CIGNA MEDICAL COVERAGE POLICIES - GASTROINTESTINAL ENDOSCOPIC PROCEDURE

Capsule Endoscopy

Effective Date: July 1, 2025

Instructions for use

The following coverage policy applies to health benefit plans administered by Cigna. Coverage policies are intended to provide guidance in interpreting certain standard Cigna benefit plans and are used by medical directors and other health care professionals in making medical necessity and other coverage determinations. Please note the terms of a customer's particular benefit plan document may differ significantly from the standard benefit plans upon which these coverage policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a coverage policy.

In the event of a conflict, a customer's benefit plan document always supersedes the information in the coverage policy. In the absence of federal or state coverage mandates, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of:

1. The terms of the applicable benefit plan document in effect on the date of service
2. Any applicable laws and regulations
3. Any relevant collateral source materials including coverage policies
4. The specific facts of the particular situation

Coverage policies relate exclusively to the administration of health benefit plans. Coverage policies are not recommendations for treatment and should never be used as treatment guidelines.

This evidence-based medical coverage policy has been developed by EviCore, Inc. Some information in this coverage policy may not apply to all benefit plans administered by Cigna.

These guidelines include procedures EviCore does not review for Cigna. Please refer to the **Cigna CPT code list** for the current list of high-tech imaging procedures that EviCore reviews for Cigna.

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Capsule Endoscopy Guidelines

Guideline Page

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General Guidelines (CAPEND-0)

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- The Gastrointestinal Endoscopy Program applies an evidence-based approach to evaluate the most appropriate care for each individual. This evaluation requires submission of medical records pertinent to the treatment and/or services being requested by the provider.
- If the medical records provided do not provide sufficiently detailed information to understand the individual's current clinical status, then the medical necessity for the request cannot be established and the request cannot be approved.
- A pertinent clinical evaluation since the new onset or change in symptoms is required prior to considering gastrointestinal endoscopy services:
  - A pertinent clinical evaluation should include the following:
    - A detailed history and physical examination
    - Appropriate laboratory studies
    - Pertinent imaging studies
    - Pathology reports
    - Procedure reports
    - Reports from other providers participating in the treatment of the relevant condition
  - For an established individual, a meaningful technological contact (telehealth visit, telephone call, electronic mail or messaging) since the onset or change in symptoms can serve as a pertinent clinical evaluation
- A recent clinical evaluation may be deferred if the individual is undergoing a guideline-supported, scheduled follow-up imaging or other designated procedural evaluation. Exceptions due to routine surveillance indications are addressed in the applicable condition-specific guideline sections.
- The Gastrointestinal Endoscopy Program reserves the right to change and update the policy as new evidence emerges. The policy undergoes a formal review at least annually. The policy is based upon major national and international association and society guidelines and criteria, peer reviewed literature, major treatises, as well as input from health plans, practicing academic and community-based physicians.
- This policy is not intended to supersede or replace sound medical judgment, but instead, should facilitate the identification of the most appropriate treatment given the individual's clinical condition. This policy is written to cover most gastrointestinal endoscopic indications. However, the policy may not be applicable in certain clinical circumstances. Physician judgment may override the policy. Clinical decisions, including treatment decisions, are the responsibility of the individual and his/her

provider. Clinicians are expected to use independent medical judgment, which takes into account the clinical circumstances to determine individual management decisions

- All time intervals in this guideline refer to capsule endoscopy, unless otherwise stated.
- Requests for Open-Access Endoscopy must meet criteria according to these guidelines.
- New and Emerging Technologies
  - Requests related to new and emerging technologies will be considered to determine whether they meet evidence-based guidelines.
    - If a specific CPT code does not exist for a new technology, the CPT code used in the request will be considered based on its typical procedure application.
  - Procedures which are inconsistent with established clinical standards or are requested for data collection and not used in direct clinical management are not supported.
- Capsule endoscopy is not a term applicable to every study that utilizes an ingested capsule device. There are specific types of capsules, some of which have their own independent CPT® code (e.g. wireless motility capsule (CPT® 91112), colon capsule (CPT® 91113), etc.). The specific CPT® should be used for the corresponding capsule request.
- State and federal legislations may need to be considered in the review of gastrointestinal endoscopy requests.
- CPT® (Current Procedural Terminology) is a registered trademark of the American Medical Association (AMA). CPT® five digit codes, nomenclature, and other data are copyright 2024 American Medical Association. All Rights Reserved. No fee schedules, basic units, relative values, or related listings are included in the CPT® book. AMA does not directly or indirectly practice medicine or dispense medical services. AMA assumes no liability for the data contained herein or not contained herein.

