Medical Policy

PARAMOUNT

HMO AND PPO
ELITE (MEDICARE ADVANTAGE)
MARKETPLACE

Wireless Capsule Endoscopy & Gastrointestinal Motility Monitoring System

Policy Number: PG0028
Last Review: 03/17/2023

GUIDELINES:

- **This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder terms, conditions, exclusions, and limitations contract. It does not constitute a contract or guarantee regarding coverage or reimbursement/payment. Self-Insured group specific policy will supersede this general policy when group supplementary plan document or individual plan decision directs otherwise.**
- **Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.**
- **This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.**

SCOPE:
X Professional
_ Facility

DESCRIPTION:
Wireless capsule endoscopy (WCE), or colon capsule endoscopy (CCE) (CPT Codes 91110, 91111 & 91113), is a noninvasive procedure, where an ingestible capsule containing a miniaturized video camera is swallowed, that contains a light, transmitter, and batteries. A video recording is taken as it moves through the gastrointestinal (GI) tract. The images are then transmitted to a computer with special software where the images are strung together to create a video. Capsule endoscopy directly studies the entire bowel and is used for detecting lesions or pathology outside the reach of upper or lower endoscopy. The provider reviews the video to look for any abnormalities within the gastrointestinal tract.

A Wireless Gastrointestinal Motility Monitoring System (CPT Code 91112) is an ingestible capsule with a trade name SmartPill. The SmartPill records data enabling the estimation of regional and total gastrointestinal motility. The device has FDA approval 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 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. An example includes, but may not be limited to:

- SmartPill® GI Monitoring System - Intended for use as a diagnostic tool in the measurement of pH pressures and temperatures throughout the GI tract, gastric emptying time, total transit time and combined small-large bowel transit time. In the stomach, the SmartPill has been used to assess gastric emptying in individuals with suspected gastroparesis. In the intestine, the SmartPill has been used to assess small and large bowel transit times in those with chronic constipation or other motility disorders.

Magnetic Capsule Endoscopy consists of a single-use ingestible capsule and magnet linked to a physician-operated console. The capsule contains a camera that wirelessly captures images of the desired anatomy. The console allows the operator to control the motion and direction of the capsule, ensuring visualization of the entire stomach. The system is non-invasive, does not require sedation, and has a procedural time of approximately 15 to 20 minutes. The capsule leaves the body in 24 hours on average but may take as long as 2 weeks. The U.S.

Food and Drug Administration (FDA) approved a novel magnetically maneuvered capsule endoscopy system (NaviCam™; AnX Robotica, Inc.) in May 2020.

POLICY:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans
Wireless Capsule Endoscopy (91110, 91111 and 91113) requires prior authorization for all product lines.

Effective 05/01/2023: Wireless Gastrointestinal Motility Monitoring System (91112) is not covered.

The ingestion of the capsule is part of the test, and an evaluation & management (E&M) service may not be billed for this purpose.

COVERAGE CRITERIA:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

Paramount may cover Wireless Capsule Endoscopy (91110, 91111 & 91113), with prior authorization when:

- Patients are receiving services using FDA approved devices.
- The service is performed by physicians trained in endoscopy or in an independent diagnostic testing facility under the general supervision of a physician trained in endoscopy procedures; AND

I. Wireless capsule endoscopy of the small bowel is considered medically reasonable and necessary when the following conditions have been met:

