



## Capsule Endoscopy (Camera Pill)

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### Definition

Telemetric gastrointestinal capsule imaging (also referred to as the camera pill or wireless capsule endoscopy) is a noninvasive diagnostic imaging system for use in viewing the **esophagus or** gastrointestinal (GI) tract, especially the small bowel, which is not accessible to standard upper endoscopy and colonoscopy. A small capsule (approximately 11 × 26 mm) is swallowed and moves through the GI tract via peristalsis, capturing video pictures which are transmitted to sensors taped to the body and stored on a portable recorder. The strength of the signal is used to calculate the position of the capsule as it passes through the GI tract. Video images are stored on a portable recorder and later downloaded to a computer, from which they may subsequently be viewed in real time. The capsule passes naturally from the body with the stool and, being disposable, is not recovered.

### Guideline

Members are eligible for esophageal or small bowel capsule endoscopy coverage (when performed by gastroenterologists or independent diagnostic testing facilities under the general supervision of a gastroenterologist) for any of the following indications:

1. **Esophageal varices** for members with cirrhosis and portal hypertension and no prior variceal bleeding

Cirrhosis and portal hypertension are defined as a Child's class B or C stage or a class A with a low platelet count (<140,000), an enlarged portal vein diameter (> 13 mm) or evidence of collateral circulation on ultrasound.

An initial camera pill evaluation is considered reasonable and will enable the presence and/or size of varices to be determined. Follow-up studies are permissible as follows:

- a. No varices — repeat at 3 years.
- b. Small — repeat every 1–2 years (diameter  $> 0$  and  $< \frac{1}{4}$  of the video circumference for the frame that shows its largest diameter).
- c. Medium to large — repeat not medically necessary; endoscopy is the appropriate modality for subsequent evaluation ( $\geq \frac{1}{4}$  of the circumference).

## 2. Small Bowel

- a. Occult GI bleeding — the medical record must document the presence of GI bleeding and contain reports of previous negative upper and lower endoscopies performed during the current episode of illness.
- b. Iron deficiency anemia with confirmed blood loss only — the medical record must document the presence of anemia secondary to blood loss and reports of previous upper and lower endoscopies.
- c. Celiac sprue — when celiac disease is present and member fails to improve post three-month trial of gluten-free diet and has abnormal weight loss and diarrhea.
- d. Crohn's disease — diagnosis known — but it is necessary to determine whether there is small bowel involvement.
- e. Crohn's disease — diagnosis suspected — when there is a strong clinical suspicion of the disease (prior radiological study to exclude stricture must have been performed, which did not demonstrate the presence of Crohn's disease). All of the following must be present:
  - i. Abdominal pain.
  - ii. Occult or overt GI bleeding.
  - iii. Diarrhea.
  - iv. Weight loss.

*Note: For this indication, coverage may be provided without the member having undergone a prior upper GI endoscopy and colonoscopy.*

*The medical record must document that a diagnosis of the disease requires confirmation; if the diagnosis is known, the documentation must reflect that it is necessary to determine small bowel involvement. For those members in whom there was a high clinical suspicion of Crohn's disease and who had a capsule endoscopy performed without prior upper endoscopy or colonoscopy, the medical record should document a prior radiologic procedure that excluded strictures.*

- f. Colitis — for those cases in which a diagnosis of colitis of an indeterminate type affecting the colon is known and in whom a more specific diagnosis is sought by evaluating for possible small bowel involvement. The medical record must document that the test is necessary in order to evaluate small bowel involvement.
- g. Angiectasias of the GI tract — for the diagnosis of angiectasias, as evidenced by recurrent episodes of obscure GI bleeding.
- h. Small bowel neoplasm — for the diagnosis of small bowel neoplasm when the diagnosis has not been previously confirmed by other studies (e.g., upper gastrointestinal endoscopy, colonoscopy, push enteroscopy, nuclear imaging or radiological procedures).

The member must have neoplasm symptoms; all of the following must be present:

- i. Abdominal pain.
- ii. Occult or overt GI bleeding.
- iii. Diarrhea.
- iv. Weight loss.

**OR**

- v. Have documented polyposis syndrome associated with small bowel neoplasia.

**OR**

- vi. Have other history suggesting the presence of small bowel neoplasia (i.e., intermittent obstruction or intussusception) and have undergone prior diagnostic testing (i.e., upper GI endoscopy and/or colonoscopy and radiological studies) to assess these symptoms.

