Description

Wireless capsule endoscopy is a device intended to visualize portions of the bowel which are not accessible via upper or lower endoscopy, primarily the small bowel. Patients swallow the capsule, and it records images of the intestinal mucosa as it passes through the gastrointestinal (GI) tract. The capsule is collected after being excreted and the images interpreted.

Background

Wireless capsule endoscopy is performed using the PillCam™ Given® Diagnostic Imaging System (previously called M2A®), which is a disposable imaging capsule manufactured by Given Imaging, Ltd. (Norcross, GA). The capsule measures 11 by 30 mm and contains video imaging, self-illumination, and image transmission modules, as well as a battery supply that lasts up to eight hours. The indwelling camera takes images at a rate of two frames per second as peristalsis carries the capsule through the gastrointestinal tract. The average transit time from ingestion to evacuation is 24 hours. The device uses wireless radio transmission to send the images to a receiving recorder device that the patient wears around the waist. This receiving device also contains some localizing antennae sensors that can roughly gauge where the image was taken over the abdomen. Images are then downloaded onto a workstation for viewing and processing.

The device received marketing clearance from the U.S. Food and Drug Administration (FDA) on August 1, 2001, through the 510(k) process. The FDA clearance provides for the capsule’s use “along with – not as a replacement for – other endoscopic and radiologic evaluations of the small bowel.” The FDA clarified that the “capsule was not studied in the large intestine.” On July 1, 2003, a supplemental 510(k) premarket notification was cleared, and the labeled indications were modified by removing the “adjunctive” use qualification: “the Given® Diagnostic System is intended for visualization of the small bowel mucosa. It may be used as a tool in the detection of abnormalities of the small bowel.”

In November 2004, the device received FDA clearance for the following labeled indication: “the Given® Diagnostic System with the PillCam™ ESO Capsule is intended for the visualization of esophageal mucosa.” A new model was cleared by the FDA in June 2007, the PillCam ESO2 Capsule. In September 2007, the FDA cleared the Olympus Capsule Endoscope System through the 510(k) process for “visualization of the small intestine mucosa.” More recent versions of both these systems also incorporate a blood indicator feature to assist with rapid screening of intestinal lesions with bleeding potential.

In the small bowel, the capsule camera has been most frequently proposed as a technique to identify the source of obscure intestinal bleeding, although recently there has been interest in exploring its use in patients with inflammatory bowel disease. Alternative diagnostic techniques include barium studies or small intestinal...
endoscopy. In the esophagus, the capsule camera has been proposed as a screening technique for Barrett’s esophagus associated with gastroesophageal reflux disease (GERD). Evaluation of the esophagus requires limited transit time, and it is estimated that the test takes 20 minutes to perform. Alternative techniques include upper endoscopy.

In 2006, the FDA also provided clearance for the Given AGILE patency system. This system is an accessory to the PillCam video capsule and, according to FDA material, is intended to verify adequate patency of the GI tract prior to administration of the PillCam in patients with known or suspected strictures. This capsule is of similar size to the endoscopy capsule but is made of lactose and barium and dissolves within 30–100 hours of entering the GI tract. It carries a tracer material that can be detected by a scanning device. Excretion of the intact capsule without symptoms (abdominal pain or obstruction) is reported to predict the uncomplicated passage of the wireless capsule.

Corporate Medical Guideline

Wireless capsule endoscopy of the small bowel may be considered medically necessary for the following indications:

- Initial diagnosis in patients with suspected Crohn’s disease without evidence of disease on conventional diagnostic tests such as small-bowel follow-through (SBFT), and upper and lower endoscopy.
- Obscure gastrointestinal (GI) bleeding suspected of being of small bowel origin, as evidenced by prior inconclusive upper and lower gastrointestinal endoscopic studies performed during the current episode of illness.
- For surveillance of the small bowel in patients with hereditary GI polyposis syndromes, including familial adenomatous polyposis and Peutz-Jeghers syndrome.

Other indications of wireless capsule endoscopy are considered investigational, including but not limited to:

- Evaluation of the extent of involvement of known Crohn’s disease or ulcerative colitis
- Evaluation of the esophagus, in patients with gastroesophageal reflux (GERD) or other esophageal pathologies
- Evaluation of other gastrointestinal diseases not presenting with GI bleeding including, but not limited to, celiac sprue, irritable bowel syndrome, Lynch syndrome, and small bowel neoplasm
- Evaluation of the colon including, but not limited to, detection of colonic polyps or colon cancer
- Initial evaluation of patients with acute upper GI bleeding.

The patency capsule is considered investigational, including use to evaluate patency of the gastrointestinal tract before wireless capsule endoscopy.

Policy Guideline

Obscure GI bleeding is defined as “recurrent or persistent iron-deficiency anemia, positive fecal occult blood test, or visible bleeding with no bleeding source found at original endoscopy.” (Van Gossum 2001)
considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. *Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.*

**References**

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.