Crohn's Disease (CAPEND-1)

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- Capsule endoscopy is medically necessary for the evaluation of known or suspected Crohn's disease in the following clinical scenarios:
  - Clinical features consistent with Crohn's disease:
    - Chronic diarrhea, chronic abdominal pain, unintentional weight loss, or +GI bleeding with associated fatigue AND one of the following:
      - Elevated biomarkers [ESR, CRP, fecal calprotectin, or lactoferrin] OR
      - Ileocolonoscopy or imaging studies (CT Abdomen, CT Abdomen/Pelvis, or MRI Abdomen) are suspicious for Crohn's disease
  - To assess for the possibility of small bowel disease (i.e. Crohn's) in the presence of an indeterminate colitis OR
  - Known Crohn's disease and ANY of the following:
    - Clinical features unexplained by ileocolonoscopy or imaging studies (CT Abdomen, CT Abdomen/Pelvis, or MRI Abdomen).
    - When assessment of small bowel mucosal healing beyond the reach of ileocolonoscopy is needed.
    - Suspected small bowel recurrence after colectomy, with negative or inconclusive ileocolonoscopy, CT, or MRI.
  - See: **Background and Supporting Information**
  - Capsule endoscopy is not medically necessary in individuals with:
    - Chronic abdominal pain or diarrhea (≥ 28 days) as their only symptoms, and no evidence of elevated biomarkers associated with Crohn's Disease.

Background and Supporting Information

- Crohn's Disease
  - In a study, in individuals with both abdominal pain and diarrhea with positive inflammatory markers, the diagnostic yield of CE was 90.1% vs. 0% in those with negative inflammatory markers.
- The consensus group of the Canadian Association of Gastroenterology concluded "CE is not warranted in most individuals who present with chronic abdominal pain the absence of positive tests for inflammatory markers or abnormal findings on endoscopy or imaging".

Evidence Discussion

Capsule endoscopy is a useful adjunct in the diagnosis of individuals with small bowel Crohn's disease in whom there is a high index of suspicion of disease. Capsule

endoscopy and small bowel imaging techniques lack the means to provide tissue when that is needed for diagnosis during evaluation of the small bowel, hence should be reserved for symptomatic individuals with abnormal inflammatory markers, who already have undergone ileocolonoscopy and advanced imaging. It can be utilized to evaluate disease activity and response to therapy with a great impact on individual management, in individuals with known Crohn's Disease.

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Celiac Disease (CAPEND-2)

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- Capsule endoscopy is medically necessary for the evaluation of suspected celiac disease in the following clinical scenarios:
  - Individuals with positive serology and negative biopsy
  - Individuals with chronic diarrhea or suspected malabsorption and a contraindication to biopsy or EGD
  - Individuals with positive celiac serology and a contraindication to biopsy or EGD
- Capsule endoscopy is medically necessary for the evaluation of confirmed celiac disease in the following clinical scenario:
  - New or continued symptoms (e.g., bloating, diarrhea, abdominal pain, unintentional weight loss, distension, evidence of malabsorption, anemia) despite adherence to 6 months of a gluten-free diet

Background and Supporting Information

- Celiac Disease
  - Celiac is an autoimmune disease in which the villi of the small intestine are damaged from eating gluten (found in wheat, barley, and rye).
  - Complications of celiac disease include ulcerative jejunitis, lymphoma, and small intestinal adenocarcinoma.
  - Screening blood tests include:
    - Anti-tissue transglutaminase antibody [anti-tTG], anti-endomysial antibody (EMA), total IgA count to assess for IgA deficiency, CBC to detect anemia, ESR, C-reactive protein, complete metabolic panel, vitamin D, E, B12 levels.

