Capsule Endoscopy

Policy Number: MMP036.13
Last Committee Approval Date: March 12, 2025
Effective Date: April 1, 2025

➲ Instructions for Use

Table of Contents **Page**

Related Medicare Advantage Medical Policy

- Gastroesophageal and Gastrointestinal (GI) Services and Procedures

Coverage Rationale

Overview

Wireless Capsule Endoscopy (WCE) requires that the patient ingest a small capsule containing a disposable light source, miniature color video camera, battery, antenna, and a data transmitter. The self-contained capsule is made of specially sealed biocompatible material that is resistant to the digestive fluids throughout the gastrointestinal (GI) tract. Following ingestion of the capsule, natural contraction and relaxation of the GI tract propels the capsule forward. The camera contained in the capsule records images as it travels through the digestive system. During the entire procedure, the patient wears a data recorder around the waist, which captures and stores images transmitted by the capsule's camera. After completion of the procedure, the patient data recorder is connected to a computer workstation where the images are downloaded, reviewed, and interpreted by the physician. The procedure lasts approximately five minutes for observing the esophageal mucosa and approximately 8 hours when observing intestinal mucosa. The capsule is designed to be disposable and is excreted naturally from the body.

A Wireless Gastrointestinal Motility Monitoring System is an ingestible capsule with the trade name SmartPill®. The SmartPill® records data enabling the estimation of regional and total gastrointestinal motility. The device is Food and Drug Administration (FDA) approved to evaluate patients with suspected delayed gastric emptying and the evaluation of colonic transit time in patients with chronic idiopathic constipation. The capsule device measures pH, temperature, and pressure while traveling through the gastrointestinal (GI) tract, sending the data to a wireless receiver worn on or near the patient. The data can be used to determine GI motility, gastric emptying, small bowel transit, colonic transit, and whole gut transit times. The capsule can also provide pressure patterns within the GI tract. The study can be done in a physician office after the patient has discontinued use of all medications that affect the GI tract.

Wireless Capsule Endoscopy (WCE)

Medicare does not have a National Coverage Determination (NCD) for wireless capsule endoscopy (WCE).

Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for Wireless Capsule Endoscopy (WCE).

For coverage guidelines for states/territories with no LCDs/LCAs, refer to the coverage rationale below.

Wireless capsule endoscopy of the esophagus is reasonable and necessary when all of the following criteria are met:

- Patient diagnosed with portal hypertension who requires immediate evaluation of esophageal varices; **and**

- The esophageal capsule endoscopy is performed in lieu of conventional endoscopy because the provider who would perform the endoscopy has determined that the patient's current medical condition prohibits a conventional endoscopy.

Performance of wireless capsule endoscopy of the esophagus for any other reason is not reasonable and necessary.

Wireless capsule endoscopy of the small bowel is reasonable and necessary when either of the following criteria are met:
- Initial diagnosis of suspected Crohn's Disease when there is no evidence provided by conventional diagnostic tests such as small bowel follow-through (SBFT), and upper and lower endoscopy; or
- Documented continuous blood loss and anemia secondary to obscure bleeding of the small bowel; and any of the following:
  - The site of bleeding could not be previously identified by colonoscopy, or endoscopy; or
  - Radiographic exams of the small bowel have failed to reveal a source; or
  - Intraoperative enteroscopy is being considered.

Wireless capsule endoscopy is not reasonable and necessary in any of the following situations:
- Colorectal cancer screening.
- Confirmation of lesions of pathology normally within the reach of upper and lower endoscopes (proximal to the ligament of Treitz, or distal to the ileum).
- Patients in whom a radiological exam of the small bowel has confirmed an intestinal blockage, a significantly narrow small bowel, or an abnormal connection between the bowel and another organ. An x-ray exam of the small bowel should be done if there is concern that it may be too narrow for the camera.
- Patients with a cardiac pacemaker, or other implanted electromagnetic devices.
- When carried out by Food and Drug Administration (FDA) non-approved devices.
- When performed by physicians not trained in endoscopy or for independent diagnostic testing facilities, which are not under the general supervision of a physician trained in endoscopy procedures.

Patency Capsule Testing is not reasonable and necessary. Sufficient peer-reviewed literature supporting its use is not currently available. On occasion Patency Capsule Testing has been reported to cause obstruction requiring urgent intervention.

Wireless Gastrointestinal Motility Monitoring System

Medicare does not have a NCD for wireless gastrointestinal motility monitoring system.

LCDs/LCAs exist and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for Wireless Gastrointestinal Motility Monitoring System.

For coverage guidelines for states/territories with no LCDs/LCAs, refer to the coverage rationale below.

The Wireless Motility Capsule (WMC) has been studied in many centers. The capsule does not use radioactive materials and has minimal safety risks. This device is reasonable and necessary when all of the following criteria are met:
- It is used by a gastroenterologist trained to use and interpret the results; and
- Basic clinical investigations, including endoscopy, have failed to elucidate a diagnosis; and
  - It is used to evaluate and/or treat patients with suspected gastroparesis of any nature; or
  - It is used to evaluate colonic transit in patients with chronic idiopathic constipation lasting over 6 months.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service; however, language may be included in the listing below to indicate if a code is non-covered. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
Wireless Capsule Endoscopy (WCE)	
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
91299	Unlisted diagnostic gastroenterology procedure
Wireless Gastrointestinal Motility Monitoring System	
91112	Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report

CPT® is a registered trademark of the American Medical Association

Diagnosis Code	Description
For CPT Code 91110	
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
C78.4	Secondary malignant neoplasm 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
C7A.019	Malignant carcinoid tumor of the small intestine, unspecified portion
D01.40	Carcinoma in situ of unspecified part of intestine
D01.49	Carcinoma in situ of other parts of intestine
D12.0	Benign neoplasm of cecum
D12.1	Benign neoplasm of appendix
D12.2	Benign neoplasm of ascending colon
D12.3	Benign neoplasm of transverse colon
D12.4	Benign neoplasm of descending colon
D12.5	Benign neoplasm of sigmoid colon
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
D37.1	Neoplasm of uncertain behavior of stomach
D37.2	Neoplasm of uncertain behavior of small intestine
D37.3	Neoplasm of uncertain behavior of appendix
D37.4	Neoplasm of uncertain behavior of colon
D37.5	Neoplasm of uncertain behavior of rectum
D3A.010	Benign carcinoid tumor of the duodenum
D3A.011	Benign carcinoid tumor of the jejunum

