.(3)(85)(90)(91) **(EG 2)**

For iron deficiency anemia, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** A systematic review and meta-analysis of 24 studies (1960 patients) supports the use of capsule endoscopy for patients with iron deficiency anemia and negative findings on a previous diagnostic evaluation (upper GI endoscopy, colonoscopy). Subset analysis of studies that focused only on patients with iron deficiency anemia found that capsule endoscopy had a pooled diagnostic yield of 67%, as compared with 44% for studies that did not focus solely on patients with iron deficiency anemia.(92) **(EG 1)** A single-arm prospective study evaluated the diagnostic accuracy of pan-intestinal capsule endoscopy followed by colonoscopy in 100 patients with suspected mid or lower GI bleeding (81% with iron deficiency anemia and 19% with overt bleeding, such as melena or hematochezia) and a nondiagnostic esophagogastroduodenoscopy, and found that capsule endoscopy identified more potentially hemorrhagic lesions than colonoscopy overall (44% vs 23% of patients) but had a similar diagnostic yield as colonoscopy for lesions only in the ileocolonic region (89.3% vs 82.1%).(97) **(EG 2)** A specialty society guideline recommends capsule endoscopy as a first-line investigation for patients with iron deficiency anemia and negative upper and lower endoscopy when small bowel evaluation is needed.(6) **(EG 2)**

For suspected small bowel bleeding, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** Capsule endoscopy is recommended after normal endoscopic evaluations of the upper and lower GI tract.(104)(105)(106)(107) **(EG 2)** A systematic review of 25 studies (1986 patients) comparing CT enterography with capsule endoscopy for the evaluation of patients with suspected small bowel bleeding found that capsule endoscopy had a higher sensitivity (74% vs 47%) but lower specificity (53% vs 94%) than CT enterography for identification of a small intestinal source of bleeding.(108) **(EG 1)** A systematic review and meta-analysis of 26 studies (3657 patients) found that the pooled rate of rebleeding after negative small bowel capsule endoscopy was 19%; it was 29% after a positive study.(109) **(EG 1)** A specialty society guideline supports the use of video capsule endoscopy for stable patients with suspected obscure small bowel bleeding and endoscopic studies (eg, esophagogastroduodenoscopy, colonoscopy) that are negative for the source of bleeding.(110) **(EG 2)** A specialty society statement and an expert consensus guideline recommend capsule endoscopy as a first-line investigation for patients with suspected small bowel bleeding (ie, overt or occult GI bleeding with negative upper and lower endoscopy). The authors recommend that capsule endoscopy be performed as soon as possible after the bleeding episode in patients with overt suspected small bowel bleeding.(6)(111) **(EG 2)**

## Inconclusive or Non-Supportive Evidence

For abdominal pain, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A systematic review of 21 studies (1520 patients) of small bowel capsule endoscopy for unexplained chronic abdominal pain found that the pooled diagnostic yield was 21%; subgroup analysis of 15 studies (1223 patients) showed that, of the 290 definitive pathologic findings, 78% were inflammatory

lesions and 9% were tumors. The authors concluded that small bowel capsule endoscopy was of limited value in the diagnosis of unexplained chronic abdominal pain.(18)(19)(20) **(EG 1)** An evidence-based review states that video capsule endoscopy is not recommended for patients with isolated chronic abdominal pain.(21) **(EG 2)** A pediatric consensus guideline does not support the use of capsule endoscopy for the diagnostic evaluation of children with chronic or recurrent abdominal pain in the absence of other clinical or laboratory findings.(3) **(EG 2)**

For Barrett esophagus, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A meta-analysis found that capsule endoscopy had only moderate sensitivity and specificity for diagnosing Barrett esophagus in patients with gastroesophageal reflux; the authors recommended esophagogastroduodenoscopy, during which biopsies may be taken, as the procedure of choice.(22)(23) **(EG 1)**