Evidence Discussion

Celiac disease is a disorder primarily involving the small bowel mucosa resulting in progressive degrees of villous inflammation and destruction, which begins in the duodenum and can progress over time to the ileum. Diagnosis is confirmed by serologic studies with antibody testing and upper endoscopy and small bowel biopsies. Complications of celiac disease include ulcerative jejunoileitis, small bowel lymphoma, and tumors of the small bowel. A study in the World Journal of Gastroenterology reviewed guidelines from seven scientific societies and Capsule Endoscopy (VCE) could support the diagnosis of celiac disease in discordant cases between serology and upper endoscopy and small bowel biopsy, in those unable to have an endoscopic procedure due to a contraindication, or if unwilling to undergo upper endoscopy and biopsy. Wireless Capsule Endoscopy (WCE) may be indicated for the evaluation of

individuals with celiac disease with a positive serology and negative biopsy, and for the re-evaluation of individuals with celiac disease who remain symptomatic despite treatment and there is no suspected or confirmed GI obstruction, stricture, fistulae. Individuals with confirmed celiac disease with anemia, GI bleeding, evidence of malabsorption, or in those with new or intractable symptoms despite an adequate trial of gluten restriction, may be at higher risk for complications related to celiac disease. Capsule Endoscopy (VCE) as a noninvasive study to visualize the small bowel has shown diagnostic utility in that population.

Gastrointestinal Bleeding (CAPEND-3)

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- Capsule endoscopy (CE) is medically necessary for the evaluation of GI Bleeding in the following clinical scenarios:
  - Documented overt GI bleeding (observed blood per rectum, melena, or black tarry stool excluding hematemesis) and negative findings on EGD and colonoscopy, CE is the next appropriate diagnostic step OR
  - Prior negative CE who have repeated obscure bleeding, CE can be repeated OR
  - Suspected obscure bleeding or UNEXPLAINED iron deficiency anemia (negative EGD and colonoscopy)

Evidence Discussion

Capsule endoscopy is non-invasive and generally safe. It permits evaluation of portions of the GI tract that may not be more accessible to invasive modalities such as gastrointestinal endoscopy. It requires no pre-evaluation bowel preparation, although some choose to give laxatives prior to the procedure. Despite use of either upper endoscopy, small bowel enteroscopy, and/or colonoscopy, the source of gastrointestinal bleeding or iron deficiency anemia may go unexplained. Capsule endoscopy has been shown to detect small intestinal bleeding sources in up to 63% of cases where traditional endoscopy has been unrevealing. It is indicated for use in those with overt GI bleeding with negative EGD and colonoscopy, suspected obscure GI bleeding or unexplained iron deficiency anemia, or prior negative capsule endoscopy with recurrent obscure bleeding.

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Small Bowel Tumors (CAPEND-4)

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- Capsule endoscopy is medically necessary for the evaluation of small bowel tumors in the following clinical scenario:
  - For the evaluation of known or suspected small bowel tumors (including genetic polyposis syndromes)

Evidence Discussion

In 2017 the AGA published the Clinical Guidelines for the use of video capsule endoscopy and specifically addresses the use of capsule endoscopy for polyposis syndromes. It states that in individuals with polyposis syndromes who require small bowel studies, capsule endoscopy be performed for ongoing surveillance. Intervals were not specified and the recommendation was conditional. In addition to familial adenomatous polyposis (FAP) and PFS, they included other hamartomatous polyposis syndromes including PTEN associated disorders, familial juvenile polyposis, and Cronkite-Canada syndrome. Capsule endoscopy was superior to endoscopy for detection of duodenal polyps. Capsule endoscopy detected greater numbers of smaller jejunal-ileal polyps than other imaging modalities including radiology and MRI Enterography with similar detection rates to device-assisted enteroscopy in individuals with familial adenomatous polyposis (FAP) and PSJ. The AGA stressed the value of surveillance especially in individuals with PJS who are at the highest risk for bleeding and intussusception related to small bowel polyps.

