CLINICAL MEDICAL POLICY	
Policy Name:	Capsule Endoscopy
Policy Number:	MP-038-MD-PA
Approved By:	Medical Management
Provider Notice Date:	2/1/2017
Original Effective Date:	3/1/2017
Annual Approval Date:	1/3/2018
Revision Date:	
Products:	Pennsylvania Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 7

Disclaimer

Gateway Health℠ (Gateway) medical payment and prior-authorization policy is intended to serve only as a general reference resource regarding payment and coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

http://gatewayhealthplan.com/MedicalPolicies

POLICY STATEMENT:

Gateway Health℠ provides coverage under the medical-surgical benefits of the Company's Medicaid products for medically necessary capsule endoscopy procedures.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

(Current applicable Pennsylvania HealthChoices Agreement Section V. Program Requirements, B. Prior Authorization of Services, 1. General Prior Authorization Requirements.)

DEFINITIONS:

Prior Authorization Review Panel – A panel of representatives from within the Pennsylvania Department of Human Services who have been assigned organizational responsibility for the review, approval and denial of all PH-MCO Prior Authorization policies and procedures.

Gastric Emptying Scintigraphy – A diagnostic test where the individual ingests a radionuclide-labeled standard meal, and then images are taken at 0, 1, 2, and 4 hours postprandial in order to measure how much of the meal has passed beyond the stomach. A typical threshold to indicate abnormal gastric emptying is more than 10% of the meal remaining at 4 hours after ingestion.

Esophageal Capsule Endoscopy (ECE) – A minimally invasive procedure that uses video capsules with the ability to acquire images from two cameras with high image storing speed of 14 to 18 frames per second. An ingestion procedure allows for prolonged esophageal transit time and an optimized view of the gastroesophageal junction.

Ingestible pH and Pressure-Sensing Capsule – An ingestible wireless device that is equipped with pH, pressure, and temperature sensors (e.g., SmartPill® GI Monitoring System).

Idiopathic Gastroparesis – The most common form of gastroparesis, in which a cause cannot be identified.

Diabetic Gastroparesis – The second most common cause of gastroparesis, in which continued high blood glucose levels damage the vagus nerve.

Postsurgical Gastroparesis – The third most common etiology of gastroparesis, most often the result of a vagotomy or vagus nerve injury.

PROCEDURES:

The wireless capsule endoscopy is considered medically necessary when the following conditions are met:

- The patient must be 2 years of age and older.
- The test must be ordered by a gastroenterologist or surgeon.
- Testing is performed using FDA-approved devices.
- The images will be interpreted by a clinician with formal training and/or sufficient experience in the interpretation of capsule endoscopy.
- The results of the testing must be likely to influence treatment decisions.

1. Occult Gastrointestinal Bleeding
    a. An acute drop in hemoglobin/hematocrit; OR
    b. Unexplained recurrent or persistent iron deficiency anemia; OR
    c. Persistently positive fecal occult blood test; OR
    d. Visible bleeding with no bleeding source found on original upper endoscopy, lower endoscopy, barium enema, nuclear imaging, or radiological procedures (UGI with small bowel follow-through).

2. Small Bowel Neoplasm
    a. Patient is symptomatic for a neoplasm (e.g., GI bleeding, partial bowel obstruction); AND
    b. Documented hereditary polyposis syndrome (including familial adenomatous polyposis and Peutz-Jeghers) that is associated with small bowel neoplasia; OR
    c. History suggesting the presence of small bowel neoplasia; AND
    d. The diagnosis has not been confirmed by upper GI endoscopy, colonoscopy, push enteroscopy, and nuclear imaging or radiologic procedures.

3. Suspected Crohn's Disease
    a. Coverage is limited to patients who are symptomatic for Crohn's disease:
        1) Persistent abdominal pain of greater than 4 weeks; AND

2) Persistent diarrhea; AND
3) Unintentional weight loss; AND
4) Negative stool cultures.

b. For the re-evaluation of patients with established diagnosis of Crohn's disease, when there are unexpected changes/suspected recurrence of disease during treatment, and re-examination may be indicated.
c. For both of the preceding indications, the patient has undergone complete lower GI studies (colonoscopy, barium enema, stool specimen, nuclear imaging [CT enterography], or radiological procedures) AND the testing has failed to reveal the source of symptoms.

4. Suspected or Refractory Malabsorptive Syndromes (e.g., Celiac disease)
   a. For patients who have had a negative biopsy; AND
   b. A diagnosis has not been confirmed by upper GI endoscopy, push enteroscopy, or colonoscopy.

5. Esophageal Varices and Esophagitis
   a. Esophagogastroduodenoscopy (EGD) is currently the gold standard.
   b. All requests for capsule endoscopy for esophageal varices or esophagitis will require review by a medical director for case-by-case review.
   c. The device is approved for patients 18 years of age and older.

   NOTE: A traditional endoscopy may still be needed for tissue samples or other treatments. For patients who are unable to ingest the capsule, the capsule can be administered by using transendoscopic delivery.

6. Contraindications
   Absolute Contraindications
   a. Patients with known or suspected gastrointestinal obstruction, strictures or fistulae. The excretion of the actual capsule may be hindered with any of these conditions.
   b. Patients who have swallowing abnormalities are at risk for aspiration of the capsule, and patients with an esophageal stricture are at risk for impaction of the capsule in the esophagus with subsequent esophageal obstruction.
   c. According to the manufacturer, cardiac pacemakers or other implanted electro-medical devices (such as implanted defibrillators) are still listed as contraindicated; however, there have been some reports that the procedure is safely performed in such patients.

