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1.0 Description of the Procedure, Product, or Service

Wireless capsule endoscopy is performed using the PillCam™ Given® Diagnostic Imaging System (previously called M2A®), which is a disposable imaging capsule manufactured by Given Imaging, Ltd. (Norcross, GA). The capsule measures 11 by 30 mm and contains video imaging, self-illumination, and image transmission modules as well as a battery supply that lasts up to eight (8) hours. The indwelling camera takes images at a rate of two (2) frames per second as peristalsis carries the capsule through the gastrointestinal tract. The average transit time from ingestion to evacuation is 24 hours.

The device uses wireless radio transmission to send the images to a receiving recorder device that the recipient wears around the waist. This receiving device also contains some localizing antennae sensors that can roughly gauge where the image was taken over the abdomen. Images are then downloaded onto a workstation for viewing and processing.

The device received marketing clearance from the U.S. Food and Drug Administration (FDA) on August 1, 2001, through the 510(k) process. The FDA clearance provides for the capsule's use "along with – not as a replacement for – other endoscopic and radiologic evaluations of the small bowel." The FDA clarified that the "capsule was not studied in the large intestine." On July 1, 2003, a supplemental 510(k) pre-market notification was cleared, and the labeled indications were modified by removing the "adjunctive" use qualification: "the Given® Diagnostic System is intended for visualization of the small bowel mucosa. It may be used as a tool in the detection of abnormalities of the small bowel."

Finally, in November 2004, the device received FDA clearance for the following labeled indication: "the Given® Diagnostic System with the PillCam™ ESO Capsule is intended for the visualization of esophageal mucosa." A new model was cleared by the FDA in June 2007, the PillCam ES02 Capsule. In September 2007, the FDA cleared the Olympus Capsule Endoscope System through the 510(k) process for "visualization of the small intestine mucosa." More recent versions of both these systems also incorporate a blood indicator feature to assist with rapid screening of intestinal lesions with bleeding potential.

In the small bowel, the capsule camera has been most frequently proposed as a technique to identify the source of obscure intestinal bleeding, although recently there has been interest in exploring its use in recipients with inflammatory bowel disease. Alternative diagnostic techniques include barium studies or small intestinal endoscopy. In the esophagus, the capsule camera has been proposed as a screening technique for Barrett's esophagus associated with gastroesophageal reflux disease (GERD). Evaluation of the esophagus requires limited transit time, and it is estimated that the test takes 20 minutes to perform. Alternative techniques include upper endoscopy.

In 2006, the FDA also provided clearance for the Given AGILE patency system. This system is an accessory to the PillCam video capsule and, according to FDA material, is intended to verify adequate patency of the GI tract prior to administration of the PillCam in recipients with known or suspected strictures. This capsule is of similar size to the endoscopy capsule, but is made of lactose and barium and dissolves within 30–100 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.

1.1 Medical Term Definitions

- a. Endoscopy: visual inspection of any cavity of the body by means of an endoscope.
- b. Obscure: hidden, indistinct, as the cause of a condition; to make less distinct or to hide.

2.0 Eligible Recipients

2.1 General Provisions

To be eligible, NC Health Choice (NCHC) recipients must be enrolled on the date of service.

3.0 When the Procedure, Product, or Service Is Covered

3.1 General Criteria

NCHC covers procedures, products, and services related to this policy when they are medically necessary and

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available; **AND**
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

3.2 Specific Criteria

The NC Health Choice Program provides coverage for wireless capsule endoscopy when it is determined to be medically necessary and the criteria are met for clinical scenarios under ANY items a, b, c, d, e, or f below:

- a. For undiagnosed obscure gastrointestinal bleeding, **ALL** of the following criteria must be met:
 1. GI bleeding is significant as demonstrated by one of the following:
 - (a) an acute drop in hemoglobin/hematocrit;
 - (b) unexplained recurrent or persistent iron deficiency anemia demonstrated by low serum iron studies or low serum ferritin level;
 - (c) persistently positive fecal occult blood test; **OR**
 - (d) visible bleeding with no bleeding source found at original endoscopy;
 2. Failure of previous diagnostic studies to diagnose the source of GI bleeding, including upper and lower GI endoscopy; within the past 12 months, esophagogastroduodenoscopy (EGD) or colonoscopy; **AND**
 3. Source of GI bleeding is thought to be in the upper gastrointestinal tract.