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Genetic Syndromes (CAPEND-5)

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- Capsule endoscopy is medically necessary for the evaluation of Juvenile Polyposis Syndrome (defined as individuals with 5 or more juvenile polyps in the colorectum or any juvenile polyps in other parts of the GI tract, or evidence of SMAD4 or BMPRI1A mutations) in the following clinical scenario:
  - Video capsule endoscopy can be performed periodically. Time interval not established.
- Capsule endoscopy is medically necessary for the evaluation of Peutz-Jehgers Syndrome (defined as individuals with perioral or buccal pigmentation and/or 2 or more histologically characteristic hamartomatous polyps, or family history of PJS, or STK11 mutations) in the following clinical scenario:
  - Video capsule endoscopy beginning at age 8 years. If no polyps, repeat at age 18 years, then every 2 years, or earlier if any symptoms occur[33].
- Capsule endoscopy is medically necessary for the evaluation of BMMRD (Biallelic Mismatch Repair Deficiency) in the following clinical scenario:
  - Video capsule endoscopy annually, beginning at age 8 years.
- Capsule endoscopy is medically necessary for the evaluation of Familial Adenomatous Polyposis (FAP), Attenuated Familial Adenomatous Polyposis (AFAP) Syndromes, and MUTYH-Associated Polyposis in the following clinical scenarios:
  - For individuals found to have Spigelman Stages III and IV (see: **EGD-1.16: Genetic Syndromes** for table of Spigelman Stages), or before duodenectomy if this is being contemplated.
    - Repeat every 2 years

Evidence Discussion

Capsule endoscopy is indicated for the evaluation of Familial Adenomatous Polyposis (FAP), Attenuated Familial Adenomatous Polyposis (AFAP) Syndromes, and MUTYH-Associated Polyposis in the following clinical scenarios: For individuals found to have Spigelman Stages III and IV, or before duodenectomy if this is being contemplated. Repeat every 2 years.

Capsule endoscopy represents a pivotal tool in the management of FAP, particularly for evaluating the small bowel in high-risk patients. The recommendations from leading guidelines, including the NCCN and AGA, support its use as part of a tailored surveillance strategy. By facilitating early detection and aiding in surgical planning, CE

contributes to reducing morbidity and improving outcomes in FAP patients. Continued research and refinement of clinical protocols will further clarify its role in routine care.

Capsule endoscopy is indicated for the evaluation of Peutz-Jeghers Syndrome (defined as individuals with perioral or buccal pigmentation and/or 2 or more histologically characteristic hamartomatous polyps, or family history of PJS, of STK11 mutations) in the following clinical scenario: Video Capsule endoscopy at age 8 years. If no polyps, repeat at age 18 years then every 2 years, or earlier if any symptoms occur.

Capsule endoscopy plays a pivotal role in the surveillance and management of Peutz-Jeghers Syndrome. By enabling the early detection of small bowel polyps and malignancies, CE enhances the ability to mitigate cancer risks and improve outcomes in this high-risk population. The integration of CE into routine care is strongly supported by major guidelines, including the NCCN, AGA, and ACG, and represents a critical component of personalized surveillance strategies for PJS patients. Continued advancements in capsule endoscopy technology are expected to further refine its role in hereditary cancer syndromes.

Capsule endoscopy is indicated for the evaluation of BMMRD (Biallelic Mismatch Repair Deficiency) in the following clinical scenario: Video capsule endoscopy annually, beginning at age 8 years.

Capsule endoscopy plays a crucial role in the surveillance of BMMRD, providing a sensitive, non-invasive method for detecting small bowel neoplasms. Supported by guidelines from the NCCN, AGA, and US Multi-Society Task Force, CE is an essential component of comprehensive surveillance strategies for this high-risk population. By enabling early detection and guiding timely interventions, capsule endoscopy significantly contributes to improving outcomes and quality of life for individuals with BMMRD. Further research and advancements in CE technology will continue to refine its application in hereditary cancer syndromes.

Capsule endoscopy is indicated for the evaluation of Juvenile Polyposis Syndrome (defined as individuals with 5 or more juvenile polyps in the colorectum or any juvenile polyps in other parts of the GI tract, or evidence of SMAD4 of BMPRI1A mutations) in the following clinical scenario: Video capsule endoscopy can be performed periodically. Time interval not established.