Diagnosis Code	Description
For CPT Code 91110	
D3A.012	Benign carcinoid tumor of the ileum
D3A.019	Benign carcinoid tumor of the small intestine, unspecified portion
D50.0	Iron deficiency anemia secondary to blood loss (chronic)
D50.9	Unspecified iron deficiency anemia
D62	Acute posthemorrhagic anemia
D72.89	Other specified disorders of white blood cells
E16.4	Increased secretion of gastrin
I77.6	Arteritis, unspecified
I85.00	Esophageal varices without bleeding
I85.10	Secondary esophageal varices without bleeding
I89.0	Lymphedema, not elsewhere classified
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 complications
K50.011	Crohn's disease of small intestine with rectal bleeding
K50.012	Crohn's disease of small intestine with intestinal obstruction
K50.013	Crohn's disease of small intestine with fistula
K50.014	Crohn's disease of small intestine with abscess
K50.018	Crohn's disease of small intestine with other complication
K50.019	Crohn's disease of small intestine with unspecified complications
K50.10	Crohn's disease of large intestine without complications
K50.111	Crohn's disease of large intestine with rectal bleeding
K50.112	Crohn's disease of large intestine with intestinal obstruction
K50.113	Crohn's disease of large intestine with fistula
K50.114	Crohn's disease of large intestine with abscess
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 complications
K50.811	Crohn's disease of both small and large intestine with rectal bleeding
K50.812	Crohn's disease of both small and large intestine with intestinal obstruction
K50.813	Crohn's disease of both small and large intestine with fistula
K50.814	Crohn's disease of both small and large intestine with abscess
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
K50.912	Crohn's disease, unspecified, with intestinal obstruction
K50.913	Crohn's disease, unspecified, with fistula
K50.914	Crohn's disease, unspecified, with abscess
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
K52.21	Food protein-induced enterocolitis syndrome

Diagnosis Code	Description
For CPT Code 91110	
K52.22	Food protein-induced enteropathy
K52.29	Other allergic and dietetic gastroenteritis and colitis
K52.3	Indeterminate colitis
K52.81	Eosinophilic gastritis or gastroenteritis
K52.82	Eosinophilic colitis
K52.89	Other specified noninfective gastroenteritis and colitis
K52.9	Noninfective gastroenteritis and colitis, unspecified
K55.011	Focal (segmental) acute (reversible) ischemia of small intestine
K55.012	Diffuse acute (reversible) ischemia of small intestine
K55.019	Acute (reversible) ischemia of small intestine, extent unspecified
K55.021	Focal (segmental) acute infarction of small intestine
K55.022	Diffuse acute infarction of small intestine
K55.029	Acute infarction of small intestine, extent unspecified
K55.051	Focal (segmental) acute (reversible) ischemia of intestine, part unspecified
K55.052	Diffuse acute (reversible) ischemia of intestine, part unspecified
K55.059	Acute (reversible) ischemia of intestine, part and extent unspecified
K55.061	Focal (segmental) acute infarction of intestine, part unspecified
K55.062	Diffuse acute infarction of intestine, part unspecified
K55.069	Acute infarction of intestine, part and extent unspecified
K55.1	Chronic vascular disorders of intestine
K55.20	Angiodysplasia of colon without hemorrhage
K55.21	Angiodysplasia of colon with hemorrhage
K55.30	Necrotizing enterocolitis, unspecified
K55.31	Stage 1 necrotizing enterocolitis
K55.32	Stage 2 necrotizing enterocolitis
K55.33	Stage 3 necrotizing enterocolitis
K56.1	Intussusception
K56.51	Intestinal adhesions [bands], with partial obstruction
K56.600	Partial intestinal obstruction, unspecified as to cause
K56.601	Complete intestinal obstruction, unspecified as to cause
K56.609	Unspecified intestinal obstruction, unspecified as to partial versus complete obstruction
K56.690	Other partial intestinal obstruction
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
K58.0	Irritable bowel syndrome with diarrhea
K58.9	Irritable bowel syndrome without diarrhea
K63.3	Ulcer of intestine
K63.5	Polyp of colon
K63.81	Dieulafoy lesion of intestine
K70.2	Alcoholic fibrosis and sclerosis of liver

Diagnosis Code	Description
For CPT Code 91110	
K70.30	Alcoholic cirrhosis of liver without ascites
K70.31	Alcoholic cirrhosis of liver with ascites
K74.01	Hepatic fibrosis, early fibrosis
K74.02	Hepatic fibrosis, advanced fibrosis
K74.3	Primary biliary cirrhosis
K74.4	Secondary biliary cirrhosis
K74.60	Unspecified cirrhosis of liver
K74.69	Other cirrhosis of liver
K76.6	Portal hypertension
K90.0	Celiac disease
K90.41	Non-celiac gluten sensitivity
K90.49	Malabsorption due to intolerance, not elsewhere classified
K90.89	Other intestinal malabsorption
K91.31	Postprocedural partial intestinal obstruction
K92.0	Hematemesis
K92.1	Melena
K92.2	Gastrointestinal hemorrhage, unspecified
Q85.81	PTEN hamartoma tumor syndrome
Q85.82	Other Cowden syndrome
Q85.83	Von Hippel-Lindau syndrome
Q85.89	Other phakomatoses, not elsewhere classified
Q85.9	Phakomatosis, unspecified
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, unspecified
R93.3	Abnormal findings on diagnostic imaging of other parts of digestive tract
For CPT Code 91111	
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
K70.2	Alcoholic fibrosis and sclerosis of liver
K70.30	Alcoholic cirrhosis of liver without ascites
K70.31	Alcoholic cirrhosis of liver with ascites

