



CAPSULE ENDOSCOPY

Effective Date: May 20, 2010

Review Dates: 2/04, 1/05, 5/05, 4/06, 4/07, 6/07, 4/08, 4/09, 4/10

Date Of Origin: February 25, 2004

Status: Current

Summary of Changes

Clarifications:

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Deletions:

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Additions:

- Pg 3, Section I, background section updated to include information regarding wireless esophageal pH monitoring.
- Pg 4, Section II, C, criteria added for coverage of wireless esophageal pH monitoring.
- Pg 4, Section II, D, criteria added for non-coverage of wireless esophageal pH monitoring.

I. DESCRIPTION

Wireless capsule endoscopy (WCE), a noninvasive procedure in which a swallowable, multivitamin-sized capsule containing a miniaturized video camera, light, transmitter, and batteries takes a video recording of the mucosal lining of the small bowel as it moves through the gastrointestinal (GI) tract. The video images are transmitted to sensors taped to the body and stored on a portable recorder. The strength of the signal is used to calculate the position of the capsule as it passes through the GI tract. Video images are stored on a portable recorder and later downloaded to computer, from which they may be viewed. The capsule passes naturally from the body with the stool, and since it is disposable, is not recovered.

Background:

A procedure known as wireless capsule endoscopy (WCE) or capsule endoscopy has been developed for the noninvasive visualization of suspected small-bowel abnormalities. For this test, a specially designed, ingestible capsule captures and records images as it travels through the GI tract. Before swallowing the capsule, the patient is fitted with the belt holding the data recorder and the battery pack, and a sensor array is attached to the abdomen. During imaging, the patient is able to leave the clinic and resume normal activities. After 6 to 8 hours, or in noticing that the capsule has been excreted, the patient returns the belt and data recorder to the clinic or office for processing and evaluation. The test is intended for patients with chronic or recurrent GI bleeding of unknown etiology and other GI symptoms who have negative findings on upper GI endoscopy, colonoscopy, and other tests. WCE was initially approved by the Food and Drug Administration



(FDA) in August 2001 for use as an adjunct to standard procedures for diagnosing suspected abnormalities of the small bowel. In July 2003, the device was cleared for use as a first-line tool in diagnosing small-bowel disease.

In August 2001, the FDA cleared for marketing a swallowable capsule containing a small camera that snaps pictures twice a second as it passes through the small intestine. The FDA classified the capsule, called the Given Diagnostic Imaging System (Given Imaging Ltd., Yoqneam, Isreal), as a Class II device that is subject only to general regulatory controls. The capsule has a clear end that allows the camera to view the lining of the small intestine. In addition to the camera, the wireless capsule, about the size of a grape, contains a lighting system and a transmitter that will send images from inside the intestine to video monitors, allowing doctors to detect sources of bleeding in the small intestine. FDA cleared the device for use along with, not as a replacement for, other endoscopic and radiological evaluations of the small intestine. The capsule was not studied in the large intestine.

When swallowed, the device travels down the digestive tract at about the same speed as food, propelled by peristalsis, and takes two to three hours to pass through. Once the device reaches the colon, things slow down, and the disposable device is eliminated like any solid waste within a few days.

The downside to this technology is that the images may not match fiber-optic endoscopes for detail, and concerns have been raised that the camera's view may be obscured by bubbly saliva or green bile. The capsule cannot be stopped or steered to collect close-up details of the small intestine's millions of interior wrinkles where ailments often occur. Nor is it fitted with surgical tools like a conventional endoscope to take biopsies or treat bleeding lesions or remove polyps. If a lesion requiring invasive therapy is found on capsule endoscopy, then the patient will need to undergo surgery with intraoperative endoscopy. In addition, if an abnormality is seen on capsule endoscopy, there is no good way to define its location within the small intestine.

Capsule endoscopy has not been proven to be of value in detecting conditions in the esophagus or colon. The esophageal transit time of the capsule is brief (less than 5 seconds) when patients ingest the capsule with water in the upright position. The transit time may be lengthened by having the patient ingest the capsule lying horizontally.

The colon is not well visualized with capsule endoscopy because stool obscures the visualization of the colonic mucosa. Visualization of the colon is more difficult than the small intestine because of its slower transit time and larger diameter; it is possible for the camera to miss suspicious areas of the colon simply by being pointed in the wrong direction. An American Cancer Society position statement (Levin, et al., 2003) has concluded that there is no evidence to support the use of capsule endoscopy for detecting colorectal polyps or cancers.



