Priority Health

MEDICAL POLICY
No. 91476-R4

CAPSULE ENDOSCOPY

Effective Date: June 2, 2014	**Review Dates: 2/04, 1/05, 5/05, 4/06, 4/07, 6/07, 4/08, 4/09, 4/10, 4/11, 4/12, 4/13, 5/14, 5/15, 5/16, 5/17, 5/18, 5/19, 5/20, 5/22, 5/23, 5/24**
Date of Origin: February 25, 2004	**Status: Current**

I. POLICY/CRITERIA

A. Capsule endoscopy is considered medically necessary 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. One of the clinical indications 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. For evaluation of locoregional carcinoid tumors of the small bowel in persons with carcinoid syndrome.
   c. For surveillance of small intestinal tumors in persons with Lynch syndrome, Peutz-Jeghers syndrome and other polyposis syndromes affecting the small bowel.
   d. 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.

e. For evaluation of persons with celiac disease with one of the following:

- a positive serology and negative biopsy; **OR**
- who remain symptomatic despite treatment and there is no suspected or confirmed gastrointestinal obstruction, stricture, or fistulae

B. Capsule endoscopy is considered experimental and investigational and therefore considered **not medically necessary 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 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 anti-reflux 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"

II. MEDICAL NECESSITY REVIEW

Prior authorization for certain drug, services, and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service, or procedure is medically necessary. For more information, please refer to the Priority Health Provider Manual.

III. 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. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.***
- **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) and/or the Evidence of Coverage (EOC); if a coverage determination has not been adopted by CMS, this policy applies.***
- **MEDICAID/HEALTHY MICHIGAN PLAN:** ***For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, the Michigan Medicaid Provider Manual will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.***

IV. DESCRIPTION

Wireless capsule endoscopy (WCE) is 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, Israel), 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.

V. CODING INFORMATION:

ICD-10 Codes that apply to this policy: *Procedure **91110** and **91113** covered only for the following diagnoses when criteria listed above are met.*

C17.0 - C17.9	Malignant neoplasm of small intestine
D37.1	Neoplasm of uncertain behavior of stomach
D37.2	Neoplasm of uncertain behavior of small intestine
D37.4	Neoplasm of uncertain behavior of colon
D37.5	Neoplasm of uncertain behavior of rectum
D50.0	Iron deficiency anemia secondary to blood loss (chronic)
D50.9	Iron deficiency anemia, unspecified
D62	Acute posthemorrhagic anemia
D64.9	Anemia, unspecified
E34.0	Carcinoid syndrome
K31.811	Angiodysplasia of stomach and duodenum with bleeding
K31.819	Angiodysplasia of stomach and duodenum without bleeding
K50.00	Crohn's disease of small intestine without complications
K50.011– K50.919	Crohn;s disease of small intestine with complications
K52.2x	Allergic and dietetic gastroenteritis and colitis
K52.89	Other specified noninfective gastroenteritis and colitis
K52.9	Noninfective gastroenteritis and colitis, unspecified
K55.20	Angiodysplasia of colon without hemorrhage
K55.21	Angiodysplasia of colon with hemorrhage
K57.01	Diverticulitis of small intestine with perforation and abscess with bleeding
K57.11	Diverticulosis of small intestine without perforation or abscess with bleeding
K57.13	Diverticulitis of small intestine without perforation or abscess with bleeding
K57.41	Diverticulitis of both small and large intestine with perforation and abscess with bleeding
K57.51	Diverticulosis of both small and large intestine without perforation or abscess with bleeding
K57.53	Diverticulitis of both small and large intestine without perforation or abscess with bleeding
K63.3	Ulcer of intestine
K63.5	Polyp of Colon

K90.0	Celiac disease
K90.1	Tropical sprue
K90.9	Intestinal malabsorption, unspecified
K92.1	Melena
K92.2	Gastrointestinal hemorrhage, unspecified
R19.5	Other fecal abnormalities
R19.7	Diarrhea, unspecified
R93.3	Abnormal findings on diagnostic imaging of other parts of digestive tract

CPT HCPCS Code:

91110	Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus through ileum, with interpretation and report
91113	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), colon, with interpretation and report
91034	Esophagus, gastroesophageal reflux test; with nasal catheter pH electrode(s) placement, recording, analysis and interpretation
91035	Esophagus, gastroesophageal reflux test; with mucosal attached telemetry pH electrode placement, recording, analysis and interpretation

Not Covered:

91111	Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus with interpretation and report
91112	Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report

VI. REFERENCES

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