Diagnosis Code	Description
For CPT Code 91111	
K74.00	Hepatic fibrosis, unspecified
K74.01	Hepatic fibrosis, early fibrosis
K74.02	Hepatic fibrosis, advanced fibrosis
K74.3	Primary biliary cirrhosis
K74.4	Secondary biliary cirrhosis
K74.5	Biliary cirrhosis, unspecified
K74.60	Unspecified cirrhosis of liver
K74.69	Other cirrhosis of liver
K76.6	Portal hypertension
For CPT Code 91112	
K31.84	Gastroparesis
K31.9	Disease of stomach and duodenum, unspecified
K58.1	Irritable bowel syndrome with constipation
K58.2	Mixed irritable bowel syndrome
K58.8	Other irritable bowel syndrome
K59.01	Slow transit constipation
K59.03	Drug induced constipation
K59.04	Chronic idiopathic constipation
K59.2	Neurogenic bowel, not elsewhere classified
R11.10	Vomiting, unspecified

Centers for Medicare and Medicaid Services (CMS) Related Documents

After checking the table below and searching the Medicare Coverage Database, if no NCD, LCD, or LCA is found, refer to the criteria as noted in the Coverage Rationale section above.

NCD	LCD	LCA	Contractor Type	Contractor Name
Wireless Capsule Endoscopy (WCE)				
N/A	L34081 Endoscopy by Capsule	A56461 Billing and Coding: Endoscopy by Capsule	Part A and B MAC	CGS
	L33774 Wireless Capsule Endoscopy	A56704 Billing and Coding: Wireless Capsule Endoscopy	Part A and B MAC	First Coast
	L35089 Wireless Capsule Endoscopy	A57753 Billing and Coding: Wireless Capsule Endoscopy	Part A and B MAC	Novitas**
	L36427 Wireless Capsule Endoscopy	A56727 Billing and Coding: Wireless Capsule Endoscopy	Part A and B MAC	Palmetto**
Wireless Gastrointestinal Motility Monitoring System				
N/A	L33455 Wireless Gastrointestinal Motility Monitoring Systems	A56724 Billing and Coding: Wireless Gastrointestinal Motility Monitoring Systems	Part B MAC	Palmetto**

Medicare Administrative Contractor (MAC) With Corresponding States/Territories	
MAC Name (Abbreviation)	**States/Territories**
CGS Administrators, LLC (CGS)	KY, OH
First Coast Service Options, Inc. (First Coast)	FL, PR, VI
National Government Services, Inc. (NGS)	CT, IL, ME, MA, MN, NH, NY, RI, VT, WI
Noridian Healthcare Solutions, LLC (Noridian)	AS, AK, AZ, CA, GU, HI, ID, MT, NV, ND, Northern Mariana Islands, OR, SD, UT, WA, WY
Novitas Solutions, Inc. (Novitas)	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX, VA**
Palmetto GBA (Palmetto)	AL, GA, NC, SC, TN, VA**, WV
Wisconsin Physicians Service Insurance Corporation (WPS)*	IA, IN, KS, MI, MO, NE
Notes	
*Wisconsin Physicians Service Insurance Corporation: Contract Number 05901 applies only to WPS Legacy Mutual of Omaha MAC A Providers. **For the state of Virginia: Part B services for the city of Alexandria and the counties of Arlington and Fairfax are excluded for the Palmetto GBA jurisdiction and included within the Novitas Solutions, Inc. jurisdiction.	

Clinical Evidence

Wireless Capsule Endoscopy (WCE)

Jiang et al. (2024) conducted a prospective, multi-center diagnostic accuracy study (CENTERS) to evaluate the diagnostic accuracy and safety of using magnetically guided capsule endoscopy with a detachable string (ds-MCE) for detecting and grading esophagogastric varices in adults with cirrhosis. The study included 14 medical centers in China with 607 adults (median age 55.0, 68.4% male) with cirrhosis who were consecutively recruited to undergo ds-MCE (index test) first, then esophagogastroduodenoscopy (EGD; reference test) within 48 hours of the ds-MCE. The certified operators performing the ds-MCE and the endoscopists performing the EGD were blinded to the results of the other test. The authors reported that ds-MCE and EGD examinations were completed in 582 (95.9%) of the 607 participants and that ds-MCE had a sensitivity of 97.5% and specificity of 97.8% for detecting esophagogastric varices when EGD is used as the reference standard. The authors also reported that results were inconsistent between the two procedures in 14 participants as esophagogastric varices were detected by ds-MCE but not confirmed by EGD in four participants, and ds-MCE failed to detect esophagogastric varices detected by EGD in 10 participants. When the authors applied the 18% threshold found in the validation cohort, the diagnostic accuracy of ds-MCE for detecting high risk esophagogastric varices was 96.4%, for esophageal varices was 96.6%, and for gastric varices was 96.7%. In the 510 participants that completed a ds-MCE examination of the small bowel, the authors reported portal hypertensive enteropathy was found in 333 (65.3%) of the participants, with spontaneous bleeding in three (0.6%) of the participants. The authors reported two serious adverse events that occurred with EGD with both participants requiring hospital admission and endoscopic band ligation; however, no serious adverse events occurred with ds-MCE. There were four adverse events that occurred during ds-MCE including one each of capsule retention in the small bowel, capsule retention in the esophagus, syncope related to glucopenia associated with the gastrointestinal preparation, and rupture and bleeding of hemorrhoids related to small bowel preparation. Limitations of the study included the small number of participants that failed to swallow the capsule endoscope and detachable string, the high percentage of participants that had cirrhosis related to hepatitis B virus which resulted in unavoidable selection bias, the influence of the order effect related to ds-MCE always occurring before EGD, and the different approaches for how the size of esophageal varices were measured between ds-MCE and EGD. The authors concluded that their findings suggest that ds-MCE is highly accurate and safe as a diagnostic tool for detecting and grading esophagogastric varices, and that it is a promising alternative to EGD for screening and surveillance of esophagogastric varices in patients with cirrhosis.