For detection of colorectal polyps, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A systematic review and meta-analysis of 14 studies evaluated the diagnostic accuracy of first-generation (1128 patients) and second-generation (1292 patients) colon capsules for detection of colorectal polyps compared with colonoscopy in patients referred for endoscopy; reasons for referral included colorectal cancer screening, postpolypectomy surveillance or family history of colon cancer, positive fecal occult blood testing, and positive imaging studies. Second-generation capsule endoscopy was found to have a sensitivity of 86% and 87% for polyps 6 mm or greater and 10 mm or greater, respectively; first-generation capsule endoscopy was found to have a sensitivity of 58% and 54% for polyps 6 mm or greater and 10 mm or greater, respectively. The authors noted that there is uncertainty regarding the diagnostic accuracy of capsule endoscopy for sessile serrated polyps and that polyp cutoff size for colonoscopy referral after a positive capsule endoscopy is not clearly defined. The authors concluded that second-generation capsule endoscopy has improved detection from earlier technology and should be considered for polyp detection in patients who are unwilling to undergo colonoscopy or in whom colonoscopy is technically not feasible.(24) **(EG 1)** A systematic review and meta-analysis of 8 studies evaluating second-generation colon capsule endoscopy for detection of colorectal polyps in patients age 50 to 75 years at average risk of colorectal cancer (with no prior testing or with positive fecal immunochemical or fecal occult blood test results) reported a sensitivity and specificity of 88% and 94%, respectively, for polyps 6 mm or greater and a sensitivity and specificity of 88% and 95%, respectively, for polyps 10 mm or greater. The authors noted that additional studies evaluating the cost-effectiveness of capsule endoscopy relative to other colorectal cancer screening strategies are needed.(25) **(EG 1)** In a prospective cohort study, 177 first-degree relatives of persons diagnosed with colorectal cancer underwent colorectal cancer screening with both colon capsule endoscopy and optical colonoscopy. Colon capsule endoscopy had a sensitivity, specificity, positive predictive value, and negative predictive value of 91%, 88%, 78%, and 95%, respectively, for colon polyps of 6 mm or greater, as compared with the referent standard of optical colonoscopy. Results were limited by small study numbers, suboptimal preparation rates, and the inability to wash away residual material with capsule colon endoscopy; further studies with larger screening populations were recommended.(26) **(EG 2)** Specialty society guidelines recommend against routinely substituting colon capsule endoscopy for colonoscopy.(2)(27) **(EG 2)** A multisociety task force on colorectal cancer suggests, based on low-quality evidence, colon capsule endoscopy every 5 years for colorectal cancer screening in individuals who decline other colorectal cancer screening modalities (eg, colonoscopy, fecal immunochemical test), but notes that disadvantages to its use include the need for a more extensive preparation than for colonoscopy and the frequent need for a repeat colonoscopy preparation if there are positive findings.(28)(29) **(EG 2)** Other specialty society guidelines do not include capsule endoscopy in recommendations for colorectal cancer screening for asymptomatic adults.(30)(31) **(EG 2)**

For follow-up after incomplete colonoscopy, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** An observational study of 96 patients who underwent capsule endoscopy following an incomplete colonoscopy found that complete visualization of the colon occurred in 72% of patients and that new lesions were identified in 60% of patients at locations not reached by previous colonoscopy; treatment modification occurred in 74% of patients with new lesions. Study limitations included lack of follow-up data for patients with negative capsule endoscopy, including those with suboptimal bowel cleansing; only suspected polyps and colon cancers were confirmed by other modalities; and lack of standardization for timing and duration of capsule endoscopy examination.(32) **(EG 2)** An observational study of 97 patients with incomplete colonoscopy suggested that capsule endoscopy may be more accurate than CT colonography for the detection of polyps or mass lesions 6 mm or larger. However, there was no difference in detection rates for polyps or mass lesions 10 mm or larger.(33) **(EG 2)** An observational study of 75 patients who underwent capsule endoscopy following an incomplete colonoscopy found significant pathology in 44% of patients. Additional workup was recommended for 30.7% of patients; within 3 months of the index colonoscopy, 15 of the 23 patients underwent a third examination that identified significant new pathology in 3 patients and nonsignificant small polyps in 6 patients.(34) **(EG 2)** An observational study of 34 patients who had an incomplete colonoscopy (for a variety of indications, including colorectal cancer screening,

