Wireless capsule endoscopy (CE) of the small bowel is COVERED as a diagnostic imaging tool for the following clinical indications:

1. **Occult gastrointestinal bleeding**: evaluation of obscure small bowel bleeding or iron deficiency anemia, suspected to be secondary to loss of blood, in individuals who have undergone upper gastrointestinal (GI) endoscopy and colonoscopy when these tests have failed to reveal a source of bleeding.

2. **Crohn’s disease**: diagnostic and/or reevaluation in symptomatic individuals with known or suspected Crohn’s disease and who have undergone upper GI endoscopy and colonoscopy and the testing has failed to reveal the source of the symptoms.

3. **Small Bowel Neoplasm**: evaluation of suspected, but undiagnosed, small bowel neoplasm, in members who are symptomatic for a neoplasm and when the diagnosis has not been confirmed by upper GI endoscopy, colonoscopy, and nuclear imaging or radiologic procedures.

4. **GI polyposis syndromes**: surveillance of the small bowel in patients with hereditary small bowel polyposis syndromes, including familial adenomatous polyposis and Peutz-Jeghers syndrome.

Wireless CE is considered investigative and unproven and therefore NOT COVERED for all other indications. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

Capsule technology to verify patency prior to capsule endoscopy is investigative and unproven and therefore NOT COVERED. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the safety or efficacy or effects on health care outcomes.

Note: See also related Medica coverage policy, *Gastrointestinal Monitoring System (Smart Pill®)*.
Description
Wireless capsule endoscopy was originally intended to noninvasively visualize small-bowel abnormalities. It is also referred to as video capsule or ingestible telemetric gastrointestinal (GI) capsule imaging. A specially designed capsule is swallowed, recording images as it travels through the GI tract. The systems consist of a capsule with an outer diameter of 11mm, an antenna lead set, data recorder worn by the patient, and a workstation that downloads image data for viewing on an LCD monitor and identification of points that correlate with areas that are suspicious for blood or red lesions.

The capsule passes through the GI tract via normal peristalsis; that is, it does not require a pushing force as do push enteroscopy and other endoscopic methods. The data recorder, attached by a belt to the patient’s waist, receives radiofrequency signals from the capsule via an array of sensors attached to the patient. The sensors obtain images of the small bowel mucosa at a rate of two per second and transmit them to the recorder along with information on the capsule’s position within the GI tract, which aids in lesion localization in preparation for potential surgeries. Once the capsule is excreted naturally, data are downloaded to the workstation where a video is produced. The clinician can view, edit, and save the video and individual images. Devices have been developed to visualize the esophageal mucosa as well as the colon.

In a small number of patients, the capsule becomes trapped due to a narrowing or stricture of the small bowel and requires surgical removal. The Agile™ Patency System was developed with the intent of assessing patency prior to capsule endoscopy. The patency capsule is the same size as the wireless capsule, but is biodegradable. It contains a radiofrequency identification tag that allows it to be detected with a handheld scanner or visualized on x-rays. If the capsule becomes lodged in the small intestine, it is designed to dissolve in 20 to 40 hours, allowing it to pass spontaneously. Patients usually undergo assessment of the small intestine with the Agile Patency System in a physician’s office or outpatient clinic with return visits to check for capsule passage 1 to 3 days after ingestion.

FDA Approval
Available devices include the PillCam SB2 and SB3, EndoCapsule and the EndoCapsule 10, Mirocam and CapsoCam for evaluation of the small bowel, and the PillCam upper for evaluation of the esophagus. A colon capsule PCC2 has also been developed and is available in Europe, the United States, and Japan.

The PillCam™ COLON 2 received FDA 510(k) marketing clearance in 2016 for visualization of the colon for:
• Detection of colon polyps in patients after an incomplete optical colonoscopy with adequate preparation, where a completed evaluation of the colon was not technically possible.
• Detection of colon polyps in patients with evidence of gastrointestinal bleeding of lower GI origin. This applies only to patients with major risks for colonoscopy or moderate sedation, but who could tolerate colonoscopy and moderate sedation in the event a clinically significant colon abnormality was identified on capsule endoscopy.

Predicate devices include older versions of the PillCam device, including but not limited to:
• Given Diagnostic System with PillCam ESO 2 capsule
• PillCam Platform System with RAPID 6.5 and Given PillCam Platform with ESO 3 capsule
• PillCam® SB 2 and SB 3 capsule endoscopy systems
• PillCam™ ESO Capsule.

Given Imaging was the original developer of the PillCam System. Covidien acquired Given Imaging in February 2014. In January 2016, Covidien merged with Medtronic, Inc., to form Medtronic plc.

The Agile™ Patency System (Given Imaging, Ltd.) was cleared by the FDA through the 510(k) marketing clearance in 2016 as a class 2 devices for determining the presence of obstructions or strictures in the gastrointestinal tract through a dissolvable capsule.

Prior Authorization
Prior authorization is not required. However, services with specific coverage criteria may be reviewed
retrospectively to determine if criteria are being met. Retrospective denial may result if criteria are not met.

**Coding Considerations**

Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

**CPT 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

**HCPC Code**

- 0355T – Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), colon, with interpretation and report

**Original Effective Date:** 12/1/2003

**Re-Review Date(s):**

- 9/27/2005
- 9/23/2008
- 9/27/2011
- 10/15/2014
- 9/20/2017
- 3/18/2020 – administrative update; format
- 9/16/2020