CLINICAL MEDICAL POLICY	
Policy Name:	Capsule Endoscopy
Policy Number:	MP-038-MD-DE
Responsible Department(s):	Medical Management
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Products:	Highmark Health Options Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 12

DISCLAIMER

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide 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.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

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

1. The wireless capsule endoscopy is considered medically necessary when the following conditions are met:
    A. The patient must be 2 years of age and older; AND
    B. The test must be ordered by a gastroenterologist or surgeon; AND
    C. Testing is performed using FDA-approved devices; AND
    D. The images will be interpreted by a clinician with formal training and/or sufficient experience in the interpretation of capsule endoscopy; AND
    E. The results of the testing must be likely to influence treatment decisions; AND
    F. The patient must have one of the following conditions:
        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);

        OR

        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;

        OR

        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; AND

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; AND
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;

OR

4) Suspected or Refractory Mal-absorptive 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;

   OR

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; AND
   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.

2. 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

3. 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. These services will deny as not medically necessary. Specific examples of non-covered indications include but are not limited to:

A. Being performed for screening purposes (e.g., colorectal cancer, asymptomatic patients); OR
B. Unexplained chronic abdominal pain; OR
C. To confirm pathology identified by other diagnostic means; OR

D. Used as a method to evaluate other GI disorders not presenting with criteria listed above; OR
E. Used as part of the initial evaluation of patients with acute upper GI bleeding; OR
F. Used to evaluate patency of the GI tract before wireless capsule endoscopy; OR
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; OR
H. Barrett's Esophagus; OR
I. A second capsule endoscopy per illness episode unless there is adequate documentation of inadequate examination on the initial capsule endoscopy; OR

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

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

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

Covered Procedure Codes

CPT Codes	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.

*Non-covered Procedure Codes

CPT/HCPCS Codes	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.

*These procedure codes will not be reimbursed without Medical Director approval.

Covered Diagnosis Codes

ICD-10 Codes	Description
A18.32	Tuberculous enteritis
A18.39	Retroperitoneal tuberculosis
A18.83	Tuberculosis of digestive tract organs, not elsewhere classified
C17.0	Malignant neoplasm of duodenum
C17.1	Malignant neoplasm of jejunum
C17.2	Malignant neoplasm of ileum

C17.3	Meckel's diverticulum, malignant
C17.8	Malignant neoplasm of overlapping sites of small intestine
C17.9	Malignant neoplasm of small intestine, unspecified
C49.A3	Gastrointestinal stromal tumor of small intestine
C49.A4	Gastrointestinal stromal tumor of large intestine
C7A.010	Malignant carcinoid tumor of the duodenum
C7A.011	Malignant carcinoid tumor of the jejunum
C7A.012	Malignant carcinoid tumor of the ileum
C7A.019	Malignant carcinoid tumor of the appendix
C7A.020	Malignant carcinoid tumor of the cecum
C7A.021	Malignant carcinoid tumor of the ascending colon
C7A.022	Malignant carcinoid tumor of the transverse colon
C7A.023	Malignant carcinoid tumor of the descending colon
C7A.024	Malignant carcinoid tumor
C7A.025	Malignant carcinoid tumor
C7A.026	Malignant carcinoid tumor
C7A.029	Malignant carcinoid tumor
C78.4	Secondary malignant neoplasm of small intestine
D01.40	Carcinoma in situ of unspecified part of intestine
D01.49	Carcinoma in situ of other parts of intestine
D13.2	Benign neoplasm of duodenum
D13.30	Benign neoplasm of unspecified part of small intestine
D13.39	Benign neoplasm of other parts of small intestine
D3A.010	Benign carcinoid tumors of the duodenum
D3A.011	Benign carcinoid tumors of the jejunum
D3A.012	Benign carcinoid tumors of the ileum
D3A.019	Benign carcinoid tumors of the small intestine, unspecified portion
D50.0	Iron deficiency anemia secondary to blood loss (chronic)
D50.9	Iron deficiency anemia, unspecified (use when anemia continues to be unexplained after upper and lower endoscopy)
D62	Acute post hemorrhagic anemia
D72.89	Other specified disorders of white blood cells
E16.4	Increased secretion of gastrin (Zollinger-Ellison syndrome)
I77.6	Arteritis, unspecified
K31.811	Angiodysplasia of stomach and duodenum with bleeding
K31.82	Dieulafoy lesion (hemorrhagic) of stomach and duodenum
K50.00	Crohn's disease of small intestine without complication
K50.011	Crohn's disease of small intestine with rectal bleeding
K50.018	Crohn's disease of small intestine with other complication
K50.019	Crohn's disease of small intestine with unspecified complication
K50.10	Crohn's disease of large intestine without complication
K50.111	Crohn's disease of large intestine with rectal bleeding
K50.118	Crohn's disease of large intestine with other complication
K50.119	Crohn's disease of large intestine with unspecified complications