Capsule endoscopy is contraindicated in patients with obstruction of the gastrointestinal tract. The available literature indicates that an upper gastrointestinal series should be performed prior to capsule endoscopy if the patient is suspected of having intestinal obstruction.

There is some evidence from several comparative clinical trials and case series that WCE can provide useful diagnostic information in carefully selected patients with documented, chronic occult or obscure GI bleeding of suspected small-bowel origin or for patients with other chronic GI symptoms suggestive of small-bowel disease who have negative or indeterminate findings on standard tests. Moreover, some studies have reported that patients who are treated based on WCE results demonstrate clinical improvement, although long-term health outcomes are unknown due to inadequate follow-up times. Therefore, WCE has the potential to improve the health outcomes of selected patients whose diagnoses remain unknown or indeterminate following standard endoscopic and imaging evaluations. However, despite these promising findings, definitive conclusions regarding the appropriate clinical role for WCE cannot be made due to limitations in study design and execution. There is a need for additional larger, well-designed trials that compare the findings of WCE with an adequate reference standard of diagnosis so that the diagnostic accuracy of this technology can be determined. The effect of WCE on clinical decision-making requires systematic evaluation in order to determine its optimal clinical role in the general healthcare setting and to identify which patients would benefit from this procedure.

Wireless esophageal pH monitoring involves the temporary attachment of a small, capsular device to the distal esophagus. This capsule contains a miniaturized pH electrode and broadcasting system that enables measurement of esophageal pH and wireless transmission of pH data to an external data recorder. Records of esophageal pH are subsequently downloaded to a computer for analysis. The goal of this procedure is to assess esophageal exposure to gastric acid and determine if the patient has gastroesophageal reflux disease (GERD) or a related disorder.

II. POLICY/CRITERIA

- A. Capsule endoscopy is a covered benefit when all of the following criteria are met:
1. The capsule is FDA approved.
 2. The service is performed by physicians trained in endoscopy or in independent diagnostic testing facilities under the general supervision of a physician trained in endoscopy procedures.
 3. Clinical indication “A” **OR** “B” below
 - a. Occult gastrointestinal bleeding
Capsule endoscopy is indicated for the diagnosis of occult gastrointestinal bleeding in the anemic patient when:



- The site of bleeding has not previously been identified by upper gastrointestinal endoscopy, colonoscopy, push endoscopy or other radiologic procedure, **OR**
- An abnormal x-ray of the small intestine is documented without an identified site of bleeding by endoscopic means, **OR**
- The diagnosis of angiodysplasias of the GI tract is suspected.

In the above clinical situations **both** of the **following criteria** must be met:

- i. Patients have undergone upper GI endoscopy and colonoscopy within the same episode of illness that have failed to reveal a source of bleeding.
 - ii. Patients have documented continuing GI blood loss and anemia secondary to bleeding.
- b. Crohn's Disease if **one** of the following is met:
- The diagnosis of Crohn's disease is suspected but not diagnosed; and the patient has undergone upper GI endoscopy, colonoscopy and either push enteroscopy or small bowel radiologic study within the same period of illness which have failed to reveal a focus of disease, or
 - The diagnosis of Crohn's disease is known but it is necessary to determine whether there is involvement of the small bowel as well.
- B. Capsule endoscopy is considered experimental and investigational and is **not a covered benefit for all other indications**, including, but not limited, to non-coverage for the following:
1. Colorectal cancer screening
 2. As an initial test in diagnosing gastrointestinal bleeding
 3. To confirm pathology identified by other diagnostic means
 4. For patients with GI bleeding of suspected small bowel origin who have not previously undergone standard endoscopic and imaging evaluations
 5. Screening of asymptomatic patients for GI disease
 6. Crohn's disease management, rather than diagnosis
- C. **Wireless esophageal pH monitoring (e.g., Bravo[™] pH Monitoring System [Medtronic, Inc., Shoreview, MN]) is considered to be medically necessary for ANY of the following:**
1. to document abnormal esophageal acid exposure in an endoscopy-negative individual being considered for surgical antireflux repair
 2. to evaluate endoscopy-negative individuals with typical reflux symptoms that are refractory to proton pump inhibitor (PPI) therapy
 3. to document adequacy of PPI therapy in esophageal acid control in individuals with complications of reflux disease that include Barrett's esophagus
 4. to evaluate endoscopy-negative individuals with atypical reflux symptoms that are refractory to twice per day PPI therapy



- 5. to evaluate individuals after antireflux surgery who are suspected to have ongoing abnormal reflux and have not responded to empiric trials of PPI therapy

