



CLINICAL MEDICAL POLICY	
Policy Name:	Capsule Endoscopy
Policy Number:	MP-038-MD-PA
Responsible Department(s):	Medical Management
Provider Notice/Issue Date:	02/01/2024; 02/01/2023; 01/21/2022; 03/19/2021; 02/17/2020; 03/19/2019; 05/01/2018; 05/01/2017
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Next Annual Review:	12/2024
Revision Date:	12/20/2023; 12/21/2022; 12/15/2021; 12/16/2020; 12/18/2019; 12/19/2018; 08/09/2017
Products:	Highmark Wholecare SM Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 15

Policy History

Date	Activity
03/01/2024	Provider Effective date
01/10/2024	PARP Approval
12/20/2023	QI/UM Committee review
12/20/2023	Annual Review: No changes to clinical criteria. Updated 'Summary of Literature' and 'Reference Sources' sections.
03/01/2023	Provider Effective date
01/11/2023	PARP Approval
12/21/2022	QI/UM Committee review
12/21/2022	Annual Review: No changes to clinical criteria. Reformatted 'Procedures' section numbering. Updated 'Summary of Literature' and 'Reference Sources' sections. Removed deleted CPT code 0355T, replaced with new CPT code 91113, procedure code is still noncovered.
02/21/2022	Provider Effective date
01/10/2022	PARP Approval
12/15/2021	QI/UM Committee Review
12/15/2021	Annual Review: No changes to clinical criteria. Added 'Wireless Capsule Endoscopy' to Definitions section. Added TAG determination. Removed the word 'physician' from codes 91110, 91111, and 0355T. Removed 'SmartPill' from code 91112 and

	removed 'Zollinger Ellison syndrome' from diagnosis code E16.4, all per AMA guidelines. Updated Reference Sources section.
04/19/2021	Provider Effective Date
02/18/2021	PARP Approval
12/16/2020	Annual Review: Formatting changes. Updated Summary of Literature and Reference Section.
12/16/2020	QIUM Committee Review Approval
03/16/2020	Provider effective date
01/09/2020	PARP approval
12/18/2019	Annual Review: No change to clinical criteria; added reference for the CapsoCam; removed the following diagnosis codes-C18.0-C18.9, C7A.019-C7A.029, C94.A4 & C94.A5, D72.89, K57.00, K57.10, K57.12, K74.69, K76.6 & Z09 as unrelated to the procedure codes ; added diagnosis codes K52.0 & K90.49 as eligible; updated references
12/18/2019	QI/UM Committee review
03/19/2019	Provider effective date
10/14/2016	Initial policy developed

Disclaimer

Highmark WholecareSM 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 WholecareSM 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 (PARP) – 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.

Wireless Capsule Endoscopy – A procedure which allows a doctor to examine the lining of the middle part of a patient’s gastrointestinal tract, which includes the three portions of the small intestine (duodenum, jejunum, & ileum). The doctor will give the patient a pill sized video camera for you to swallow. This camera has its own light source and takes pictures of the patient’s small intestine as it passes through. These pictures are sent to a small recording device the patient has to wear on their body.

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

Program Exception

Procedure code 91110 (*Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus through ileum, with interpretation and report*) requires a Program Exception, the ordering physician must provide a supporting statement indicating why the requested therapy or device is medically necessary, and the alternative options have been or are likely to be ineffective, adversely affect patient compliance, or cause an adverse reaction.