K50.80	Crohn's disease of both small and large intestine without complication
K50.811	Crohn's disease of both small and large intestine with rectal bleeding
K50.818	Crohn's disease of both small and large intestine with other complication
K50.819	Crohn's disease of both small and large intestine with unspecified complications
K50.90	Crohn's disease, unspecified, without complications
K50.911	Crohn's disease, unspecified, with rectal bleeding
K50.918	Crohn's disease, unspecified, with other complication
K50.919	Crohn's disease, unspecified, with unspecified complications
K52.0	Gastroenteritis and colitis due to radiation
K52.1	Toxic gastroenteritis and colitis
K52.2	Allergic and dietetic gastroenteritis and colitis
K52.81	Eosinophilic gastritis or gastroenteritis
K52.82	Eosinophilic colitis
K52.89	Other specified gastroenteritis and colitis, unspecified
K52.9	Noninfective gastroenteritis and colitis, unspecified
K55.1	Chronic vascular disorders of intestine
K55.21	Angiodysplasia of colon with hemorrhage
K57.11	Diverticulosis of small intestine without perforation or abscess with bleeding
K57.13	Diverticulitis of small intestine without perforation or abscess with bleeding
K57.51	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
K63.81	Dieulafoy lesion of intestine
K90.0	Celiac disease
K92.1	Melena
R10.0	Acute abdomen
R10.10	Upper abdominal pain, unspecified
R10.11	Right upper quadrant pain
R10.12	Left upper quadrant pain
R10.13	Epigastric pain
R10.2	Pelvic and perineal pain
R10.30	Lower abdominal pain, unspecified
R10.31	Right lower quadrant pain
R10.32	Left lower quadrant pain
R10.33	Periumbilical pain
R10.84	Generalized abdominal pain
R10.9	Unspecified abdominal pain
R19.5	Other fecal abnormalities
R19.7	Diarrhea
R50.81	Fever presenting with conditions classified elsewhere
R50.9	Fever, unspecified
R63.4	Abnormal loss of weight
R70.0	Elevated erythrocyte sedimentation rate

Z09	Encounter for follow-up examination after completing treatment for conditions other than malignant neoplasm [re-evaluation of celiac disease]

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

SUMMARY OF LITERATURE

The capsule endoscopy procedure is performed using an imaging system that consists of a swallowable disposable capsule. The capsule contains a video camera, light source, radio transmitter, and batteries. Additional equipment includes an externally worn data recorder and an office-based workstation. The video camera is capable of recording up to 50,000 images which are transmitted to the data recorder as the capsule travels through the gastrointestinal tract via peristalsis. Typically, the capsule is excreted approximately 8 to 72 hours after ingestion and is discarded.

The SmartPill® GI Monitoring system is an ingestible capsule that is able to sense and record pH and pressure measurements from the entire length of the gastrointestinal tract. It is reported that this device is useful to evaluate patients with suspected delayed gastric emptying. The measurements that are obtained from the monitoring system are used to determine gastric emptying time (GET), total transit time (TTT), and combined small-large bowel transit time (SLBTT). The pressure contraction patterns from the antrum and duodenum are used to calculate motility indices.

Crohn's disease (CD) is a chronic inflammatory disorder associated with mucosal and transmural inflammation of the bowel wall. This disease can affect the entire gastrointestinal tract from the mouth to the anus although the most common presentation is ileum-colon in approximately 50% of the cases, Ileocolonoscopy and biopsies of the terminal ileum and each colonic segment are the first-line procedures to establish diagnosis (Arguelles-Arias et al., 2014). The authors examined several published studies reporting the use of capsule endoscopy (CE) in suspected Crohn's disease or the evaluation for the extension or recurrence of CD. The authors also reported on the use of capsule endoscopy in pediatric populations and complications of the device. The authors reported that capsule endoscopy depicted a higher number of inflammatory lesions and concluded that CE is a very useful tool to observe small bowel lesions undetectable by conventional endoscopy or radiologic studies. In addition, ileocolonoscopy should not be replaced to evaluate recurrence; however, CE is a suitable alternative that can detect lesions more proximally.