- For investigating suspected small intestinal bleeding in persons with objective evidence of recurrent, obscure gastrointestinal bleeding (e.g., persistent or recurrent iron-deficiency anemia and/or persistent or recurrent positive fecal occult blood test, or visible bleeding) who have had upper and lower gastro-intestinal endoscopies within the past 12 months (EGD and colonoscopy) that have failed to identify a bleeding source (e.g. colonoscopy, endoscopy, radiographic exams); or
- For the evaluation of known or suspected small bowel tumors; or
- For evaluation of extent of small bowel involvement with arteriovenous malformations or lymphangiectasia for patients who are contemplated for surgical resection of the small bowel to control recurrent bleeding or protein loss is reasonable; or
- Initial diagnosis of suspected Crohn's Disease (abdominal pain or diarrhea plus 1 or more signs of inflammation (fever, elevated white blood cell count, elevated erythrocyte sedimentation rate, or bleeding) when there is no evidence provided by conventional diagnostic tests such as small bowel follow-through (SBFT), abdominal CT scan/CT enterography, and upper and lower endoscopy; or
- For evaluation of persons with celiac disease with a positive serology and a negative biopsy; or
- For re-evaluation of persons with celiac disease who remain symptomatic despite treatment and there is no suspected or confirmed gastrointestinal obstruction, stricture, or fistulae; or
- For surveillance of small intestinal tumors in persons with Lynch syndrome, Peutz-Jeghers syndrome and other polyposis syndromes affecting the small bowel; or
- 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); or
- For screening or surveillance of esophageal varices in cirrhotic persons with significantly compromised liver function (i.e., Child-Pugh score of Class B or greater) or other situations where a standard upper endoscopy with sedation or anesthesia is contraindicated.
- For evaluation of malabsorption syndrome, chronic diarrhea, or protein-losing enteropathy of obscure origin is reasonable when it is suspected to originate in the small intestinal mucosa. Appropriate prior negative or non-diagnostic evaluations of the esophagus, stomach, duodenum/small intestine, and colon by flexible endoscopy, and complementary radiologic procedures and/or microbiologic studies must be documented.

II. Wireless capsule endoscopy of the esophagus is considered medically reasonable and necessary for the

following condition, if all the criteria have been 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; and
    - patients with non-reversible coagulopathy; or
    - recent MI; or
    - evaluation of esophageal varices in cirrhotic individuals who are unable to tolerate or undergo EGD
- The medical record clearly reflects why the patient was not a candidate for conventional endoscopy and how the capsule endoscopy would contribute to the patient's care.

III. For diagnostic and/or surveillance purposes, <u>colon capsule endoscopy</u> is medically necessary when either of the following criteria are met:

- Primary procedure in patients with major risks for Optical Colonoscopy (OC) or moderate sedation as indicated from an evaluation of the patient by a board certified or board eligible gastroenterologist, a surgeon trained in endoscopy, or a physician with equivalent endoscopic training and EITHER of the following criteria are met:
    - Fecal Occult Blood Test (FOBT) positive (guaiac or immunochemical); or
    - Multitarget Stool DNA (sDNA) Test positive; or
    - Other evidence of lower GI bleeding in hemodynamically stable patients
- Secondary procedure:
    - For the detection or surveillance of colon polyp(s) if the diagnostic OC was incomplete; or
    - When an incomplete diagnostic OC was performed for either:
        - Fecal Occult Blood Test (FOBT) positive (guaiac or immunochemical) or
        - Multitarget Stool DNA (sDNA) Test positive or
        - Other evidence of lower GI bleeding in hemodynamically stable patients

Wireless Gastrointestinal Motility Monitoring System (91112)
Measurement of gastrointestinal transit times, including gastric emptying and colonic transit times, using an ingestible pH and pressure capsule is considered experimental and investigational for the evaluation of suspected gastroparesis, constipation, or other gastrointestinal motility disorders. The peer-reviewed literature has not yet shown that the use of this capsule has sufficient diagnostic accuracy to provide clinically relevant information when compared to other available diagnostic testing, including gastric emptying scintigraphy.

Magnetic capsule endoscopy is not covered for the evaluation of individuals with unexplained upper abdominal complaints and all other indications. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Non-Covered (not an all-inclusive list):

- Wireless capsule endoscopy (e.g., PillCam) is not reimbursable for colorectal cancer screening, used as a colorectal screening tool is considered experimental/investigational, regardless of family history or other risk factors for the development of colonic disease
- Wireless capsule endoscopy is not indicated for the 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).
- Wireless capsule endoscopy is contraindicated and experimental/investigational in persons with known or suspected gastrointestinal obstruction, strictures, or fistulae
- The use of wireless capsule endoscopy should not be used in patients with a cardiac pacemaker, or other implanted electromagnetic device.
- Testing is not indicated for 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.