   Relative Contraindications
   a. Pregnancy
   b. Large or numerous small-bowel diverticuli that may increase the risk of the capsule becoming lodged in transit

7. When capsule endoscopy services are not covered
   Capsule endoscopy is not covered for any other conditions other than those listed above because the scientific evidence has not been established. Specific examples of noncovered indications include but are not limited to:
   a. Being performed for screening purposes (e.g., colorectal cancer, asymptomatic patients)
   b. Unexplained chronic abdominal pain
   c. To confirm pathology identified by other diagnostic means
   d. Used as a method to evaluate other GI disorders not presenting with criteria listed above
   e. Used as part of the initial evaluation of patients with acute upper GI bleeding

f. Used to evaluate patency of the GI tract before wireless capsule endoscopy
g. Measurement obtained via an ingestible pH and pressure capsule for measuring gastric emptying parameters (e.g., SmartPill® GI Monitoring System) is considered experimental/investigational for the evaluation of gastric disorders (e.g., gastroparesis), intestinal motility disorders (e.g., chronic constipation), and all other indications. There is inadequate published scientific evidence of the capsule's diagnostic performance and clinical utility over conventional means of measuring gastric emptying.
h. Barrett's Esophagus
i. A second capsule endoscopy per illness episode unless there is adequate documentation of inadequate examination on the initial capsule endoscopy

8. Post-payment Audit Statement
The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Gateway Health℠ at any time pursuant to the terms of your provider agreement.

9. Place of Service
The place of service for capsule endoscopy is the outpatient setting.

10. Governing Bodies Approval
PillCam™ Given® Diagnostic Imaging System and the PillCam™ SB Capsule
In August 2001, this device was cleared for marketing by the FDA 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 stated that the capsule was not studied in the large intestine.

Supplemental 510(k) pre-market approval was granted on July 1, 2003, stating that 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.

In October 2003, the device was given FDA approval as a tool in the detection of abnormalities in the small bowel mucosa to include adults and children 10 years of age and older.

PillCam™ COLON 2
In January 2014, the PillCam Colon 2 Capsule Endoscopy System was approved by the FDA. 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.

Given Agile™ Patency System
The Given AGILE Patency System was cleared by the FDA in May 2006 through the 510(k) process. The device is an accessory to the PillCam™ video capsule and is intended to verify the adequate patency of the gastrointestinal tract prior to the administration of the PillCam™ in patients with known or suspected strictures. In September 2009, the FDA expanded the indications to include children from 2 years of age and older.

PillCam™ ESO AKA Ingestible Telemetric Gastrointestinal Capsule Imaging System
The device received FDA clearance in November 2004 for the following labeled indications:

"The Given® Diagnostic System with the PillCam™ ESO Capsule is intended for the visualization of esophageal mucosa." In June 2007, the new model PillCam ESO2 Capsule was cleared by the FDA.

This capsule has dual cameras and a faster frame rate developed specifically to assess the esophagus. On average, the procedure takes under 30 minutes and is performed in the provider's office.

PillCam® Express™ Video Capsule Deliver Device

This device received FDA approval in September 2010 as an accessory to the PillCam® and is indicated for the transendoscopic delivery of the PillCam® SB video capsule in patients aged 8 years and older who are either unable to ingest the PillCam capsule or are known to have slow gastric emptying time.

Olympus Endoscope System and Endo Capsule®

The FDA approved the Olympus Capsule Endoscope in September 2007. This system was designed to be used for visualization of the small intestine mucosa.

MicroCam® Capsule Endoscope System

In May 2012, the FDA approved this device as substantially equivalent to predicate devices. It is intended for use in visualization of the small bowel mucosa as a tool for the detection of abnormalities in the small bowel of adults.

CODING REQUIREMENTS:

Procedure Codes

CPT/HCPCS Code	Description
91110	Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus through ileum, with physician interpretation and report.
91111	Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus with physician interpretation and report.

NOT COVERED

CPT/HCPCS Code	Description
91112	Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report (Smart Pill™).
0355T	Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), colon with physician interpretation and report.

REIMBURSEMENT:

Participating facilities will be reimbursed per their Gateway Health℠ contract.

POLICY SOURCE(S):

Pennsylvania Department of Human Services. Technology Assessment Group Coverage Decisions. Managed Care Operations Memorandum: OPS # 05/2010-009; Wireless Capsule Endoscopy (Colon). Option #4. Available at: https://dpwintra.dpw.state.pa.us/HealthChoices/custom/post/mcopsmemo/2010/mc_ops_05-2010-009.asp. Accessed on October 7, 2016.

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Eisen GM, Eliakim R, Zaman A, et al. The accuracy of PillCam ESO capsule endoscopy versus conventional upper endoscopy for the diagnosis of esophageal varices: a prospective three-center pilot study. Endoscopy. 2006; 38(1): 31-5. Available at: https://www.thieme-connect.com/DOI/DOI?10.1055/s-2005-921189. Accessed on: October 12, 2016.

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Policy History:

Date	Activity
1/3/2017	Initial policy developed
3/1/2017	Provider effective date