

1. **Indications:**

The indications below were derived in part from The American Society for Gastrointestinal Endoscopy (ASGE) Technology Status Evaluation Report : Wireless Capsule Endoscopy

Endoscopy by Capsule of the Small Intestine

PillCam™ SB is an ingestible telemetric gastrointestinal capsule imaging system that is used for visualization of the small bowel mucosa. It is an adjunctive tool used in the detection of abnormalities of the small bowel, which is not accessible to standard upper endoscopy and colonoscopy. A small capsule is swallowed and moves through the GI tract propelled by peristalsis, transmitting video pictures. The video images 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 be viewed. The capsule passes naturally from the body with the stool, and since it is disposable, it is not recovered.

Gastrointestinal Bleeding

The test is indicated for the diagnosis of gastrointestinal bleeding, the site of which has not been identified previously by any of the following: upper gastrointestinal endoscopy, colonoscopy, push enteroscopy, nuclear imaging, or radiological procedures. The test is especially helpful in the diagnosis of angiodysplasias of the gastrointestinal tract.

Endoscopy by capsule is limited to those patients who have generally undergone both upper GI endoscopy and colonoscopy, and when these tests have failed to reveal a source of bleeding. In rare situations where hematemesis occurs repeatedly and upper GI endoscopy is repeatedly negative capsule endoscopy may be indicated.

Small Bowel Neoplasm

The test is indicated for the detection of neoplasms of the small bowel, 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 patient must be symptomatic for a neoplasm (e.g., GI bleeding) or have a documented polyposis syndrome that is associated with small bowel neoplasia or there is other history suggesting the presence of small bowel neoplasia and other diagnostic testing to assess these symptoms (i.e., upper GI endoscopy and/or colonoscopy) must have been performed.

Crohn's Disease

Endoscopy by capsule is indicated for the diagnosis of Crohn's disease when the condition has not been previously confirmed or gastrointestinal capsule imaging is indicated when a diagnosis of colitis of an indeterminate type affecting the colon is known, and a more specific diagnosis is sought by evaluating for possible small bowel involvement. Endoscopy by capsule is reasonable in those patients in whom there is strong clinical suspicion of Crohn's disease (with abdominal pain, weight loss, diarrhea, anorexia, bleeding and biochemical indicators of inflammation) and in whom a prior radiologic study to exclude stricture is performed but does not demonstrate Crohn's disease. Capsule endoscopy may be reasonable without the patient having undergone upper GI endoscopy and colonoscopy.

Other Conditions

Evaluation of malabsorption syndrome, chronic diarrhea, or protein-losing enteropathy of obscure origin is reasonable when it is suspected to originate in the small intestinal mucosa. 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.

Evaluation Prior to Surgery

Evaluation of extent of small bowel involvement with arteriovenous malformations or lymphangiectasia for patients who are contemplated for surgical resection of the small bowel to control recurrent bleeding or protein loss is reasonable.

2. **Limitations:**

Patency Capsule Testing

The Given® Agile Patency System or similar devices will also not be covered. Sufficient peer-reviewed literature supporting its use is not currently available. On occasion the Agile Patency System has been reported to cause obstruction requiring urgent intervention.

The ASGE Technology Status Evaluation Report Wireless Capsule Endoscopy lists, "Patients with known or suspected gastrointestinal (GI) obstruction, strictures, or fistulas based on the clinical picture or preprocedure testing" under contraindications for the small bowel capsule.

Endoscopy by Capsule of the Small Intestine

ICD-9-CM codes 564.1 and 789.01-789.09 for irritable bowel syndrome and abdominal pain have been placed on the list of covered diagnoses for use when a capsule endoscopy exam is normal in the face of compelling symptoms. When representing chronic stable symptoms, these conditions rarely represent reasonable indications for endoscopy by capsule. When

these diagnostic codes are used, the codes must be applicable and the rationale for capsule endoscopy must be carefully documented in the medical record.

The ingestion of the capsule is part of the test and an evaluation & management (E&M) service may not be billed for this purpose.