*Note: The requirement for prior examination by upper and lower endoscopies may be waived for members with documented intussusception of the small bowel without established etiology.*

- i. Inflammatory bowel disease. All of the following must be present:
  - i. Abdominal pain.
  - ii. Occult or overt GI bleeding.
  - iii. Diarrhea.
  - iv. Weight loss.
- j. Other conditions — evaluation of malabsorptions syndrome or protein-losing enteropathy of an obscure origin, as evidenced by the following:
  - i. Diarrhea with greasy voluminous foul smelling stool, and
  - ii. Weight loss despite adequate food intake.

**OR**

- iii. Anorexia, and
- iv. Flatulence, and
- v. Abdominal distention.

Appropriate prior negative or non-diagnostic evaluations of the esophagus, stomach, duodenum/small intestine, and colon by flexible endoscopy, and complementary radiologic procedures and/or microbiologic studies must be documented.

- k. Evaluation prior to surgery — evaluation of extent of small bowel involvement with arteriovenous malformations or lymphangiectasia for members who are contemplated for surgical resection of the small bowel to control recurrent bleeding or protein loss is reasonable.

### **Limitations/Exclusions**

1. Gastrointestinal tract must be patent
2. Patency systems to verify GI tract patency prior to camera pill ingestion (e.g., Given® AGILE as an accessory to the PillCam™) are not considered medically necessary, as there is insufficient evidence to support its use.
3. The camera pill colon (e.g., PillCam Colon®) is not considered medically necessary, as there is insufficient evidence of therapeutic value.

**4. The camera pill is not considered medically necessary for any of the following:**

- a. Bright red blood per rectum.
- b. Colorectal cancer screening.
- c. Hematemesis.
- d. Crohn's disease, when used for management rather than diagnosis. (Coverage is provided when utilized to determine extent of small bowel disease).
- e. Detection of small bowel malignancies in the absence of obscure GI bleeding or symptoms suggesting Crohn's disease.
- f. For the evaluation of gastroesophageal reflux.
- g. For the follow-up evaluation of medium to large esophageal varices.
- h. Confirmation of lesions or pathologies that are:
  - i. Normally within the reach of upper or lower endoscopes (lesions proximal to the second portion of the duodenum or distal to the ileum).

**OR**

- ii. Previously discovered by any of the following diagnostic modalities:
  - 1. Prior endoscopy (including push enteroscopy).
  - 2. Colonoscopy.
  - 3. Radiology.

**Applicable Procedure Codes**

91110	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), esophagus through ileum, with physician interpretation and report
91111	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), esophagus with physician interpretation and report

**Applicable ICD-10 Diagnosis Codes**

A18.32	Tuberculous enteritis
A18.39	Retroperitoneal tuberculosis
A18.83	Tuberculosis of digestive tract organs, not elsewhere classified
C17.0	Malignant neoplasm of duodenum
C17.1	Malignant neoplasm of jejunum
C17.3	Meckel's diverticulum, malignant
C17.8	Malignant neoplasm of overlapping sites of small intestine
C17.9	Malignant neoplasm of small intestine, unspecified
C49.A3	Gastrointestinal stromal tumor of small intestine (Eff. 10/01/2016)
C49.A4	Gastrointestinal stromal tumor of large intestine (Eff. 10/01/2016)
C78.4	Secondary malignant neoplasm of small intestine
D01.40	Carcinoma in situ of unspecified part of intestine
D01.49	Carcinoma in situ of other parts of intestine