hematochezia, and abdominal pain) found that the use of capsule endoscopy allowed for the formulation of a treatment plan in 59% of patients. Polyps found by this technique required subsequent intervention for removal. Additional studies were recommended to validate these results and investigate how to improve the performance of capsule endoscopy for this indication.(35) **(EG 2)** A specialty society guideline states that there is low-quality evidence to recommend capsule endoscopy in patients with incomplete colonoscopy but notes that it is an option.(36) **(EG 2)** An expert consensus guideline notes that CT colonography or capsule endoscopy may be considered as an option to complete colorectal cancer screening in patients who have had an incomplete colonoscopy.(37) **(EG 2)**

For GI motility, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** Multiple small studies demonstrate that the role of capsule endoscopy for measuring GI motility has yet to be clearly defined.(38)(39)(40)(41)(42) **(EG 2)** A specialty society guideline makes a conditional recommendation for the use of wireless motility capsules as an alternative to scintigraphic gastric emptying studies for assessment of gastroparesis in patients with upper GI symptoms but notes that measurements of gastric motility obtained using the 2 methods differ.(43) **(EG 2)**

## Rationale

Use of this MCG care guideline helps the clinician determine if a particular treatment, medication, or service might be appropriate for a specific patient, taking into account their unique health complexities.

Use of these evidence-based clinical criteria to support decision making benefits the patient by identifying patient-specific complex clinical factors and conditions, promoting personalized treatment. Utilizing evidence-based clinical criteria promotes patient safety by helping ensure that potential patient benefits outweigh the risks. In addition, the use of evidence-based guidelines can increase consistency in treatment thresholds, leading to less variation in care and promoting equitable treatment among patients.

## Related CMS Coverage Guidance

This guideline supplements but does not replace, modify, or supersede existing Medicare regulations or applicable National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs).

**Code of Federal Regulations (CFR):** 42 CFR 419.22(127); 42 CFR 422.101(128)

**Internet-Only Manual (IOM) Citations:** CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 14 - Medical Devices(129); CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 15 - Covered Medical and Other Health Services(130); CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 16 - General Exclusions from Coverage(131)

**Medicare Coverage Determinations:** Medicare Coverage Database(132)

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# Footnotes

[A] For symptomatic patients, serologic finding of IgA anti-tissue transglutaminase antibody is suggestive of celiac disease and warrants further investigation, including duodenal biopsy or additional serologic testing, to establish the diagnosis. IgA anti-tissue transglutaminase antibody testing may be unreliable in the setting of IgA deficiency; if celiac disease is suspected when IgA deficiency is present, IgG serology testing (IgG anti-tissue transglutaminase antibody, IgG anti-endomysial antibody, and/or IgG deamidated gliadin peptide) should be performed to determine the need for biopsy.(51) Children with a high-level anti-tissue transglutaminase antibody level with a positive endomysial antibody result on a second sample may be able to be diagnosed with celiac disease without a biopsy.(51)(52) [ A in Context Link 1 ]

[B] Up to 10% of patients with celiac disease may be seronegative. Duodenal biopsy should be considered for patients who have clinical symptoms strongly suggestive of celiac disease even if serologies are negative.(51)(53)(54) [ B in Context Link 1 ]

[C] Device-assisted enteroscopy is a generic term for endoluminal examination of the small bowel with any endoscopic technique that includes assisted progression of the endoscopy into the small bowel, allowing tissue acquisition and foreign body removal. Methods include double-balloon enteroscopy with a balloon pump system and overtube, single-balloon enteroscopy, and spiral enteroscopy.(10) [ C in Context Link 1 ]

# Codes

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