D. Wireless esophageal pH monitoring is considered experimental, investigational or unproven for these indications:

- 1. to detect or verify reflux esophagitis
- 2. to evaluate for “alkaline reflux”

III. MEDICAL NECESSITY REVIEW

- Required Not Required Not Applicable

IV. APPLICATION TO PRODUCTS

Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

- ❖ **HMO/EPO:** *This policy applies to insured HMO/EPO plans.*
- ❖ **POS:** *This policy applies to insured POS plans.*
- ❖ **PPO:** *This policy applies to insured PPO plans.*
- ❖ **ASO:** *For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.*
- ❖ **INDIVIDUAL:** *For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.*
- ❖ **MEDICARE:** *Coverage is determined by the Centers for Medicare and Medicaid Services (CMS).*
- ❖ **MEDICAID:** *If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual and the Michigan Medicaid Fee Schedule, the Michigan Medicaid Provider Manual and the Michigan Medicaid Fee Schedule at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--00.html will govern.*
- ❖ **MICHILD:** *For MICHILD members, this policy will apply unless MICHILD certificate of coverage limits or extends coverage.*

V. CODING INFORMATION:

ICD9 Codes:

Procedure 91110 covered for these diagnoses when criteria listed above is met.

- 152.0-152.9 Malignant neoplasm of small intestine, including duodenum
- 235.2 Neoplasm of uncertain behavior-stomach, intestines and rectum
- 280.0 Iron deficiency anemia secondary to blood loss (chronic)



- 280.9 Iron deficiency anemia, unspecified
- 285.9 Unspecified anemia

- 537.82 Angiodysplasia of stomach and duodenum intestine without mention of hemorrhage
- 537.83 Angiodysplasia of stomach and duodenum intestine with hemorrhage

- 555.0 Regional enteritis of small intestine
- 555.1 Regional enteritis of large intestine
- 555.2 Regional enteritis of small intestine with large intestine
- 555.9 Regional enteritis of unspecified site

- 558.9 Other and unspecified noninfectious gastroenteritis and colitis
- 562.02 Diverticulosis of small intestine with hemorrhage
- 562.03 Diverticulitis of small intestine
- 569.82 Ulceration of intestine
- 569.84 Angiodysplasia of intestine without mention of hemorrhage
- 569.85 Angiodysplasia of intestine with hemorrhage

- 578.1 Blood in stool
- 578.9 Unspecified, hemorrhage of gastrointestinal tract
- 579.0 Celiac disease
- 792.1 Nonspecific abnormal finding in stool contents
- 793.4 Nonspecific abnormal findings on radiological and other examination of body structure, gastrointestinal tract

* Covered for **PriorityMedicare** only

- *579.1 Tropical sprue
- *579.9 Unspecified intestinal malabsorption
- *787.91 Diarrhea

CPT HCPCS Code:

- 91110 Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus through ileum, with physician interpretation and report

- 91035 Esophagus, gastroesophageal reflux test; with mucosal attached telemetry pH electrode placement, recording, analysis and interpretation

Not Covered:

- 91111 Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), esophagus with physician interpretation and report

VI. REFERENCES

“WPS Medicare Part B-GI-009 Telemetric Gastrointestinal Capsule Imaging” Available on the World Wide Web at <http://www.wpsic.com/cgi-bin/polsearchil.cgi> (Retrieved December 30, 2003). Updated version 11/01/04 @ <http://www.wpsic.com/medicare/policies/illinois/gi09.shtml> (Retrieved March 21, 2005).



- “Wireless Capsule Endoscopy” HAYES, Inc. November 2003. Updated Search December 2004.
- “Capsule Endoscopy” Aetna Clinical Policy Bulletins, Number 0588, April 25, 2003 & November 2005. Available on the World Wide Web at <http://www.aetna.com/cpb/data/CPBA0588.html>. (Retrieved December 30, 2003 and February 14, 2006).
- “Wireless Capsule Endoscopy”, Blue Cross Blue Shield Massachusetts, Policy Number 7, October 2003. Available on the World Wide Web at http://www.bcbsma.com/common/en_US/medical_policies/007.htm#scientific. (Retrieved December 30, 2003).
- “Wireless Esophageal pH monitoring” HAYES, Inc. Medical Technology Directory, May 2008, Updated May 2009. Aetna Clinical Policy Bulletin: Esophageal/Airway pH Monitoring #0667- 11/20/2009. Accessed February 26, 2010.
- Cigna Medical Coverage Policy: Wireless esophageal pH monitoring) #0329-4/15/2009. Accessed February 26, 2010.

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