D13.2	Benign neoplasm of duodenum
D13.30	Benign neoplasm of unspecified part of small intestine
D13.39	Benign neoplasm of other parts of small intestine
D37.2	Benign neoplasm of endocrine pancreas
D50.0	Iron deficiency anemia secondary to blood loss (chronic)
D50.9	Iron deficiency anemia, unspecified
E16.4	Increased secretion of gastrin
I77.6	Arteritis, unspecified
I85.10	Secondary esophageal varices without bleeding
I85.11	Secondary esophageal varices with bleeding
K31.811	Angiodysplasia of stomach and duodenum with bleeding
K31.82	Dieulafoy lesion (hemorrhagic) of stomach and duodenum
K50.00	Crohn's disease of small intestine without complications
K50.011	Crohn's disease of small intestine with rectal bleeding
K50.118	Crohn's disease of large intestine with other complication
K50.119	Crohn's disease of large intestine with unspecified complications
K50.012	Crohn's disease of small intestine with intestinal obstruction
K50.013	Crohn's disease of small intestine with fistula
K50.014	Crohn's disease of small intestine with abscess
K50.018	Crohn's disease of small intestine with other complication
K50.019	Crohn's disease of small intestine with unspecified complications
K50.10	Crohn's disease of large intestine without complications
K50.111	Crohn's disease of large intestine with rectal bleeding
K50.80	Crohn's disease of both small and large intestine without complications
K50.811	Crohn's disease of both small and large intestine with rectal bleeding
K50.812	Crohn's disease of both small and large intestine with intestinal obstruction
K50.813	Crohn's disease of both small and large intestine with fistula
K50.814	Crohn's disease of both small and large intestine with abscess
K50.818	Crohn's disease of both small and large intestine with other complication
K50.819	Crohn's disease of both small and large intestine with unspecified complications
K50.90	Crohn's disease, unspecified, without complications
K50.911	Crohn's disease, unspecified, with rectal bleeding
K50.918	Crohn's disease, unspecified, with other complication
K50.919	Crohn's disease, unspecified, with unspecified complications
K52.0	Gastroenteritis and colitis due to radiation
K55.1	Chronic vascular disorders of intestine
K55.21	Angiodysplasia of colon with hemorrhage
K57.11	Diverticulosis of small intestine without perforation or abscess with bleeding
K57.13	Diverticulitis of small intestine without perforation or abscess with bleeding

K57.51	Diverticulosis of both small and large intestine without perforation or abscess with bleeding
K57.53	Diverticulitis of both small and large intestine without perforation or abscess with bleeding
K63.81	Dieulafoy lesion of intestine
K76.6	Portal hypertension
K90.0	Celiac disease
K92.0	Hematemesis
K92.1	Melena
K92.2	Gastrointestinal hemorrhage, unspecified
R10.10	Upper abdominal pain, unspecified
R10.11	Right upper quadrant pain
R10.12	Left upper quadrant pain
R10.13	Epigastric pain
R19.5	Other fecal abnormalities
R19.7	Diarrhea, unspecified
R63.0	Anorexia
R63.4	Abnormal weight loss
R93.3	Abnormal findings on diagnostic imaging of other parts of digestive tract

## References

- National Digestive Diseases Information Clearinghouse (NDDIC). Diarrhea. 2017. <http://digestive.niddk.nih.gov/ddiseases/pubs/diarrhea/>. Accessed May 15, 2017.
- Appleyard M, Fireman Z, Glukhovsky A et al. A randomized trial comparing wireless capsule endoscopy with push enteroscopy for the detection of small-bowel lesions. *Gastroenterology*. 2000;119:1431-1438.
- Appleyard M, Glukhovsky A, Swain P. Wireless-capsule diagnostic endoscopy for recurrent small-bowel bleeding. *N Engl J Med*. 2001;344:232-233.
- Armstrong D, Marshall JK, Chiba N et al. Canadian Consensus Conference on the management of gastroesophageal reflux disease in adults - update 2004. *Can J Gastroenterol*. 2005;19:15-35.
- Barkay O, Moshkowitz M, Fireman Z et al. Initial experience of videocapsule endoscopy for diagnosing small-bowel tumors in patients with GI polyposis syndromes. *Gastrointest Endosc*. 2005;62:448-452.
- Boivin ML, Lochs H, Voderholzer WA. Does passage of a patency capsule indicate small-bowel patency? A prospective clinical trial? *Endoscopy*. 2005;37:808-815.
- Catanzaro A, Faulx A, Isenberg GA et al. Prospective evaluation of 4-mm diameter endoscopes for esophagoscopy in sedated and unsedated patients. *Gastrointest Endosc*. 2003;57:300-304.
- Dellon ES, Shaheen NJ. Does screening for Barrett's esophagus and adenocarcinoma of the esophagus prolong survival? *J Clin Oncol*. 2005;23:4478-4482.
- DeVault KR, Castell DO. Updated guidelines for the diagnosis and treatment of gastroesophageal reflux disease. *Am J Gastroenterol*. 2005;100:190-200.
- Eisen GM, Eliakim R, Zaman A et al. The accuracy of PillCam ESO capsule endoscopy versus conventional upper endoscopy for the diagnosis of esophageal varices: a prospective three-center pilot study. *Endoscopy*. 2006;38:31-35.
- Eliakim R, Sharma VK, Yassin K et al. A prospective study of the diagnostic accuracy of PillCam ESO esophageal capsule endoscopy versus conventional upper endoscopy in patients with chronic gastroesophageal reflux diseases. *J Clin Gastroenterol*. 2005;39:572-578.