1. Wireless capsule endoscopy may be considered medically necessary when ALL of the following conditions are met:
 - A. The individual must be at least two (2) years of age or older; AND
 - B. The endoscopy must be ordered by a gastroenterologist or surgeon; AND
 - C. The endoscopy must be performed using FDA-approved devices; AND
 - D. The endoscopy 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 endoscopy must be likely to influence treatment decisions; AND
 - F. The individual must present with ANY ONE of the following conditions:
 - 1) **Occult Gastrointestinal Bleeding**, with ANY of the following symptoms:
 - 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**, with ANY of the following:
 - a) Neoplasm (e.g., GI bleeding, partial bowel obstruction), with documented hereditary polyposis syndrome (including familial adenomatous polyposis, Lynch Syndrome and Peutz-Jeghers) that is associated with small bowel neoplasia; OR
 - b) History suggesting the presence of small bowel neoplasia, and the diagnosis has not been confirmed by upper GI endoscopy, colonoscopy, push enteroscopy, and nuclear imaging or radiographic procedures; OR
 - 3) **Suspected Crohn's Disease**, when the individual has undergone complete lower GI studies (colonoscopy, barium enema, stool specimen, nuclear imaging [CT enterography], radiological procedures), the testing has failed to reveal the source of symptoms, and ALL of the following symptoms are currently present:
 - a) Persistent abdominal pain of greater than four (4) weeks; AND
 - b) Persistent diarrhea; AND
 - c) Unintentional weight loss; AND
 - d) Negative stool cultures (Note: Wireless capsule endoscopy may be medically necessary for the re-evaluation of individuals with established diagnosis of Crohn's disease, when there are unexpected changes/suspected recurrence of disease during treatment, and re-examination may be indicated.); OR
 - 4) **Suspected or Refractory Malabsorptive Syndromes (e.g., Celiac disease)**, with ALL of the following present:
 - a) A previous negative biopsy; AND
 - b) A diagnosis that has not been confirmed by upper GI endoscopy, push enteroscopy, or colonoscopy; OR

- 5) **Esophageal Varices**, esophagogastroduodenoscopy (EGD) is currently the gold standard, however the following are circumstances when wireless capsule endoscopy would be appropriate:
- a) In cirrhotic individuals with significantly compromised liver function (Child-Pugh of Class B or greater) follow-up capsule endoscopy is appropriate to assess the adequacy of prior sclerotherapy and/or band ligation of esophageal varices every 6 to 24 months after the initial sclerotherapy/banding sessions are completed; OR
 - b) Evaluation of esophageal varices with cirrhosis and portal hypertension as an alternative to upper GI endoscopy.

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

2. Contraindications

Absolute Contraindications

- Individuals with a suspected or known gastrointestinal obstruction, strictures or fistulae. The excretion of the actual capsule may be hindered with any of these conditions.
- Individuals who have swallowing abnormalities are at risk for aspiration of the capsule, and individuals with an esophageal stricture are at risk for impaction of the capsule in the esophagus with subsequent esophageal obstruction.
- Application of capsule endoscopy is feasible and safe in individuals with implanted cardiac devices such as pacemakers, cardioverter defibrillators, and left heart assist devices.

Relative Contraindications

- Pregnancy
- Large or numerous small-bowel diverticuli that may increase the risk of the capsule becoming lodged in transit

3. Wireless capsule endoscopy is not considered medically necessary for any conditions other than those listed above because the scientific evidence has not been established. Specific examples of not medically necessary indications include, but are not limited to, ANY of the following:

- Screening purposes (e.g., colorectal cancer, asymptomatic individuals)
- To diagnose unexplained chronic abdominal pain
- To confirm pathology identified by other diagnostic means
- When used as a method to evaluate other GI disorders not presenting with criteria listed above
- When used as part of the initial evaluation of individuals with acute upper GI bleeding
- When used to evaluate patency of the GI tract before wireless capsule endoscopy
- 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
- Barrett's Esophagus

- A second capsule endoscopy per illness episode unless there is adequate documentation of inadequate examination on the initial capsule endoscopy
- The detection of hookworms
- In the treatment planning for radiation therapy
- Wireless capsule endoscopy of the colon

4. Post-payment Audit Statement

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark WholecareSM at any time pursuant to the terms of your provider agreement.

5. Place of Service

The proper place of service for capsule endoscopy is the outpatient setting.

6. Related Policy

- MP-092-MD-PA Upper Gastrointestinal Endoscopy (EGD – Esophagogastroduodenoscopy)

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. 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.

Pill Cam SB 2 and 3

The Pill Cam SB video capsule is intended for visualization of the small bowel mucosa and was approved by the FDA in 2001. In March 2011, the device received FDA approval for updated labeling to include monitoring lesions that may indicate Crohn’s disease.

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.

CapsoCam® (CapsoVision)

In early 2016 the first generation CapsoCam small bowel capsule endoscope system received FDA approval. In November 2016 the FDA approved the CapsoCam® Plus received FDA approval. This system is a third generation capsule and provides 360°panormaic lateral image of the small bowel with a 15 hour battery life.

