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Wireless Capsule Endoscopy

Policy Number: HS-104

Original Effective Date: 5/15/2009

Revised Date(s): 5/25/2010; 7/18/2011

DISCLAIMER

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

BACKGROUND

Wireless capsule endoscopy, or capsule endoscopy (CE), is a noninvasive procedure in which an ingestible capsule containing a miniaturized video camera, light, transmitter, and batteries, is swallowed. A video recording is taken as it moves through the gastrointestinal (GI) tract. The CE was developed to reach inaccessible areas that standard endoscopic examination cannot reach due to significant length and distance from accessible orifices.

Wireless capsule endoscopy is performed using a variety of capsules which contain video imaging, self-illumination, and image transmission modules, as well as a battery supply. These devices have been developed for both esophageal and small bowel imaging. The patient is first fitted with thoracic or abdominal sensors. Prior to being swallowed, the capsule is activated by removing it from a magnetic holder. Once swallowed, the indwelling camera takes images at a rate of two frames per second, as peristalsis carries the capsule through the esophagus or gastrointestinal tract. 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. Images are then downloaded onto a workstation for viewing and processing.

At least two of these devices are currently available. The PillCam (previously called M2A®) manufactured by Given Imaging, Ltd. is available in two forms. The PillCam ESO device is meant to view the esophagus, while the PillCam SB device is used to view the small bowel. Both devices are similar in size and image production. The PillCam ESO utilizes thoracic sensors, generally transitions through the esophagus in 5 minutes and has a battery life of 20 minutes. The PillCam SB employs abdominal sensors, usually passes through the small intestine within 3 hours and has a battery life of up to 8 hours. The average transit time for both devices from ingestion to evacuation is 24 hours.

More recently (2006), the Food and Drug Administration (FDA) granted 510(k) clearance for the Given® AGILE™ Patency System. According to the FDA approval letter, "the Given® AGILE Patency System is 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."

POSITION STATEMENT

Wireless capsule endoscopy of the small bowel **is considered medically necessary** when ANY of the following conditions are met:

- Member has documented continuous blood loss and anemia secondary to obscure bleeding of the small bowel and the member has had a radiological examination including SBFT, upper endoscopy and colonoscopy that has failed to identify the source of the bleeding; **OR**,
- Interoperative enteroscopy is being considered; **OR**,
- For initial diagnosis of suspected Crohn's Disease when there is no evidence provided by conventional tests such as small bowel follow-through (SBFT) and upper and lower endoscopy; **OR**,
- For evaluation of members with celiac disease with a positive serology and negative biopsy

Wireless capsule endoscopy of the esophagus **is considered medically necessary** for the following condition if ALL of the following criteria are met:

- Member is diagnosed with portal hypertension and requires immediate evaluation of esophageal varices; **AND**,
- The esophageal capsule endoscopy is performed in lieu of conventional endoscopy because it is determined that the member's current medical condition prohibits conventional endoscopy; **AND**,
- The medical record clearly reflects why the member was not a candidate for conventional endoscopy and how the capsule endoscopy would contribute to the member's care

Wireless capsule endoscopy **is considered NOT medically necessary**, contraindicated or experimental in the following circumstances:

- For V76.51 Colorectal Cancer Screening; **OR**,
- For members with 578.0 Hematemesis; **OR**,
- For confirmation of 235.2 and 235.5 lesions of pathology normally within reach of upper and lower endoscopes (proximal to the ligament of Treitz, or distal to the ileum); **OR**,
- For use in members with V45.00 - V45.091 Cardiac Pacemaker or other Implanted Electromagnetic Device; **OR**,
- For members in whom a radiological examination of the small bowel has confirmed an 560.9 intestinal blockage, a 751.5 Significantly Narrow Small Bowel, or 751.4 Abnormal Connection between the Bowel and another organ; **OR**,
- As an initial test for 578.9 Gastrointestinal Bleeding; **OR**,
- Any indication not listed above.

NOTE: The procedure must be performed by a gastroenterologist.

CODING

Covered CPT® Codes

- 91110** Gastrointestinal tract imaging, intraluminal capsule endoscopy, esophagus through ileum, with physician interpretation and report.
- 91111*** Gastrointestinal tract imaging, intraluminal capsule endoscopy, esophagus, with physician interpretation and report
*Dual diagnosis of 572.3 and 456.20 or 572.3 and 456.21 is required to meet medical necessity.

ICD-9-CM Procedure Code - No applicable codes

HCPCS® Codes - No applicable codes

Covered ICD-9-CM Diagnosis Codes

- 280.0** Iron deficiency anemia, secondary to blood loss (chronic)
- 280.9** Iron deficiency anemia, unspecified
- 285.1** Acute posthemorrhagic anemia; acute blood loss anemia

456.20	Esophageal varices in Portal Hypertension with bleeding (dual diagnosis required)
456.21	Esophageal varices in Portal Hypertension without bleeding (dual diagnosis required)
555.0 - 555.9	Regional enteritis (Crohn's disease)
562.02	Diverticulosis of small intestine with hemorrhage
562.03	Diverticulitis of small intestine with hemorrhage
569.85	Angiodysplasia of intestine with hemorrhage
572.3	Portal Hypertension with Esophageal varices (dual diagnosis required)
579.0	Celiac disease

Non-Covered ICD-9-CM Diagnosis Codes

235.2	Neoplasm of uncertain behavior of stomach, intestines
235.5	Neoplasm of uncertain behavior of esophagus
560.9	Intestinal blockage
578.0	Hematemesis
578.9	Gastrointestinal Bleeding
751.4	Abnormal Connection between the Bowel and another organ
751.5	Significantly Narrow Small Bowel
792.1	Nonspecific abnormal findings in stool contents
793.4	Nonspecific Abnormal Findings on Radiological and other examination of gastrointestinal tract
V45.00 - V45.091	Cardiac Devices in Situ, i.e. Pacemaker, AICD
V76.51	Screening for Colorectal Cancer

*Current Procedural Terminology (CPT®) ©2010 American Medical Association: Chicago, IL.

REFERENCES

Peer Reviewed

1. Hayes Directory. Capsule Endoscopy for Diagnostic Imaging of the Small Bowel. January 13, 2008.
2. Hayes Directory. Capsule Endoscopy for Diagnostic Imaging of the Esophagus. January 3, 2008.

Government Agencies, Professional and Medical Organizations

1. American Society of Gastrointestinal Endoscopy. ASGE guideline: Endoscopy in the diagnosis and treatment of inflammatory bowel disease.
2. Centers for Medicare and Medicaid Services Local Coverage Determination for Wireless Capsule Endoscopy (L29008). First Coast Service Options, Inc. February 16, 2009.
3. European Society of Gastrointestinal Endoscopy (ESGE). Video capsule endoscopy: Update to guidelines. May, 2006. National Institute for Health and Clinical Excellence (NICE). Wireless capsule endoscopy for investigation of the small bowel-guidance. December, 2004.

HISTORY AND REVISIONS

Date	Action
12/1/2011	• New template design approved by MPC.
7/18/2011	• Approved by MPC. No changes.