- b. For suspected esophageal varices
- c. For suspected Barrett's esophagus
- d. For suspected Crohn's Disease when diagnosis has not been established by upper and lower endoscopy studies, all of the following must be met:
 - 1. Persistent abdominal pain of greater than 4 weeks;
 - 2. Persistent diarrhea;
 - 3. Unintentional weight loss;
 - 4. Negative stool cultures; AND
 - 5. Negative upper/lower endoscopy studies
- e. For suspected Celiac disease with a positive serology and negative biopsy.
- f. For surveillance of the small bowel in recipients with hereditary GI polyposis syndromes, including familial adenomatous polyposis and Peutz-Jeghers syndrome.

4.0 When the Procedure, Product, or Service Is Not Covered

4.1 General Criteria

Procedures, products, and services related to this policy are not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;
- c. the procedure, product, or service unnecessarily duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental or investigational.

4.2 Specific Criteria

The NC Health Choice Program does not cover capsule endoscopy wireless in the following situations:

- a. Capsule endoscopy for undiagnosed obscure GI bleeding or for diagnosis of suspected Crohn's disease is considered to be not medically necessary when all the criteria in **Subsection 3.2.a** (GI bleeding) or **Subsection 3.2.b** (Crohn's disease) are not met.
- b. Capsule endoscopy for any indication other than undiagnosed obscure GI bleeding, diagnosis of suspected Crohn's disease, or surveillance of the small bowel in recipients with hereditary GI polyposis syndromes is considered investigational including the following indications:
 - 1. When the test is performed for screening.
 - 2. When the wireless capsule endoscopy is used to view the esophagus.
 - 3. When used as a technique to evaluate other gastrointestinal diseases not presenting with gastrointestinal bleeding, including celiac sprue, irritable bowel syndrome, small bowel neoplasm, or non-familial intestinal polyposis syndrome.

4. When used for the evaluation of the extent of involvement of known Crohn's disease.
 5. When used for the evaluation of the colon including the detection of colonic polyps or colon cancer.
- c. The patency capsule is considered investigational, including use to evaluate patency of the gastrointestinal tract before capsule endoscopy wireless.

4.3 Policy Guidelines

To date there has been minimal published literature regarding the diagnostic performance of this device for the esophagus which is inadequate to permit scientific conclusions regarding the clinical role of esophageal capsule endoscopy. One article published in 2005 explored the use of capsule endoscopy to determine the extent of Crohn's disease in recipients already diagnosed. The clinical trial did show that capsule endoscopy was able to identify additional areas of Crohn's disease that had not been previously identified by enteroclysis. It is still unclear how knowledge regarding the extent of the disease would impact recipient medical management.

Esophageal endoscopy is the standard of care at this time in that it allows for a biopsy at the time of the procedure if needed. Capsule endoscopy offers a potential alternative to endoscopy; those recipients with a negative study could potentially forego conventional endoscopy. An assessment of the capsule endoscopy of the esophagus requires a comparison of its diagnostic performance against the conventional esophageal endoscopy.

Capsule endoscopy has been evaluated in comparison to traditional optical colonoscopy for detection of polyps and cancer. In the largest study of 328 patients, the sensitivity of capsule endoscopy was 64% for polyps 6 mm or larger, 73% for advanced adenoma, and 74% for cancer. Other smaller studies show the sensitivity of capsule endoscopy for various types of lesions to be less than 80%. Based on these data, the use of capsule endoscopy for evaluation of the colon is investigational.

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval

Prior approval is required.

5.2 Prior Approval Requirements

The provider(s) shall submit to DMA's designee the following:

- a. the prior approval request, and
- b. all health care records and any other records that support the recipient has met the specific criteria in **Subsection 3.2** of this policy.

6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services related to this policy, providers shall

- a. meet NCHC qualifications for participation;
- b. be currently enrolled with NCHC; **AND**

- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

7.0 Additional Requirements

7.1 Compliance

Providers shall comply with all applicable federal, state, and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

8.0 Policy Implementation/Revision Information

Original Effective Date: July 1, 2010

Revision Information:

Date	Section Revised	Change
July 1, 2010		Policy Conversion: Implementation of Session Law 2009-451, Section 10.32 “NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY.”
1/1/12	Throughout	Policy revised comparable to Medicaid Clinical Coverage Policy 1A-31 due to Session Law 2011-145
1/1/12	Subsection 5.1	Prior approval is required
1/1/12	Subsection 5.2	Prior approval requirements
1/1/12	Attachment A (C)	Added description of codes

Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines.

A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

C. Procedure Code(s)

91110	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), esophagus through ileum, with physician interpretation and report
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D. Modifiers

Providers are required to follow applicable modifier guidelines.

E. Billing Units

The appropriate procedure code(s) used determines the billing unit(s).

F. Place of Service

Inpatient Hospital and Outpatient Hospital

G. Co-payments

Co-payment(s) may apply to covered prescription drugs and services.

H. Reimbursement

Providers must bill their usual and customary charges.