Cortegoso Valdivia et al. (2022) conducted a systematic review and meta-analysis to evaluate performance measures such as completion, detection, and retention rates of capsule endoscopy (CE). The literature search included all capsule types (capsule for the small bowel (SBCE), double-headed capsule for the colon (CCE) or PillCam®Crohn's capsule (PCC), magnetically controlled capsule endoscopy (MCCE), esophageal capsule (ESO) and patency capsule (PC) resulting in the inclusion of 328 studies (122 retrospective and 206 prospective) with 86,930 patients who underwent CE. The authors reported that the most used capsule type was SBCE in 236 studies and that obscure GI bleeding (OGIB) was the most common indication (n = 44,750), followed by clinical symptoms (CS; n = 17,897), Crohn's disease (CD; n = 11,299), neoplastic lesions (NL; n = 4989) and celiac disease (CeD; n = 947). The authors also reported that the pooled detection rate (DR) was 59%, and the DR differed significantly by capsule type with the highest rate for PCC

(DR = 0.693), then CCE (DR = 0.643); however, the authors noted that, in the indication subgroup analyses, there were no significant differences in DRs by capsule type. With regards to the completion rate (CR), the authors reported a pooled CR of 89.6% with OGIB and CD subgroup analyses by capsule type demonstrating no significant differences in CRs; however, the CRs for NL, and CS differed significantly by capsule type with the highest rates for CCE (NL: CR = 0.921) and MCCE (CS: CR = 0.997). Finally, the pooled capsule retention rate (RR) was 2% according to the authors, and the RRs did not differ significantly by capsule types in the OGIB and CD indication groups while there were significant differences for other indications, including NL and CS when the lowest RRs were for PC (RR = 002), and for CCE (RR = 0.008) and MCCE (RR = 0.01). Limitations of this study include the heterogeneity of the included studies, the exclusion of studies with less than 30 participants, and that the meta-regression was performed at a study level which did not allow for further analyses on the demographic data. The authors concluded that pooled DR, CR, and RR were acceptable for all capsule types and that technological advancements have expanded the scope of CCE devices in detecting gastrointestinal pathology with acceptable rates for a complete examination.

A Hayes Evolving Evidence Review (2022, updated 2024) on the dissolvable PillCam patency capsule and its predecessors stated that there is potential for the device to prevent insoluble video capsule retention in most patients at high risk of non-patency by identifying them prior to undergoing capsule endoscopy; however, the small amount of evidence showed incidence of false-negative and false-positive results. Hayes reviewed full-text clinical studies and found that they suggested minimal support for using the PillCam patency capsule as the studies were of very poor or poor quality and retrospective in nature, that the majority (three out of four studies) did not have comparison groups and compared pretest-posttest metrics only, and that the findings were generally positive for verification of functional patency but that some results were confounded due to confirmatory radiographic imaging use in some study protocols. Hayes did not find any published systematic reviews to review but there was strong support for the use of PillCam patency capsule from clinical practice guidelines and position statements who based their guidance on their own evidence evaluation processes. In their review, Hayes found that patency capsule retention prior to dissolving may cause abdominal pain and intestinal obstruction. Hayes stated that guidance on routine use of patency capsules prior to capsule endoscopy varied based on patient clinical history as it relates to risk level for preexisting intestinal stricture, such as in Crohn's disease and obscure gastrointestinal bleeding.

In a 2021 Hayes Evidence Analysis Research Brief on the use of the patency capsule to verify small bowel patency prior to capsule endoscopy, Hayes reviewed 11 abstracts including two comparative studies, one case-control study and eight single-arm studies. Patency capsules were compared with small bowel cross-sectional imaging, radiological tests or no imaging and the study population mainly consisted of patients with known or suspected small bowel stenosis or Crohn's disease; however, there was one study that evaluated the use of patency capsules in patients with seronegative spondyloarthropathy that did not have any symptoms or signs of intestinal stenosis.

In their systematic review and meta-analysis evaluating the efficacy of WCE for screening and diagnosing esophageal varices in patients with portal hypertension (PH), McCarty et al. (2017) analyzed 17 studies with 1328 adults (age range 20 to 88 years old). Most of the studies were assessed to have a low risk of bias although, in eight studies, a high risk of bias was found. The authors reported that the diagnostic accuracy of WCE in the diagnosis esophageal varices was 90% and that the diagnostic pooled sensitivity and specificity were 83% and 85%, respectively. The authors also reported that, when subgroup analysis was performed with the seven studies that evaluated the grading of medium to large varices, the diagnostic accuracy was 92%, the sensitivity was 72%, and the specificity was 91%. When the authors completed a sensitivity analysis that excluded the eight studies with high risk of bias, they reported finding a diagnostic accuracy of 85%, sensitivity of 80% and specificity of 86% and that, when evaluating the grading of medium and large varices, the diagnostic accuracy was 92%, the sensitivity was 79%, and the specificity was 89%. Limitations of the study include the heterogeneity of the inclusion criteria for participants and the individual study designs, the use of both first generation and second generation wireless capsules, and the high number of studies (eight of the 17) with high risk of bias. The authors concluded that WCE of the esophagus is well tolerated and safe in patients with liver cirrhosis and suspicion of PH; however, the sensitivity of the WCE is not currently sufficient to replace endogastroduodenoscopy (EGD) as first line screening in these patients although, it may have a role in cases of refusal or contraindication to EGD. The authors stated that more studies are needed to further evaluate the role of WCE for patients with portal hypertension.

Yung et al. (2017) conducted a systematic review and meta-analysis to evaluate clinical outcomes of negative small-bowel capsule endoscopy (SBCE) for small-bowel bleeding. Twenty-six studies with a total of 3,657 patients who underwent SBCE for obscure GI bleeding (OGIB) were included in the review. Pediatric studies (patients age < 18 years) and studies that did not detail patient follow-up and/or rebleeding episodes were among those excluded. Most studies were classified as high quality. The primary outcome measured was the pooled odds ratios (ORs) for rebleeding after a negative CE for OGIB. The authors reported the pooled rate of rebleeding after negative CE was 19%. The pooled OR of rebleeding was .59, indicating a lower risk of rebleeding after a negative CE. The effect was more pronounced in studies with a short (< 2 years) follow-up. There was no statistically significant difference in rebleeding after CE for occult versus

overt OGIB. Prospective studies showed a lower OR of rebleeding of .24. The authors concluded that negative CE provides adequate evidence of a subsequently low risk of rebleeding. Therefore, such patients can be safely managed with watchful waiting. However, the authors recommend that patients who rebleed after two years may need to be investigated for a new source of blood loss. Limitations include the study design consisting of largely retrospective studies with varying follow-up lengths.

