Cigna Medical Coverage Policies – Gastrointestinal Endoscopic Procedure Capsule Endoscopy

Effective June 15, 2023

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 gastrointestinal procedures that eviCore reviews for Cigna.

Capsule Endoscopy

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CAPEND-0: General Guidelines

- The cobranded Cigna-eviCore Gastrointestinal Endoscopy Program applies an evidence-based approach to evaluate the most appropriate care for each patient. 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 patient's current clinical status, then the medical necessity for the request cannot be established and the request cannot be approved.
- Specific elements of a patient's medical records commonly required to establish medical necessity include, but are not limited to:
  - Recent virtual or in-person clinical evaluation which includes a detailed history and physical examination
  - Laboratory studies
  - Imaging studies
  - Pathology reports
  - Procedure reports
  - Reports from other providers participating in treatment of the relevant condition
- Adequate clinical information must be submitted to eviCore in order to establish medical necessity for gastrointestinal endoscopy services. Pertinent clinical evaluation (within 60 days) including a recent detailed history, physical examination, and/or laboratory and prior imaging studies should be performed prior to considering endoscopy. Other meaningful contact (telehealth visit, telephone or video call, electronic mail or messaging) by an established patient can substitute for an in-person clinical evaluation.
- Cigna and eviCore reserve the right to change and update the Gastrointestinal Endoscopy guideline. The guidelines undergo a formal review at least annually. Cigna-eviCore's guidelines are 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 guideline is not intended to supersede or replace sound medical judgment, but instead, should facilitate the identification of the most appropriate treatment given the patient's clinical condition. This guideline is written to cover most gastrointestinal endoscopic indications. However, the guideline may not be applicable in certain clinical circumstances. Physician judgment may override the guideline. Clinical decisions, including treatment decisions, are the responsibility of the patient and his/her provider. Clinicians are expected to use independent medical judgment, which takes into account the clinical circumstances to determine patient management decisions
- All time intervals in this guideline refer to capsule endoscopy, unless otherwise stated.
- Requests for Open-Access Endoscopy must meet criteria according these Guidelines.

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- 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.
- The terms “male” and “female” used in these guidelines refer to anatomic-specific diseases and disease predispositions associated with individuals’ sex assigned at birth rather than their gender identity. It should be noted that gender identity and anatomic specific diseases as well as disease predispositions are not always linked. As such, these guidelines should be applied to the individual’s corresponding known or suspected anatomic-specific disease or disease predisposition. At Cigna and eviCore, we believe that it is important to understand how all individuals, including those who are gender diverse, choose to identify themselves. To ensure that gender-diverse individuals are treated with respect and that decisions impacting their healthcare are made correctly and with sensitivity, Cigna and eviCore recognize all individuals with the following gender marker options: Male, Female, Transgender male, Transgender female, “X”, and “Not specified”.
- State and federal legislations may need to be considered in the review of gastrointestinal endoscopy requests.
- Cigna and eviCore support the Choosing Wisely initiative (www.choosingwisely.org) by the American Board of Internal Medicine (ABIM) Foundation and many national physician organizations, to reduce the overuse of diagnostic tests that are low value, no value, or whose risks are greater than the benefits.
- CPT® (Current Procedural Terminology) is a registered trademark of the American Medical Association (AMA). CPT® five digit codes, nomenclature, and other data are copyright 2019 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.

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CAPEND-1: Crohn's Disease

- Capsule endoscopy (CPT® 91110) is indicated for the evaluation of known or suspected Crohn's Disease in the following clinical scenarios:
  - Clinical features consistent with Crohn's Disease (e.g. chronic diarrhea, abdominal pain, weight loss, +GI bleeding, with associated fatigue), negative ileocolonoscopy, and imaging studies (CT abdomen, CT abdomen/pelvis, or MRI abdomen) OR
  - 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 ileocolonosocpy 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: Crohn's Disease**
- Capsule endoscopy is not indicated in individuals with:
  - Chronic abdominal pain or diarrhea (> 30 days) as their only symptoms, and no evidence of elevated biomarkers associated with Crohn's Disease
    - Biomarkers include ESR, CRP, fecal calprotectin, or lactoferrin

CAPEND-2: Celiac Disease

- Capsule endoscopy (CPT® 91110) is indicated for the evaluation of Celiac Disease in the following clinical scenario:
  - Known celiac disease and unexplained symptoms (e.g. bloating, diarrhea, abdominal pain, weight loss, distension, evidence of malabsorption) despite treatment (refractory disease defined as persistent or recurrent symptoms despite 6 months of a gluten-free diet)
    See: **Background and Supporting Information**: **Celiac Disease**
- Capsule endoscopy is not indicated for individuals with suspected celiac disease in whom endoscopy with biopsy is negative, even if serology is positive

CAPEND-3: Gastrointestinal Bleeding

- Capsule endoscopy (CPT® 91110) is indicated for the evaluation of GI Bleeding in the following clinical scenarios:
  - Documented overt GI bleeding (observed blood per rectum, melena, or black 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)

CAPEND-4: Small Bowel Tumors

- Capsule endoscopy (CPT® 91110) is indicated for the evaluation of small bowel tumors in the following clinical scenario:
  - For the evaluation of known or suspected small bowel tumors

CAPEND-5: Genetic Syndromes

- Capsule endoscopy (CPT® 91110) 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 or BMPRI1A mutations) in the following clinical scenario:
  - Video capsule endoscopy can be performed periodically. Time interval not established.
- Capsule endoscopy (CPT® 91110) is indicated 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 at age 8 years. If no polyps, repeat at age 18 years, then every 3 years, or earlier if any symptoms occur.
- Capsule endoscopy (CPT® 91110) 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 (CPT® 91110) 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 patients 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

CAPEND-6: Patency Capsule

- Patency Capsule
  - At this time, the use of a patency capsule for the pre-evaluation of the small intestine for capsule endoscopy is considered investigational/experimental.

CAPEND-7: Colon Capsule Endoscopy

- Colon Capsule Endoscopy (CPT® 91113) is indicated 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 investigational/experimental for Colorectal Cancer Screening and as such is not approvable for this indication.

CAPEND-8: Esophageal Capsule Endoscopy

- Esophageal Capsule Endoscopy (CPT® 91111) is indicated 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

CAPEND-9: Wireless Motility Capsule Endoscopy

- Wireless motility capsule (CPT® 91112) (also known as SmartPill Gastrointestinal Monitoring System™) is indicated 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 indicated 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

- 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."
- Celiac Disease
  - In 2 studies, despite positive serology, no individuals with negative endoscopy and histology showed mucosal changes compatible with celiac disease on CE. CE performed after endoscopy is unlikely to detect any additional individuals with celiac disease that had been missed on duodenal biopsy.
- Patency Capsule
  - While the American Gastroenterologic Association provides a recommendation for a patency capsule in individuals with known or suspected strictures of the small bowel, this is a conditional recommendation with very low quality of evidence for efficacy and low quality evidence for safety. The AGA notes: *"Therefore, the consensus group suggested that in patients with obstructive symptomatology, imaging should be performed before CE. In patients with negative imaging, most investigators will not use a patency capsule. In patients with abnormalities, suggesting a high risk of capsule retention, patency capsules can be considered although some recent data have questioned their benefit."*
  - In addition, it has been reported that the positive predictive value of a patency capsule was relatively low at 44%.
- 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.

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