Capsule endoscopy represents a promising tool for small bowel surveillance in Juvenile Polyposis Syndrome, complementing traditional endoscopic techniques. While current guidelines do not mandate CE use, its ability to detect small bowel polyps underscores its potential to improve disease management and outcomes. Further research is needed to establish CE's role in JPS-specific surveillance protocols and optimize care for this high-risk population.

Colon Capsule Endoscopy (CAPEND-7)

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- Colon capsule endoscopy is medically necessary in the following clinical scenarios:
  - As a primary procedure in individuals with major risk for standard optical colonoscopy or moderate sedation as indicated from an evaluation by a board-certified or board-eligible gastroenterologist, a surgeon trained in endoscopy, or a physician with equivalent endoscopic training AND one of the following:
    - Fecal occult blood test positive OR
    - Multitarget Stool DNA (sDNA) Test positive OR
    - Other evidence of lower GI bleeding in hemodynamically stable individuals
  - As a secondary procedure:
    - For the detection or surveillance of colon polyp(s) if the diagnostic optical colonoscopy was incomplete OR
    - When an incomplete diagnostic optical colonoscopy was performed for either:
      - Multitarget Stool DNA (sDNA) Test Positive OR
      - Other evidence of lower GI bleeding in hemodynamically stable individuals
- Colorectal Cancer Screening
  - Colon capsule endoscopy is considered not medically necessary for colorectal cancer screening and as such is not approvable for this indication.

Evidence Discussion

The video colon capsule affords the benefit of visualizing colonic mucosa under physiologic conditions without exposing the individual to radiation or sedation.

The USFDA approved colon capsule endoscopy in 2014 to detect colon polyp only in individuals with incomplete colonoscopy. In 2017, the Multi-Society Task Force (MSTF) representing the American College of Gastroenterology, American Gastroenterology Association, and American Society of Gastrointestinal Endoscopy recommended colon capsule endoscopy every 5 years as the third tier test for colon cancer screening. The ESGE also recommends colon capsule endoscopy as a screening test for colon cancer screening in average-risk individuals when optical colonoscopy is contraindicated, vehemently opposed by the individual, or technically impossible.

Although colon capsule endoscopy (CCE) has a high level of accuracy, it is less sensitive and specific than colonoscopy in individuals undergoing colorectal cancer (CRC) screening/surveillance or those with known or suspected colonic diseases.

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In cases in which a previous colonoscopy was incomplete or for individuals who are unable/unwilling to undergo colonoscopy, colon capsule endoscopy (CCE) has been shown to be a reasonable alternative and may be as good as or better than CT Colonography in detecting significant polyps.

In addition to lower sensitivity and specificity than colonoscopy, colon capsule endoscopy (CCE) also is limited by an inability to insufflate the colon, aspirate liquids, control the transit of the CCE, and clean the mucosal surface. Individuals with significant polyps on colon capsule endoscopy (CCE) also theoretically will require subsequent polypectomy, thereby requiring 2 procedures and increasing resource utilization.

Based on the higher polyp detection rate with colonoscopy and the added benefit of being able to perform polypectomy during the same procedure, it is recommended that colon capsule endoscopy (CCE) not be substituted routinely for colonoscopy. However, in individuals who are unwilling or unsuitable for colonoscopy, colon capsule endoscopy (CCE) is an appropriate alternative.

In individuals with inflammatory bowel disease (IBD), substituting colon capsule for colonoscopy to assess the extent and severity of disease is not recommended. Colon capsule endoscopy (CCE) has been shown to underestimate the extent and severity of disease compared with colonoscopy in individuals with ulcerative colitis or Crohn's disease. Consequently, colonoscopy should remain the preferred procedure to assess active disease in individuals with colitis or small bowel disease.

Esophageal Capsule Endoscopy (CAPEND-8)

GI.EC.0008.0.A

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- Esophageal capsule endoscopy is medically necessary in the following clinical scenario:
  - When endoscopic procedures may be inappropriate or contraindicated, such as:
    - Individuals with non-reversible coagulopathy OR
    - Recent MI OR
    - Evaluation of esophageal varices in cirrhotic individuals who are unable to tolerate or undergo EGD

Evidence Discussion

Esophageal capsule endoscopy (ECE) provides the opportunity of visualizing esophageal mucosa under physiologic conditions without exposing the individual to radiation or sedation. PillCam ESO was approved by the FDA in 2004. Esophageal capsule endoscopy (ECE) may be beneficial in the evaluation of esophagitis, Barrett's esophagus, esophageal cancer, and esophageal varices for individuals who are unwilling or unable to have an endoscopy.