Hayes published a Health Technology Assessment in 2017 (updated 2021) that addressed capsule endoscopy (CE), also called wireless capsule endoscopy or video capsule endoscopy, for the diagnosis of small bowel Crohn's disease (CD). The assessment included nine cohort studies and eight cross-sectional studies that evaluated the capacity of CE to detect CD in patients with suspected disease, to detect CD activity in patients with a prior diagnosis of CD, and/or to evaluate the influence of CE on patient management. Hayes reported that, overall, CE has been found to provide about the same or somewhat better diagnostic information than competing technologies and that the evidence was of moderate quality that CE is safe and is equivalent to, or superior to other imaging techniques for the identification of disease activity, or of recurrence in the small bowel of patients with known CD. Hayes stated the evidence that CE improves patient management and health outcomes was of low-quality. Hayes also concluded that CE was safe and equivalent or superior to other imaging techniques for the diagnosis of CD in the small bowel when there is a clinical suspicion of disease and equivocal findings on endoscopy or on other standard diagnostic tests based on the moderate quality of the studies reviewed.

In their 2013 (updated 2017) Health Technology Assessment on the use of capsule endoscopy (CE) of the small bowel for obscure gastrointestinal (GI) bleeding, Hayes reviewed 25 studies, consisting of 17 prospective studies that compared CE, also called wireless capsule endoscopy, with other small bowel investigations, two randomized comparative studies that evaluated two different capsule endoscopes, and six case series and chart reviews that evaluated CE for obscure GI bleeding (OGIB)/iron deficiency anemia (IDA). The studies compared CE with double-balloon endoscopy (nine studies), push enteroscopy (three studies), computed tomography (CT) (two studies), angiography (one study), small bowel follow through (SBFT) (one study), intraoperative enteroscopy (one study), and another CE device (two studies). Hayes reported that a small number of studies compared the diagnostic performance of CE with alternative investigations and these studies showed that CE had higher sensitivity (92%-100%) and lower specificity (48%) compared with push enteroscopy (56%-69% and 80%, respectively). Hayes also reported that the studies showed that CT had significantly better sensitivity (88%) than CE (38%). However, Hayes stated that the number of studies was too small to form definitive conclusions regarding the comparative diagnostic performance of CE versus these alternative small bowel investigations. All of the studies evaluated the diagnostic yield of CE for OGIB, although the diagnostic yield varied (range from 30% to 88%) among studies reflecting the confounding factors that might have impacted the diagnostic yield. Hayes also reported that 13 studies reported on rates of incomplete small bowel imaging where the CE failed to reach the colon in 4% to 34% of procedures and CE failed completely due to technical difficulties in 0.6% to 9.7% of procedures. The quality of evidence was of moderate quality, according to Hayes and study limitations, such as small sample sizes (for prospective studies), the lack of well-defined reference standards, lack of blinding, and lack of standardized follow-up in some studies, were the primary factors reducing the overall evidence quality. However, Hayes reported that the settings and patient populations were representative of those in clinical practice, thus the results were applicable to the United States healthcare environment. Hayes concluded that CE could be used as a first-line investigation of the small bowel to guide treatment or select patients for alternative investigations, and that CE was relatively safe but that patients with bowel obstructions should not receive CE due to the risk of capsule retention, which was the most important complication.

Clinical Practice Guidelines

American Gastroenterological Association (AGA)

The AGA's position statement on obscure gastrointestinal (GI) bleeding (Raju, 2007) recommends capsule endoscopy as the third test in the evaluation of patients with occult GI blood loss and iron deficiency anemia. Once all of the findings on standard examinations including esophagogastoduodenoscopy (EGD) and colonoscopy are negative, the blood loss is presumed to be from the small bowel. The authors reported that in patients with active bleeding, capsule endoscopy can confirm the small bowel as the source of bleeding. If the capsule endoscopy findings are negative for the small bowel, the study may suggest that the active bleed is rather colonic or gastric in origin. In the patient with an active bleed within the small bowel, the capsule findings will guide subsequent evaluation and therapy. Additionally, in patients with obscure GI bleeding and negative findings on capsule endoscopy, further invasive investigations can be deferred.

American Society for Gastrointestinal Endoscopy (ASGE) and American College of Gastroenterology (ACG)

In a consensus document on quality indicators for capsule endoscopy and deep enteroscopy, the ASGE and the ACG stated that all patients undergoing capsule endoscopy (CE) should be evaluated for risk factors for capsule retention, including Crohn's disease, history of small-bowel obstruction or previous resection, previous abdominal or pelvic

radiotherapy, chronic use of a high dose of nonsteroidal anti-inflammatory medications, and known stricture or mass. If any of these conditions are present or the patient has symptoms concerning for obstruction, results from a patency capsule test, a computed tomography (CT) or magnetic resonance (MR) enterography procedure, or a combination of these procedures should be obtained before standard capsule administration with CT or MR enterography being the preferred methods. The authors stated that a patency capsule test is preferred if NSAID-associated diaphragmatic strictures are suspected because they may be missed by cross-sectional imaging and that a patency capsule test should be performed if concerns remain, even if CT or MR enterography shows no obstructive areas in patients with Crohn's disease. In regards to the diagnostic yield of CE, the ASGE and the ACG stated that the procedure should be performed within 48 hours for hospitalized patients with overt, suspected small-bowel bleeding. The diagnostic yield of CE is more than 90% when administered within 48 hours. For outpatients, performance of CE within 14 days of a bleeding episode also improves diagnostic yield (Leighton, 2022).

