Medica Coverage Policy

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare, Medicaid and MinnesotaCare members, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

Coverage Policy

Wireless capsule endoscopy (CE) of the small bowel is COVERED for patients with obscure small intestinal bleeding/iron deficiency anemia or known or suspected Crohn’s disease when results of upper endoscopy and colonoscopy are inconclusive or negative concerning suspected pathology.

Wireless CE is investigative and therefore NOT COVERED for all other indications including but not limited to the esophagus or colon.

Capsule technology to verify patency prior to capsule endoscopy is investigative and therefore NOT COVERED.

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
The Given® Imaging Diagnostic System, (now known as the PillCam™ system) manufactured by Given Imaging Ltd, Yoqneam, Israel, received 510(k) approval as a Class II device in 2001. The intended use is for visualization of the small bowel mucosa as an adjunctive tool in the detection of abnormalities of the small bowel in adults. Supplementary approval was granted in July 2003 to revise the indications to state that the Given® Diagnostic System is indicated for visualization of the small bowel mucosa. It may be used as a tool in the detection of abnormalities of the small bowel. The FDA expanded its approved indications for the Given Diagnostic System in October 2003 to include visualization of the small bowel and detection of abnormalities in symptomatic children age 10 to 18 years.

In September, 2007, the FDA granted approval to the Olympus Capsule Endoscope System, under a 510k process as substantially equivalent to the predicate devices. The system is manufactured by Olympus Medical Systems Corp, Tokyo, Japan. The system has been designed to be used for visualization of the small intestine mucosa.

The Given® Diagnostic System with the PillCam™ ESO Capsule was FDA approved in November 2004. It is intended for visualization of the esophageal mucosa.

The Given® Agile Patency System was approved by the FDA in May 2006 as an accessory to the PillCam video capsule and is intended to verify adequate patency of the gastrointestinal tract prior to administration of the PillCam video capsule in patients with known or suspected strictures.

The PillCam Colon 2 Capsule Endoscopy System (Given Imaging) was approved by the FDA as a class II device by the FDA in January 2014. It is indicated for use in patients who had an incomplete optical colonoscopy with adequate preparation and a complete evaluation of the colon was not technically possible.

The Pillcam® Express™ Video Capsule Delivery Device was approved by the FDA in September 2010 as an accessory to the PillCam and is indicated for the transendoscopic delivery of the PillCam® SB video capsule in patients 8 and above who are either unable to ingest the PillCam capsule or are known to have slow gastric emptying time.

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. (split)

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

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