Cigna Medical Coverage Policies – Gastrointestinal Endoscopic Procedure
Capsule Endoscopy

Effective April 1, 2024

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

General Guidelines (CAPEND-0)

- The cobranded Cigna-eviCore 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.
- Specific elements of an individual's medical records commonly required to establish medical necessity should include, but are not limited to:
  - recent virtual or in-person clinical evaluation which includes a detailed history and physical examination pertinent to the current request
  - 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 individual 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 individual'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 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 these Guidelines.

- 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.
- New and Emerging Technologies

Requests related to new and emerging technologies will be considered to determine whether they meet eviCore's 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.

- 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 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.

Crohn's Disease (CAPEND-1)

- 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 (i.e. chronic diarrhea or chronic abdominal pain with elevated biomarkers [ESR, CRP, fecal calprotectin, or lactoferrin], 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 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 indicated 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".

Celiac Disease (CAPEND-2)

- Capsule endoscopy (CPT® 91110) is indicated 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 (CPT® 91110) is indicated for the evaluation of confirmed celiac disease in the following clinical scenario:

- New or continued symptoms (e.g., bloating, diarrhea, abdominal pain, 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.

Gastrointestinal Bleeding (CAPEND-3)

- 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)

Small Bowel Tumors (CAPEND-4)

- 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 (including genetic polyposis syndromes)

Genetic Syndromes (CAPEND-5)

- 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 2 years, or earlier if any symptoms occur[33].

- 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 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

Patency Capsule (CAPEND-6)

- 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.

Background and Supporting Information

- 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 individuals with obstructive symptomatology, imaging should be performed before CE. In individuals with negative imaging, most investigators will not use a patency capsule. In individuals 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%.

Colon Capsule Endoscopy (CAPEND-7)

- 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.

Esophageal Capsule Endoscopy (CAPEND-8)

- 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

Wireless Motility Capsule Endoscopy (CAPEND-9)

- 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

- 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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