ENDOSCOPY BY VIDEO CAPSULE

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member’s specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Capsule video endoscopy is performed using the PillCam™ Given® Diagnostic Imaging System, an ingestible wireless endoscope the size of a large capsule which contains a camera, lights, transmitter and batteries. The capsule is swallowed and propelled through the digestive tract by natural muscular waves. The capsule transmits images of the esophagus and/or small intestine to a data recorder worn around the waist. The data is recorded and then transferred to a computer for processing and analysis. Capsule video endoscopy has also been investigated as a technique for evaluation of the colon.

The Given® AGILE Patency System is an accessory capsule to the PillCam system. It has been investigated as a device to verify adequate patency of the gastrointestinal tract before administration of the PillCam in individuals with known or suspected strictures. This capsule is made of lactose and barium and dissolves within 30 to 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.

The PillCam COLON has been investigated for detection of colon polyps in individuals after an incomplete colonoscopy with adequate preparation and a complete evaluation of the colon was not technically possible.
ENDOSCOPY BY VIDEO CAPSULE (cont.)

Definitions:

Obscure Gastrointestinal Bleeding:
Obscure gastrointestinal bleeding is defined as bleeding of unknown origin that persists or recurs after a negative initial upper and lower endoscopy (may be visible or occult). Bleeding may be described as:

- Obscure, occult: Recurrent iron deficiency anemia and/or recurrent fecal occult blood test
- Obscure, overt: Recurrent passage of visible blood

Criteria:

- Capsule video endoscopy as an adjunct[^1] to other endoscopic and radiologic evaluations of the gastrointestinal system is considered **medically necessary** with documentation of ANY of the following:
  
  1. Suspected Crohn’s disease of the small bowel with negative upper and lower endoscopy and documentation of ANY of the following:
     - Abdominal pain, persistent
     - Bleeding
     - Diarrhea
     - Negative stool cultures
     - Weight loss
  
  2. In individuals with an established diagnosis of Crohn’s disease, when there are unexpected change(s) in the course of disease or response to treatment, suggesting the initial diagnosis may be incorrect and re-examination may be indicated.
  
  3. Obscure gastrointestinal bleeding suspected to be of small bowel origin as evidenced by prior inconclusive upper and lower gastrointestinal bleeding endoscopic studies performed during the current episode of illness (see Definition section)
  
  4. Small bowel surveillance with documentation of ANY of the following hereditary gastrointestinal polyposis syndromes:
     - Familial adenomatous polyposis including but not limited to Gardner’s syndrome
     - Peutz-Jeghers syndrome

[^1]: Capsule video endoscopy must not be provided as a replacement for endoscopic or radiologic evaluation or as a first-line test for evaluation of obscure gastrointestinal bleeding. Other types of endoscopic or radiologic evaluations include colonoscopy, upper esophago-gastroduodenoscopy, small bowel follow through and enteroclysis.
ENDOSCOPY BY VIDEO CAPSULE (cont.)

Criteria: (cont.)

- Capsule video endoscopy for all other indications not previously listed or if above criteria not met is considered experimental or investigational based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

These indications include, but are not limited to:

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

- The patency capsule to evaluate patency of the gastrointestinal tract before wireless capsule endoscopy is considered experimental or investigational based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.
ENDOSCOPY BY VIDEO CAPSULE (cont.)

Resources:


ENDOSCOPY BY VIDEO CAPSULE (cont.)

Resources: (cont.)


21. Leighton JA. Recent advances in endoscopic capsule imaging: see what we have been missing. Rev Gastroenterol Disord. 2006;6 Suppl 1:S19-27.


ENDOSCOPY BY VIDEO CAPSULE (cont.)

**Resources:** (cont.)