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Gay G, Delvaux M, Laurent V et al. Temporary intestinal occlusion induced by a "patency capsule" in a patient with Crohn's disease. *Endoscopy*. 2005;37:174-177.

Hahne M, Adamek HE, Schilling D, Riemann JF. Wireless capsule endoscopy in a patient with obscure occult bleeding. *Endoscopy*. 2002;34:588-590.

Hampel H, Abraham NS, El-Serag HB. Meta-analysis: obesity and the risk for gastroesophageal reflux disease and its complications. *Ann Intern Med.* 2005;143:199-211.

Kamath PS. Esophageal variceal bleeding: primary prophylaxis. *Clin Gastroenterol Hepatol.* 2005;3:90-93.

Leighton JA, Goldstein J, Hirota W et al. Obscure gastrointestinal bleeding. *Gastrointest Endosc.* 2003;58:650-655.

Leighton JA, Shen B, Baron TH et al. ASGE guideline: endoscopy in the diagnosis and treatment of inflammatory bowel disease. *Gastrointest Endosc.* 2006;63:558-565.

Lewis, BS. Expanding role of capsule endoscopy in inflammatory bowel disease. *World J Gastroenterol* 2008 July 14; 14(26): 4137-4141.

Maieron A, Hubner D, Blaha B et al. Multicenter retrospective evaluation of capsule endoscopy in clinical routine. *Endoscopy.* 2004;36:864-868.

Marmo R, Rotondano G, Piscopo R et al. Capsule endoscopy versus enteroclysis in the detection of small-bowel involvement in Crohn's disease: a prospective trial. *Clin Gastroenterol Hepatol.* 2005;3:772-776.

Mata A, Bordas JM, Feu F et al. Wireless capsule endoscopy in patients with obscure gastrointestinal bleeding: a comparative study with push enteroscopy. *Aliment Pharmacol Ther.* 2004;20:189-194.

Mishkin DS, Chuttani R, Croffie J et al. ASGE Technology Status Evaluation Report: wireless capsule endoscopy. *Gastrointest Endosc.* 2006;63:539-545.

Olliver JR, Hardie LJ, Gong Y et al. Risk factors, DNA damage, and disease progression in Barrett's esophagus. *Cancer Epidemiol Biomarkers Prev.* 2005;14:620-625.

Prediction of the first variceal hemorrhage in patients with cirrhosis of the liver and esophageal varices. A prospective multicenter study. The North Italian Endoscopic Club for the Study and Treatment of Esophageal Varices. *N Engl J Med.* 1988;319:983-989.

Qureshi W, Adler DG, Davila R et al. ASGE Guideline: the role of endoscopy in the management of variceal hemorrhage, updated July 2005. *Gastrointest Endosc.* 2005;62:651-655.

Sharma P, Sidorenko EI. Are screening and surveillance for Barrett's oesophagus really worthwhile? *Gut.* 2005;54 Suppl 1:i27-i32.

Specialty-matched clinical peer review.

Tatar EL, Shen EH, Palance AL, Sun JH, Pitchumoni CS. Clinical utility of wireless capsule endoscopy: experience with 200 cases. *J Clin Gastroenterol.* 2006;40:140-144.

Veldhuyzen van Zanten SJ, Bradette M, Chiba N et al. Evidence-based recommendations for short- and long-term management of uninvestigated dyspepsia in primary care: an update of the Canadian Dyspepsia Working Group (CanDys) clinical management tool. *Can J Gastroenterol.* 2005;19:285-303.

Westhoff B, Brotze S, Weston A et al. The frequency of Barrett's esophagus in high-risk patients with chronic GERD. *Gastrointest Endosc.* 2005;61:226-231.

Wildi SM, Glenn TF, Woolson RF, Wang W, Hawes RH, Wallace MB. Is esophagoscopy alone sufficient for patients with reflux symptoms? *Gastrointest Endosc.* 2004;59:349-354.