CMS

The Centers for Medicare and Medicaid Services (CMS) has issued the following guidance:

- National Coverage Determination (NCD) Endoscopy (100.2)
- Local Coverage Determination (LCD) Wireless Capsule Endoscopy (L35089)
- Local Coverage Article (LCA) Billing and Coding: Wireless Capsule Endoscopy (A57753)

The Pennsylvania Department of Human Services Technology Assessment Group (TAG) workgroup meets quarterly to discuss issues revolving around new technologies and technologies or services that were previously considered to be a program exception. During this meeting, decisions are made as to whether or not certain technologies will be covered and how they will be covered. TAG’s decisions are as follow:

- Option #1: Approved - Will be added to the Fee Schedule
- Option #2: Approved as Medically Effective - Will require Program Exception
- Option #3: Approved with (or denied due to) Limited/Minimal Evidence of Effectiveness - Will require Program Exception
- Option #4: Denied - Experimental/Investigational

On July 2005, the TAG workgroup assigned capsule endoscopy (gastrointestinal tract imaging, intraluminal, esophagus thru ileum, with physician interpretation & report) an Option # 3, specifically for CPT code 91110.

Program Exception

Procedure code 91110 (*Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus through ileum, with interpretation and report*) requires a Program Exception, the ordering physician must provide a supporting statement indicating why the requested therapy or device is medically necessary, and the alternative options have been or are likely to be ineffective, adversely affect patient compliance, or cause an adverse reaction.

On May 2010, the TAG workgroup assigned wireless capsule endoscopy of the colon an Option # 4.

Summary of Literature

The wireless 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.

Capsule endoscopy can be useful for diagnosing and treating suspected small-bowel disease. Small-bowel capsule endoscopy is a relatively new procedure that enables evaluation of the entire small bowel. Capsule endoscopy has revolutionized small-bowel assessment, particularly for suspected small bowel bleeding. Currently, capsule endoscopy is a purely diagnostic test. Wireless capsule endoscopy is justified for any of the following indications: overt and occult suspected small-bowel bleeding, including iron-deficiency anemia, diagnosis and surveillance of Crohn's disease, evaluation of refractory celiac disease, surveillance of polyposis syndromes, evaluation of suspected small-bowel tumors, and further evaluation of abnormal small-bowel imaging (ASGE/GIE, 2022).

Crohn's disease is a chronic inflammatory bowel disease (IBD) affecting the gastrointestinal tract, from the oral mucosa to the anus, with a particular predilection for the small intestine. It has been linked to low quality of life and a high rate of morbidity, and it frequently leads to problems that necessitate hospitalizations and surgical operations. In order to make a Crohn's disease diagnosis, a combination of medical history, physical examination, and complementary diagnostic tests are employed. Among these diagnostic tests is capsule endoscopy, which provides a safe, patient-friendly, and sensitive method for determining the accurate diagnosis and monitoring disease activity. Capsule endoscopy allows for reduced reading time, improved diagnostic accuracy, and enhanced image quality. It is especially crucial in Crohn's disease diagnosis and treatment, given its proclivity for the small intestine and the difficulty in assessing its length and tortuosity (Odeyinka, Alhashimi, Thoota, et al., 2022).

Celiac disease is an immune-mediated disorder triggered in genetically susceptible individuals by ingestion of foods that contain gluten. The prevalence of celiac disease in the United States has been estimated at approximately 1 percent, but it appears to be increasing for reasons that are unclear. Risk factors for celiac disease include family history, trisomy 21, Turner syndrome, Williams syndrome, and several autoimmune

diseases (including type 1 diabetes). Capsule endoscopy is only recommended as the initial diagnostic procedure in people unwilling or unable to undergo biopsy. Capsule endoscopy is a safe and accurate means of diagnosing celiac disease in adults who wish to avoid biopsy, although it has a 0.9- to 4.6-percent capsule retention rate. No data are available on how capsule endoscopy accuracy varies by population characteristics or setting (AHRQ, 2016).

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.

Wireless 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.

The downside of capsule endoscopy technology is that the captured 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.”

Hayes, Inc.