Wireless Gastrointestinal Motility Monitoring System

Eriksson et al. (2023) conducted a retrospective, single center study to assess the impact of objective regional and whole gut motility data on the outcomes of anti-reflux surgery (ARS) to evaluate whether there is a relationship between colonic dysmotility and suboptimal surgical outcomes. The study included 48 adults (87.5% female; mean age 53.0 years) who underwent wireless motility capsule (WMC) testing before undergoing ARS (Nissen fundoplication [n = 29, mean age 57.0 years, 63% female] and magnetic sphincter augmentation [n = 19, mean age 44.0 years, 57% female]). The study analyzed transit times, motility, and pH data obtained from different GI tract regions to determine factors that impact surgical outcomes with a favorable outcome defined as a complete resolution of the predominant reflux symptom and freedom from antisecretory medications. The authors reported that, at follow-up (mean 16.8 +/-13.2 months), 89.6% of patients had complete resolution of their predominant preoperative symptom, 93.7% were free from use of antisecretory medications and that favorable outcomes were achieved in 87.5% of all patients. The authors also reported that patients with unfavorable outcomes had significantly longer median whole gut transit times (76.9 vs 47.8) mean whole gut transit times (92.0 hours vs. 55.7 hours), colonic transit times (78.6 hours vs. 47.3 hours), higher mean peak colonic pH (8.8 vs. 8.15) and higher mean antral motility indexes (310 vs. 90). Limitations of the study include the single center design, the limited sample size, the retrospective approach, and the lack of randomization. The authors concluded that the study demonstrated that objective colonic dysmotility leads to suboptimal outcomes after ARS and that WMC testing can assist with preoperative risk assessment and counseling for patients seeking ARS. The authors recommended RCTs and large volume studies to fully assess the utility of WMC in practice.

A Hayes Health Technology Assessment (2023) evaluated the use of wireless capsule systems for the diagnosis and guidance of the management of gastroparesis with a review of nine clinical studies (three prospective cross-sectional studies, three retrospective pretest-posttest studies, and one each of a prospective cohort study, a prospective comparative case control and a retrospective cross-sectional study). These studies evaluated the clinical validity of the SmartPill Wireless GI Motility System based on measures between WCE and another established technique, or sensitivity and specificity of WCE for detection of gastroparesis. Hayes reported that four of the studies evaluated the clinical utility of WCE based on how it influenced patient management and that one study reported on how changes in management affected patient outcomes. Study participants were adults with an average age of 39 to 47 years who primarily had symptoms of gastroparesis. Two of the studies also enrolled patients with symptoms of small or large bowel motility disorders, and one study enrolled healthy adults who were assumed to be negative for gastroparesis. Hayes also reported that the results from six clinical validity studies suggested that WCE and gastric scintigraphy do not consistently provide highly similar results as five of the studies found that agreement ranged from 53% to 86%. The quality of evidence in this Health Technology Assessment was divided into three tiers including individual studies (quality rating of fair to poor), outcomes (quality was rated from low to very low), and overall evidence (quality rating of very low). Hayes concluded that the overall very low-quality body of evidence suggested that WCE was reasonably safe, but the evidence was insufficient to support conclusions concerning effectiveness of WCE when compared to established techniques for diagnosing and guiding management of gastroparesis.

Sangnes et al. (2020) conducted a prospective, single-center study to compare wireless motility capsule (WMC) with gastric emptying scintigraphy (GES) to assess diabetic gastroparesis. The study included 72 adults (n = 49 women, average age 50 years) with diabetes mellitus (n = 59 with Type 1) who presented with symptoms consistent with gastroparesis. Each patient was previously examined with upper endoscopy to rule out obstructing lesions or other pathology explaining their symptoms prior to simultaneously undergoing WMC and GES. Symptoms were assessed with the Patient Assessment of Upper Gastrointestinal Symptom Severity Index (PAGI-SYM) questionnaire, and its subset Gastroparesis Cardinal Symptom Index (GCSI). One of the participants did not complete the GES, four participants did not complete the WMC, and the WMC gastric emptying time (WMC GET) was not able to be defined in one patient, resulting in the results of 66 participants being included in the test comparison. The authors reported that WMC and GES correlated r = .74 and that WMC at ordinary cutoff for delayed gastric emptying (GE; 300 minutes) had a sensitivity of 0.92, a specificity of 0.73, and accuracy of 0.80, while a cutoff value for delayed GE of 385 minutes resulted in the same

sensitivity, a specificity of 0.83 and an accuracy of 0.86. The authors also reported that the inter-rater reliability for GE time with WMC was r = .996 and that, except for worsening of symptoms in some patients due to pause of medication for seven days prior to the WMC and GES, no other test related adverse events were reported during the study. In their subgroup analysis, the authors reported that, in patients with Type 1 diabetes mellitus (T1DM), the median WMC GET was 611 minutes while the WMC GET in patients with Type 2 diabetes (T2DM) was 229 minutes. When symptom scores were analyzed, the authors reported that neither WMC GET nor GES correlated with PAGI-SYM, GCSI or any of its subsets at any time point and that they did not find any difference in symptoms between patients with normal and rapid GE, nor in symptom severity between patients with T1DM and T2DM. The limitations of this study include the small sample size, the single-center design, the use of additional caloric load in the testing than is standard, and the disproportionate number of women and of patients with T1DM in the study population. The authors concluded that their findings demonstrated the applicability of WMC as a reliable test to assess GE in patients with diabetic gastroparesis showing very high inter-observer correlation and that, by elevating the cutoff value for delayed emptying from 300 to 385 minutes, they found higher specificity without reducing sensitivity.