Several studies have been conducted to evaluate capsule endoscopy as a less invasive and more convenient endoscopic procedure for diagnosing GERD and Barrett's esophagus. However, the diagnostic rates for Barrett's esophagus were not sufficiently accurate for esophageal capsule endoscopy (ECE) to replace EGD as the standard diagnostic modality. Lacking the ability to obtain histological samples or perform therapeutic procedures, both of which are required during the diagnosis and surveillance of Barrett's esophagus, is a significant limitation of esophageal capsule endoscopy (ECE).

Esophageal capsule endoscopy (ECE) was investigated as a less-invasive alternative to EGD for diagnosing esophageal varices. Esophageal capsule endoscopy (ECE) could be an alternative to EGD in the evaluation of esophageal varices, for the screening of cirrhotic individuals, and for indicating primary prophylactic treatment. It can play a role in individuals with contraindications for EGD or those who refuse it. Although ECE may be beneficial for screening, unlike endoscopic treatment, including band ligation and chemical sclerotherapy, this cannot be performed with ECE.

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The diagnostic yield of ECE has proven insufficient for it to replace EGD in the evaluation of esophageal diseases. Because of this, combined with its limitations, ECE is not recommended as a first-line diagnostic tool in evaluating esophageal disease.

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Wireless Motility Capsule Endoscopy (CAPEND-9)

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- Wireless motility capsule (also known as SmartPill Gastrointestinal Monitoring System™) is medically necessary for suspected GI motility disorders after structural issues are ruled out by imaging or traditional endoscopy:
  - Evaluation and/or treatment of individuals with suspected gastroparesis in the absence of obstruction
  - Evaluation of colonic transit in individuals with chronic idiopathic constipation lasting over 6 months
  - Evaluation of small bowel motility
- Motility capsule endoscopy is NOT medically necessary for individuals with any of the following:
  - History of gastric bezoar
  - Swallowing disorders
  - Dysphagia
  - Suspected strictures or fistulae in the gastrointestinal tract
  - Physiologic gastrointestinal obstruction
  - Recent (within the last 3 months) gastrointestinal surgery
  - Crohn's disease
  - Diverticulitis
  - Implanted electromechanical medical devices (i.e. pacemaker, infusion pump)

Background and Supporting Information

- SmartPill Gastrointestinal Monitoring System™
  - SmartPill™ motility testing features a swallowed sensor-based capsule. SmartPill™ measures pressure, pH, transit time and temperature as it passes through the entire gastrointestinal tract. SmartPill™ assesses gastric emptying time, colonic transit time, whole gut transit time, as well as pressure patterns from the antrum and duodenum.
  - SmartPill™ is FDA-authorized for use in evaluation of gastroparesis and chronic constipation.

Evidence Discussion

Wireless Motility Capsule (WMC) is FDA authorized for evaluation of gastroparesis and chronic constipation.

Wireless Motility Capsule (WMC) offers several advantages over scintigraphy such as the following:

- detects a higher proportion of subjects with delayed gastric emptying in non-diabetics
- provides a measure of gastric contractile amplitude corresponding to the timing of capsule emptying as documented by change in pH when the capsule traverses the pylorus

Capsule Endoscopy CPT Codes

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CPT Codes

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The inclusion of any code in this table does not imply that the code is under management or requires prior authorization. Refer to the applicable health plan for management details. Prior authorization of a code listed in this table is not a guarantee of payment. The Certificate of Coverage or Evidence of Coverage policy outlines the terms and conditions of the member's health insurance policy.

CPT Code	Code Description
91110	Gastrointestinal tract imaging, intraluminal (eg. capsule endoscopy), esophagus through ileum, with physician interpretation and report
91111	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), esophagus with physician interpretation and report
91112	Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report
91113	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), colon, with interpretation and report

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