- Colon capsule endoscopy is not medically indicated when performed in conjunction with CT Colonography
- Patency Capsule Testing (CPT 91299) (e.g., Agile Patency Capsule): Is considered experimental/investigational, and thus, not covered. Patency capsule testing is used to verify adequate patency of the gastrointestinal tract prior to administration of the PillCam video capsule in patients with known or suspected strictures. There are insufficient studies available to support coverage.

CODING/BILLING INFORMATION:

The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

CPT CODES	
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
91112	Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report Effective 05/01/2023 - Not Covered
91113	Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), colon, with interpretation and report (Effective 01/01/2022)
91299	Unlisted diagnostic gastroenterology procedure [is not covered related to: Patency Capsule Testing]
0651T	Magnetically controlled capsule endoscopy, esophagus through stomach, including intraprocedural positioning of capsule, with interpretation and report Not Covered

REVISION HISTORY EXPLANATION: ORIGINAL EFFECTIVE DATE: 02/01/2011

Date	Explanation & Changes
01/01/2006	• No changes
12/01/2006	• Revised codes
01/01/2008	• No changes
03/01/2009	• No changes
01/01/2011	• Updated
01/01/2021	• Updated
12/13/2012	• Updated
06/24/2014	• Changed title of policy title from Wireless Capsule Endoscopy to Wireless Capsule Endoscopy & Gastrointestinal Motility Monitoring System • Policy reviewed and updated to reflect most current clinical evidence per Medical Policy Steering Committee
10/14/2014	• Added procedure code 0355T effective 07/01/2014 • Policy reviewed and updated to reflect most current clinical evidence per Medical Policy Steering Committee
12/13/2016	• PPO now requires prior authorization for codes 91110, 91111, 91112 • Changed title of policy PG0028 Wireless Capsule Endoscopy & Gastrointestinal Motility Monitoring System to PG0028 Wireless Capsule Endoscopy • Wireless Gastrointestinal Motility Monitoring System (91112) removed from PG0028 and put in new medical policy PG0394 Wireless Gastrointestinal Motility Monitoring System • Wireless Gastrointestinal Motility Monitoring System (91112) will continue to be covered with prior authorization, but will now use homegrown criteria • Policies reviewed and updated to reflect most current clinical evidence per Medical Policy Steering Committee

12/18/2020	• Medical policy placed on the new Paramount Medical Policy Format
02/01/2023	• Medical Policy updated to reflect Medicaid coverage to Anthem as of 02/01/2023
03/17/2023	• Policy reviewed and updated to reflect most current clinical evidence • Changed the medical policy title from Wireless Capsule Endoscopy to Wireless Capsule Endoscopy & Gastrointestinal Motility Monitoring System • Combined medical policy Gastrointestinal Motility Monitoring System, PG0394 with medical policy Wireless Capsule Endoscopy, PG0028 • Effective 05/01/2023 Wireless Gastrointestinal Motility Monitoring System (91112) is noncovered for ALL product lines • Removed deleted procedure code 0355T (Deleted 12/31/2021-see 91113) • Added procedure code 91113 • Added noncovered procedure code 0651T
02/01/2024	• Medical Policy placed on the new Paramount Medical Policy format

Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to https://www.paramounthealthcare.com/providers/medical-policies/policy-library

REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs

American Medical Association, *Current Procedural Terminology (CPT®)* and associated publications and services https://www.ama-assn.org/amaone/cpt-current-procedural-terminology

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update

U.S. Preventive Services Task Force, https://www.uspreventiveservicestaskforce.org/uspstf/
Industry Standard Review

Hayes, Inc., https://www.hayesinc.com/

Industry Standard Review