- Colon Capsule Endoscopy for Colorectal Cancer Screening, Diagnosis, and Surveillance
 - **C Rating** - For use of colon capsule endoscopy (CCE) for diagnosis or surveillance in adults with signs or symptoms of colorectal cancer (CRC) and risk factors for the disease. This Rating reflects an overall low-quality body of evidence suggesting that CCE is relatively safe and can detect most colorectal lesions and CRC. CCE may be a suitable alternative for patients who cannot tolerate or refuse to undergo conventional colonoscopy (CC) and for patients with an incomplete CC. However, uncertainty exists regarding the accuracy of CCE versus CC and versus computed tomography colonography. This Rating also reflects a paucity of evidence regarding the clinical utility of CCE for this indication.
 - **D2 Rating** - For use of CCE for screening for CRC in asymptomatic individuals at average risk of the disease. This Rating reflects very-low-quality evidence that is insufficient to draw conclusions regarding the clinical validity, clinical utility, and safety of CCE for screening for CRC in this patient population. Substantial uncertainty exists due to the lack of well-designed, long-term comparative studies of the effectiveness of CCE relative to established standards, particularly CC, and the role of this test in reducing CRC morbidity and mortality.
- PillCam Patency Capsule (Medtronic) to Assess Small Bowel Patency
 - Clinical Studies Level of Support - **Minimal**: A review of full-text clinical studies suggests minimal support for using the PillCam patency capsule for verifying small bowel patency in adult patients with known or suspected strictures prior to video capsule endoscopy. This level of support reflects:
 - Studies were of very poor or poor quality and retrospective in nature.
 - Three out of 4 studies did not have comparison groups and compared pretest-posttest metrics only.
 - Findings were generally positive for verification of functional patency; however, some results were confounded due to confirmatory radiographic imaging use in some protocols, even with a passing patency capsule screen.
 - Systematic Reviews Level of Support – **No/Unclear**: A review of full-text clinical studies suggests minimal support for using the PillCam patency capsule for verifying small bowel patency in adult patients with known or suspected strictures prior to video capsule endoscopy. This level of support reflects:
 - Studies were of very poor or poor quality and retrospective in nature.
 - Three out of 4 studies did not have comparison groups and compared pretest-posttest metrics only.
 - Findings were generally positive for verification of functional patency; however, some results were confounded due to confirmatory radiographic imaging use in some protocols, even with a passing patency capsule screen.
 - **Guidelines Level of Support – Strong Support For**: A review of full-text clinical studies suggests minimal support for using the PillCam patency capsule for verifying small bowel patency in adult patients with known or suspected strictures prior to video capsule endoscopy. This level of support reflects:
 - Studies were of very poor or poor quality and retrospective in nature.

- Three out of 4 studies did not have comparison groups and compared pretest-posttest metrics only.
- Findings were generally positive for verification of functional patency; however, some results were confounded due to confirmatory radiographic imaging use in some protocols, even with a passing patency capsule screen.

Coding Requirements

Procedure Codes

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

*Requires a Program Exception, see *Governing Bodies Approval* section above.

Non-Covered Procedure Codes

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

CPT Code	Description
91112	Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report
91113	Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), colon with interpretation and report.

Diagnosis Codes

ICD-10 Code	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
C7A.010	Malignant carcinoid tumor of the duodenum
C7A.011	Malignant carcinoid tumor of the jejunum
C7A.012	Malignant carcinoid tumor of the ileum
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
D37.2	Neoplasm of uncertain behavior of the small intestine
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
E16.4	Increased secretion of gastrin '
I77.6	Arteritis, unspecified
I85.00	Esophageal varices without bleeding
I85.01	Esophageal varices with bleeding
I85.10	Secondary esophageal varices without bleeding
I85.11	Secondary esophageal varices with bleeding
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
K55.1	Chronic vascular disorders of intestine
K55.21	Angiodysplasia of colon with hemorrhage
K57.01	Diverticulosis 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
K63.81	Dieulafoy lesion of intestine
K90.0	Celiac disease
K90.49	Malabsorption due to intolerance, not elsewhere classified
K92.1	Melena
K92.2	Gastrointestinal hemorrhage, unspecified
Q43.0	Meckel's diverticulum (displaced) (hypertrophic)
Q85.8	Other phakomatoses, not elsewhere classified

Reimbursement

Participating facilities will be reimbursed per their Highmark WholecareSM contract.

Reference Sources

Pennsylvania Department of Human Services. Technology Assessment Group (TAG) Coverage Decisions. Managed Care Operations Memorandum: OPS # 05/2010-009; Wireless Capsule Endoscopy (Colon). Option #4. Accessed on November 14, 2023.