In a multi-center, prospective, comparative, cohort study that compared the performance characteristics of WMC versus gastric emptying scintigraphy (GES) to assess gastric emptying in patients with suspected gastroparesis, Lee et al. (2019) enrolled 167 adults with two or more upper GI symptoms for 12 weeks or more suggestive for gastroparesis (nausea, vomiting, upper abdominal pain, early satiation, bloating, postprandial fullness) including 53 patients with diabetes and 114 without diabetes. Each participant underwent simultaneous GES with a WMC to measure gastric emptying and regional transit. Data from 154 participants who underwent simultaneous WMC and GES were available to review. The authors reported that delayed gastric emptying was detected in a higher percentage of subjects by WMC (n=53, 34.6%) than by GES (n=39, 24.5%) and that the overall agreement in results between methods was 75.7% with positive agreement seen in 72.2% (n=26) and negative agreement in 76.7%. In participants without diabetes, the subgroup analysis by the authors reported that the WMC detected a higher percentage of patients with delayed gastric emptying (n=37; 33.3%) than GES (n=19; 17.1%); however, there was a higher percentage of subjects with diabetes who had delayed gastric emptying detected by GES (41.7%) than by WMC (17.1%). The authors also reported that severe delays in gastric emptying were observed in a higher percentage of patients by WMC (13.8%) than by GES (6.9%) while rapid gastric emptying was detected in a higher percentage of patients by GES (13.8%) than by WMC (3.3%). The authors concluded that WMC provided higher diagnostic yield than GES and that WMC detected delayed gastric emptying more frequently than GES and identified extra-gastric transit abnormalities. Limitations of the study include the high prevalence of patients with normal gastric emptying, the homogeneity of the study population (Caucasian female), the use of a liquid meal after WMC ingestion, and the lack of correlation of physiologic results with symptoms or outcome data. The authors also concluded that diabetic vs. non-diabetic patients had different results from GES compared to WMC and that their findings could affect management of patients with suspected gastroparesis.

Clinical Practice Guidelines

American College of Gastroenterology (ACG)

The ACG clinical guideline on gastroparesis completed a systematic review and meta-analysis of 92 studies that included evaluating the association between gastric emptying and nausea, vomiting, early satiety/postprandial fullness, abdominal pain and bloating. This study included three articles that addressed the use of wireless motility capsules (WMC). Based on this review, the ACG gave a conditional recommendation (based on a low GRADE level of evidence) for wireless motility capsule (WMC) testing indicating that it may be an alternative to the scintigraphic gastric emptying (SGE) assessment for the evaluation of gastroparesis in patients with upper GI symptoms. The guideline stated that research supports WMC testing as an alternative test to SGE for the evaluation of gastroparesis in patients with upper GI symptoms, and an advantage to WMC is that it provides a measure of gastric contractile amplitude which can correspond to the timing of capsule emptying documented by the change in pH measured as the capsule traverses the pylorus. The ACG stated that the diagnostic value of WMC for gastroparesis and for measurements of pan-gastrointestinal transit and pressure profiles has a potential future impact on the management of gastroparesis (Camilleri et al., 2022)

American Gastroenterological Association (AGA)

The AGA published a clinical practice update (Lacy et al. 2022) on the management of medically refractory gastroparesis that states that gastric emptying can be measured by using several techniques (e.g., scintigraphy, 13Cspirulina breath test, WMC) and that most U.S. centers perform gastric scintigraphy; however, because the scintigraphy is often done incorrectly with short measurement times, results may lead to misdiagnosis and mismanagement. The practice update stated that a meal-based test provides better physiological assessment of gastric emptying and is recommended as the first-line test of gastric emptying over the WMC because the WMC identifies phase III activity front of the migrating motor complex rather than overall gastric emptying.

National Institute for Health and Care Excellence (NICE)

In their 2014 interventional procedures guidance on assessing motility of the GI tract using a wireless capsule, NICE stated that the evidence on assessing motility of the GI tract using a wireless capsule raised no major safety concerns and that there is evidence of efficacy in measuring GI function but uncertainty about the clinical benefits and about patient selection. NICE recommended that this procedure should be used only with special arrangements for clinical governance, consent and audit or research.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

For information on wireless capsule endoscopy devices, refer to the following website (use product code NEZ): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed January 27, 2025)

SmartPill GI Monitoring System was granted FDA 510(k) marketing clearance in July 2006, based on its substantial equivalence to other legally marketed predicate devices.

SmartPill GI Monitoring System, Version 2.0 was granted FDA 510(k) marketing clearance in October 2009, based on its substantial equivalence to other legally marketed predicate devices.

According to the FDA's 510(k) Summary, the SmartPill GI Monitoring System senses and records pH and pressure measurements from the entire length of the gastrointestinal tract for use by physicians to aid in the evaluation of gastrointestinal motility diseases and conditions. Sensors on board an ingestible capsule measure pH and pressure as the capsule travels the length of the GI tract. Measurements are transmitted from the capsule within the GI tract to a patient-worn data receiver and subsequently downloaded to a PC for analysis and review. MotiliGI™ Software performs data analyses automatically and provides the physician with a printable report containing regional gut transit times: GET - Gastric emptying (transit) time, SBTT – Small bowel transit time, SLBTT – Combined small and large bowel transit time, CTT – Colonic transit time, WGTT – Whole gut transit time.

The SmartPill GI Monitoring System measures whole gut and regional gut (stomach, small bowel, and colon) transit times. Measurements of gastrointestinal tract transit times are used for evaluating motility disorders. Gastric transit time (gastric emptying time, GET) is indicated for the evaluation of patients with suspected gastroparesis. Delayed gastric emptying is implicated in such disorders as idiopathic and diabetic gastroparesis and functional non-ulcer dyspepsia. Colonic transit time (CTT) is indicated for the evaluation of colonic transit in patients with chronic constipation and used to aid in differentiating slow and normal transit constipation. Combined small and large bowel transit time (SLBTT) is used as a surrogate measure of colonic transit in patients with chronic constipation when colonic transit time alone cannot be determined. The System measures pH, pressure, and temperature throughout the GI tract. Pressure contraction data from the antrum and duodenum can be used to calculate motility indices. The SmartPill GI Monitoring System is not for use in pediatric patients.

Refer to the following website for more information at: https://www.accessdata.fda.gov/cdrh_docs/pdf9/K092342.pdf. (Accessed January 27, 2025)

References

Camilleri M, Kuo B, Nguyen L, et al. ACG Clinical Guideline: Gastroparesis. Am J Gastroenterol. 2022 Aug 1;117(8):1197-1220.