Gastroparesis is defined as a chronic condition in which patients experience symptoms of delayed gastric emptying in the absence of an actual physical blockage/obstruction. Symptoms include nausea, vomiting, early satiety, bloating, abdominal pain, and postprandial fullness (Hasler, 2011). The most common etiologies of gastroparesis are: idiopathic (36%), diabetic (29%), or postsurgical (13%) (American College of Gastroenterology, 2013). However, the disease can also be related to autoimmune, paraneoplastic or neurologic disorders.

An accurate gastroparesis diagnosis is vital in management decisions. There are several diagnostic testing options for the evaluation of possible gastroparesis. These options include:

- gastric scintigraphy which is considered to be the reference standard
- antroduodenal manometry

Scintigraphic gastric emptying of solids is the standard for the evaluation of gastric emptying and the diagnosis of gastroparesis. The most reliable method and parameter for the diagnosis of gastroparesis is gastric retention of solid foods at 4 hours measured by scintigraphy (American College of Gastroenterology, 2013). Use of the wireless capsule motility testing is an alternative method of testing; however, further validation is necessary before the wireless capsule can be considered an alternative to scintigraphy in the diagnosing of gastroparesis.

In 2011, the federal Agency for Healthcare Research and Quality (AHRQ) commissioned a comparative effectiveness review of the wireless motility capsule (WMC) compared to other diagnostic technologies for the evaluation of gastroparesis and constipation. Overall, the study reported that capsule endoscopy appears to be an accurate diagnostic tool in the detection of gastroparesis and slow-transit constipation. However, the available scientific evidence is insufficient to determine whether use of the wireless capsule will improve outcomes of care.

The downside of 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. The device is not 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, the patient will need to undergo surgery with intra-operative endoscopy. In addition, if an abnormality is seen on capsule endoscopy, there is no good way to define its location within the small intestine. Fleischer (2002) has noted that, with capsule endoscopy, “the pylorus is usually seen, and in many patients the ileocecal valve can be demonstrated, but apart from a rough estimate linked to 'time beyond the pylorus' or 'time in front of the ileocecal valve,' specific localization is not possible.”

Capsule endoscopy has also been studied as an enhanced detection evaluation of esophageal varices compared to EGD. For many years, EGD under conscious sedation is considered the gold standard for variceal screening (Waterman M, Gralnek IM, 2009). However, several clinical trials have reported capsule esophageal endoscopy as a potential alternative. Reported advantages of the capsule endoscopy over EGD include an accurate noninvasive test, avoidance of sedation in patients with liver cirrhosis, and the ability to perform the capsule endoscopy during an office visit. It has been reported that the overall concordance between capsule esophageal endoscopy and EGD was 96.9% for the diagnosis of esophageal varices and 90.6% for portal hypertensive gastropathy (Eisen et al., 2006).

Colli et al. (2014) conducted a review of scientific clinical studies through October 2013 evaluating the accuracy of capsule endoscopy for the diagnosis of esophageal varices as triage or replacement esophago-gastro-duodenoscopy. A total of 16 studies were identified in which only adults with cirrhosis were included. The authors reported there is little support for the use of capsule endoscopy as a triage test in adults with cirrhosis, administered before esophago-duodenoscopy. Furthermore, they found no data assessing capsule endoscopy in children or in patients with portal thrombosis.

It is important to note that most of the literature on the capsule esophageal endoscopy was performed on early version of the capsule esophageal endoscopy.

Abbreviations

CE	Conventional endoscopy
ECE	Esophageal capsule endoscopy
EGD	Esophagogastroduodenoscopy
ESLD	End-stage liver disease
FDA	Food and Drug Administration
GERD	Gastroesophageal reflux disease
SE	Standard endoscopy
WCE	Wireless capsule endoscopy
WMC	Wireless Motility Capsule

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. Accessed on October 7, 2016 and available at: https://dpwintra.dpw.state.pa.us/HealthChoices/custom/post/mcopsmemo/2010/mc_ops_05-2010-009.asp

Pennsylvania Department of Human Services. Technology Assessment Group Coverage Decisions. Managed Care Operations Memorandum: OPS # 02/2009-005; Wireless Capsule Endoscopy (Esophageal). Option #3. Accessed on October 7, 2016 and available at: https://dpwintra.dpw.state.pa.us/HealthChoices/custom/post/mcopsmemo/2009/mc_ops_02-2009-005.asp

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Policy History

Date	Activity
01/03/2017	Initial policy developed
03/14/2017	QI/UM Committee Review
05/01/2017	Provider effective date
08/09/2017	Added Disclaimer Statement in opening of medical policy. Added 'Issue Date' to opening policy box
12/20/2017	Annual Review: No changes
03/13/2018	QI/UM Committee Review Approval
05/15/2018	New Provider Effective Date