Endoscopy by capsule of the small intestine is not covered in the following situations:

- Colorectal cancer screening
- When carried out by FDA non-approved devices
- Confirmation of lesions or pathology normally within the reach of upper or lower endoscopy (lesions proximal to the ligament of Treitz or distal to the ileum) or for the confirmation of lesions or pathology discovered by prior endoscopy (including push enteroscopy), colonoscopy, or radiology

When performed by physicians not trained in endoscopy or for independent diagnostic testing facilities, which are not under the general supervision of a physician trained in endoscopy procedures

Endoscopy by capsule performed to diagnose obscure gastrointestinal bleeding, is only covered if it is documented that the beneficiary had continuing GI blood loss or anemia secondary to bleeding or iron deficiency anemia.

Endoscopy by capsule is not generally reimbursable when used for management of patients with a confirmed diagnosis of Crohn's disease. Onset of new symptoms suggestive of Crohn's disease at an undiagnosed small bowel region may make endoscopy by capsule reasonable.

Endoscopy by capsule for the detection of small bowel malignancies, in the absence of obscure gastrointestinal bleeding, or symptoms suggesting Crohn's disease, or the presence of a polyposis syndrome associated with small bowel neoplasia or other history suggesting the presence of small bowel neoplasia.

Endoscopy by capsule of the esophagus is not covered in patients with a current history of dysphagia suggestive of esophageal stricture.

CPT/HCPCS Codes

For Wireless Capsule Endoscopy of the Small Intestine ONLY:

91110 Gastrointestinal Tract Imaging, Intraluminal (eg, Capsule Endoscopy), Esophagus through Ileum, with Physician Interpretation and Report

ICD-9 Codes that Support Medical Necessity

It is the responsibility of the provider to code to the highest level specified in the *ICD-9-CM* (e.g., to the fourth or fifth digit). The correct use of an ICD-9-CM code listed below does not assure coverage of a service. The service must be reasonable and necessary in the specific case and must meet the criteria specified in this determination.

ICD-9-CM Codes for the Small Bowel Capsule (CPT Code 91110)

152.0	MALIGNANT NEOPLASM OF DUODENUM
152.1	MALIGNANT NEOPLASM OF JEJUNUM
152.2	MALIGNANT NEOPLASM OF ILEUM
152.3	MALIGNANT NEOPLASM OF MECKEL'S DIVERTICULUM
152.8	MALIGNANT NEOPLASM OF OTHER SPECIFIED SITES OF SMALL INTESTINE
152.9	MALIGNANT NEOPLASM OF SMALL INTESTINE UNSPECIFIED SITE
197.4	SECONDARY MALIGNANT NEOPLASM OF SMALL INTESTINE INCLUDING DUODENUM
211.2	BENIGN NEOPLASM OF DUODENUM JEJUNUM AND ILEUM
211.3*	BENIGN NEOPLASM OF COLON
230.7	CARCINOMA IN SITU OF OTHER AND UNSPECIFIED PARTS OF INTESTINE
235.2	NEOPLASM OF UNCERTAIN BEHAVIOR OF STOMACH INTESTINES AND RECTUM
280.0	IRON DEFICIENCY ANEMIA SECONDARY TO BLOOD LOSS (CHRONIC)
457.1	OTHER LYMPHEDEMA
555.0	REGIONAL ENTERITIS OF SMALL INTESTINE
555.1	REGIONAL ENTERITIS OF LARGE INTESTINE
555.2	REGIONAL ENTERITIS OF SMALL INTESTINE WITH LARGE INTESTINE
555.9	REGIONAL ENTERITIS OF UNSPECIFIED SITE
558.9	OTHER AND UNSPECIFIED NONINFECTIOUS GASTROENTERITIS AND COLITIS
560.9	UNSPECIFIED INTESTINAL OBSTRUCTION
562.02	DIVERTICULOSIS OF SMALL INTESTINE WITH HEMORRHAGE
562.03	DIVERTICULITIS OF SMALL INTESTINE WITH HEMORRHAGE
564.1	IRRITABLE BOWEL SYNDROME