Cortegoso Valdivia P, Skonieczna-Żydecka K, Elosua A, et al. Indications, Detection, Completion and Retention Rates of Capsule Endoscopy in Two Decades of Use: A Systematic Review and Meta-Analysis. Diagnostics (Basel). 2022 Apr 28;12(5):1105.

Eriksson SE, Maurer N, Zheng P, et al. Impact of Objective Colonic and Whole Gut Motility Data as Measured by Wireless Motility Capsule on Outcomes of Antireflux Surgery. J Am Coll Surg. 2023 Feb 1;236(2):305-315.

Hayes, Inc. Evidence Analysis Research Brief. Use of a patency capsule to verify small bowel patency prior to capsule endoscopy. Hayes, Inc.; May 17, 2021.

Hayes, Inc. Evolving Evidence Review. PillCam Patency Capsule (Medtronic) to assess small bowel patency. Hayes, Inc.; April 26, 2022. Updated April 12, 2024.

Hayes, Inc. Health Technology Assessment. Capsule endoscopy for the diagnosis of small bowel Crohn's disease. Hayes, Inc.; March 23, 2017. Updated May 4, 2021.

Hayes, Inc. Health Technology Assessment. Capsule endoscopy of the small bowel for obscure gastrointestinal bleeding. Hayes, Inc.; June 20, 2013. Updated May 24, 2017.

Hayes, Inc. Health Technology Assessment. Wireless capsule systems for diagnosis of gastroparesis. Hayes, Inc.; November 27, 2023.

Jiang X, Pan J, Xu Q, et al. Diagnostic accuracy of magnetically guided capsule endoscopy with a detachable string for detecting oesophagogastric varices in adults with cirrhosis: prospective multicentre study. BMJ. 2024 Mar 5;384:e078581.

Lacy BE, Tack J, Gyawali CP. AGA Clinical Practice Update on Management of Medically Refractory Gastroparesis: Expert Review. Clin Gastroenterol Hepatol. 2022 Mar;20(3):491-500.

Leighton JA, Brock AS, Semrad CE, et al. Quality indicators for capsule endoscopy and deep enteroscopy. Gastrointest Endosc. 2022 Nov;96(5):693-711.

Lee AA, Rao S, Nguyen LA, et al. Validation of Diagnostic and Performance Characteristics of the Wireless Motility Capsule in Patients With Suspected Gastroparesis. Clin Gastroenterol Hepatol. 2019 Aug;17(9):1770-1779.e2.

McCarty TR, Afinogenova Y, Njei B. Use of Wireless Capsule Endoscopy for the Diagnosis and Grading of Esophageal Varices in Patients With Portal Hypertension: A Systematic Review and Meta-Analysis. J Clin Gastroenterol. 2017 Feb;51(2):174-182.

National Institute for Health and Care Excellence (NICE). Interventional procedures guidance [IPG502]. Assessing motility of the gastrointestinal tract using a wireless capsule. August 2014.

Raju GS, Gerson L, Das A, et al. American Gastroenterological Association. American Gastroenterological Association (AGA) Institute technical review on obscure gastrointestinal bleeding. Gastroenterology. 2007 Nov;133(5):1697-717.

Sangnes DA, Søfteland E, Bekkelund M et al. Wireless motility capsule compared with scintigraphy in the assessment of diabetic gastroparesis. Neurogastroenterol Motil. 2020 Apr;32(4):e13771.

Yung DE, Koulaouzidis A, Avni T, et al. Clinical outcomes of negative small-bowel capsule endoscopy for small-bowel bleeding: a systematic review and meta-analysis. Gastrointest Endosc. 2017 Feb;85(2):305-317. e2.

Policy History/Revision Information

Date	Summary of Changes
04/01/2025	**Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version MMP036.12

Instructions for Use

The Medicare Advantage Policy documents are generally used to support UnitedHealthcare coverage decisions. It is expected providers retain or have access to appropriate documentation when requested to support coverage. This document may be used as a guide to help determine applicable:

- Medical necessity coverage guidelines; including documentation requirements, and/or
- Medicare coding or billing requirements.

Medicare Advantage Policies are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates. This Policy is provided for informational purposes and does not constitute medical advice. It is intended to serve only as a general reference and is not intended to address every aspect of a clinical situation. Physicians and patients should not rely on this information in making health care decisions. Physicians and patients must exercise their independent clinical discretion and judgment in determining care. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes this policy. For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.

Medicare Advantage Policies are developed as needed, are regularly reviewed, and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policies at any time by publishing a new version on this website. Medicare source materials used to develop these policies may include, but are not limited to, CMS statutes, regulations, National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and manuals. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. The information presented in this Policy is believed to be accurate and current as of the date of publication. Where there is a conflict between this document and Medicare source materials, the Medicare source materials apply. Medicare Advantage Policies are the property of UnitedHealthcare. Unauthorized copying, use, and distribution of this information are strictly prohibited.

UnitedHealthcare follows Medicare coverage guidelines found in statutes, regulations, NCDs, and LCDs to determine coverage. The clinical coverage criteria governing certain items or services referenced in this Medical Policy have not been fully established in applicable Medicare guidelines because there is an absence of any applicable Medicare statutes, regulations, NCDs, or LCDs setting forth coverage criteria and/or the applicable NCDs or LCDs include flexibility that explicitly allows for coverage in circumstances beyond the specific indications that are listed in an NCD or LCD. As a result, in these circumstances, UnitedHealthcare applies internal coverage criteria as referenced in this Medical Policy. The internal coverage criteria in this Medical Policy was developed through an evaluation of the current relevant clinical evidence in acceptable clinical literature and/or widely used treatment guidelines. UnitedHealthcare evaluated the evidence to determine whether it was of sufficient quality to support a finding that the items or services discussed in the policy might, under certain circumstances, be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Providers are responsible for submission of accurate claims. Medicare Advantage Policies are intended to ensure that coverage decisions are made accurately. UnitedHealthcare Medicare Advantage Policies use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

For members in UnitedHealthcare Medicare Advantage plans where a delegate manages utilization management and prior authorization requirements, the delegate’s requirements need to be followed.