Pennsylvania Department of Human Services. Technology Assessment Group (TAG) Coverage Decisions. Managed Care Operations Memorandum: HCALL-07-2005-017; Wireless Capsule Endoscopy (Gastrointestinal tract imaging, intraluminal, esophagus thru ileum, with physician interpretation & report). Option #3. Accessed on November 14, 2023.

U.S. Food and Drug Administration. K123666. PillCam Colon 2 Capsule Endoscopy System. Accessed on October 29, 2021.

American College of Gastroenterology (ACG). ACG Clinical Guidelines: Diagnosis and Management of Celiac Disease. Am J Gastroenterol. 2013. Accessed on October 29, 2021.

Hasler WL. Gastroparesis: pathogenesis, diagnosis and management. Nat Rev Gastroenterol Hepatol. July 19, 2011. Accessed on October 29, 2021.

Camilleri M, Parkman H, Shafi M, Abell T, Gerson L. American Journal of Gastroenterology. Clinical guideline: management of gastroparesis. Volume 108, Issue 1. January 2013. Accessed on October 29, 2021.

Colli A, Gana JC, Turner D, et al. Capsule endoscopy for the diagnosis of oesophageal varices in people with chronic liver disease or portal vein thrombosis. Cochrane Database of Systemic Reviews. 2014. Accessed on October 29, 2021.

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. Accessed on October 29, 2021.

Fleischer DE. Capsule endoscopy: the voyage is fantastic-will it change what we do? *American Society of Gastrointestinal Endoscopy*. 2002. Accessed on October 29, 2021

Waterman M, Gralnek IM. Capsule endoscopy of the esophagus. *J Clin Gastroenterol*. August 2009. Accessed on October 29, 2021.

Arguelles-Arias F, Rodriguez-Oballe J, Duarte-Chang C, et al. Capsule endoscopy in the small bowel Crohn's disease. *Gastroenterology Research and Practice*. 2014. Accessed on October 29, 2021.

The Centers for Disease Control and Prevention (CDC). DPDx-Laboratory identification of parasites of public health concern. Last review on September 17, 2019. Accessed on October 29, 2021.

Centers for Medicare and Medicaid Services (CMS). Local Coverage Article (LCA) Billing and Coding: Wireless Capsule Endoscopy (A57753). Effective date November 21, 2019. Revision Effective date January 1, 2022. Accessed on November 13, 2023.

Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD) Wireless Capsule Endoscopy (L35089). Original Effective date October 1, 2015. Revision Effective date November 21, 2019. Accessed on November 13, 2023.

Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) Endoscopy (100.2). Accessed on November 13, 2023.

Enns RA, Hookey L, Armstrong D, Bernstein CN, Heitman SJ, Teshima C, Leontiadis GI, Tse F, Sadowski D. Clinical Practice Guidelines for the Use of Video Capsule Endoscopy. *Gastroenterology*. February 1, 2017. Accessed on October 29, 2021.

Bandorski D, Kurniawan N, Baltes P, et al. Contraindications for video capsule endoscopy. *World J Gastroenterol*. 2016. Accessed on October 29, 2021.

Hayes, Inc. Health Technology Assessment: Colon Capsule Endoscopy for Colorectal Cancer Screening, Diagnosis, and Surveillance. November 25, 2019. Annual Review November 9, 2022. Accessed on November 13, 2023.

Hayes, Inc. Evolving Evidence Review: PillCam Patency Capsule (Medtronic) to Assess Small Bowel Patency. April 26, 2022. Annual Review May 17, 2023. Accessed on November 13, 2023.

Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults, *American Journal of Gastroenterology*. April 2018. Accessed October 29, 2021.

American Society for Gastrointestinal Endoscopy (ASGE)/Gastrointestinal Endoscopy (GIE). Quality indicators for capsule endoscopy and deep enteroscopy. 2022. Accessed on November 2, 2022.

Agency for Healthcare Research and Quality (AHRQ). Diagnosis of Celiac Disease: Current State of the Evidence. July 2016. Accessed on November 2, 2022.

Odeyinka O, Alhashimi R, Thoota S, et al. The Role of Capsule Endoscopy in Crohn's Disease: A Review. July 25, 2022. Accessed on November 2, 2022.