569.82	ULCERATION OF INTESTINE
569.84	ANGIODYSPLASIA OF INTESTINE (WITHOUT HEMORRHAGE)
569.85	ANGIODYSPLASIA OF INTESTINE WITH HEMORRHAGE
569.86	DIEULAFOY LESION (HEMORRHAGIC) OF INTESTINE
578.0	HEMATEMESIS
578.1	BLOOD IN STOOL
578.9	HEMORRHAGE OF GASTROINTESTINAL TRACT UNSPECIFIED
579.8	OTHER SPECIFIED INTESTINAL MALABSORPTION
759.6	OTHER CONGENITAL HAMARTOSES NOT ELSEWHERE CLASSIFIED
787.91	DIARRHEA
789.01	ABDOMINAL PAIN RIGHT UPPER QUADRANT
789.02	ABDOMINAL PAIN LEFT UPPER QUADRANT
789.03	ABDOMINAL PAIN RIGHT LOWER QUADRANT
789.04	ABDOMINAL PAIN LEFT LOWER QUADRANT
789.05	ABDOMINAL PAIN PERIUMBILIC
789.06	ABDOMINAL PAIN EPIGASTRIC
789.07	ABDOMINAL PAIN GENERALIZED
789.09	ABDOMINAL PAIN OTHER SPECIFIED SITE
792.1	NONSPECIFIC ABNORMAL FINDINGS IN STOOL CONTENTS
793.4	NONSPECIFIC ABNORMAL FINDINGS ON RADIOLOGICAL AND OTHER EXAMINATION OF GASTROINTESTINAL TRACT
V45.89*	OTHER POSTSURGICAL STATUS

*ICD-9-CM code 211.3 should be reported for patients with polyposis syndrome that may have small bowel neoplasia.

*ICD-9-CM code V45.89 for purposes of this LCD indicates that medically necessary flexible upper and lower flexible endoscopy were carried out before endoscopy by capsule was done. Therefore, ICD-9-CM code V45.89 must be reported on all claims for endoscopy by capsule of the small bowel except for some patients suspected of having Crohn's disease in order for coverage to occur. In addition to reporting ICD-9-CM code V45.89, one (or more) of the ICD-9-CM codes below must be reported in order to support medical necessity.

ICD-9 Codes that DO NOT Support Medical Necessity

Not Applicable

Diagnoses that DO NOT Support Medical Necessity

Not Applicable

General Information

Documentation Requirements:

1. The patient's medical record must contain documentation that fully supports the medical necessity for services included within this LCD. (See "Indications and Limitations of Coverage.") This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures.
1. Medical record documentation must be available to Medicare upon request.
2. Photographic copies of the video images, with the beneficiary's name and the date of service included in the picture, must be available for review.
3. Additional documentation is required according to the specific indication for performing endoscopy by capsule:
 - ▶ If the beneficiary has GI blood loss or iron deficiency anemia or anemia secondary to the bleeding, the medical record must document that the prior upper GI endoscopy or colonoscopy failed to adequately reveal the source of bleeding.
 - ▶ If the provisional diagnosis is occult gastrointestinal bleeding without iron deficiency anemia, the medical record must document the presence of occult blood in fecal samples.
 - ▶ If the provisional diagnosis is Crohn's disease, the medical record must document the signs, symptoms, and previous diagnostic work supporting this diagnosis.
 - ▶ If the provisional diagnosis is Crohn's disease but neither upper GI endoscopy nor colonoscopy were performed prior to the endoscopy by capsule, the medical record must document a prior radiologic procedure that excluded strictures if the patient has symptoms of obstruction.
 - ▶ If small bowel involvement is suspected in a patient with known Crohn's disease or other colitis, the medical record must document the signs, symptoms, and previous diagnostic work supporting this hypothesis.
5. The medical record must document the need for capsule endoscopy and contain reports or reference to the previous appropriate negative endoscopies (LCD exception suspected Crohn's disease) performed prior to endoscopy by capsule.