



Geisinger Health Plan Policies and Procedure Manual

Policy: MP112

Section: Medical Benefit Policy

Subject: Wireless Capsule Endoscopy

Applicable Lines of Business

Commercial	X	CHIP	X
Medicare	X	ACA	X
Medicaid	X		

I. Policy: Wireless Capsule Endoscopy

II. Purpose/Objective:

To provide a policy of coverage regarding Wireless Capsule Endoscopy

III. Responsibility:

- A. Medical Directors
- B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.

- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

DESCRIPTION:

Capsule endoscopy is performed using an imaging system consisting of a swallowable disposable capsule containing a video camera, light source, radiotransmitter and batteries; an externally worn data recorder and an office based workstation. Up to 50,000 images are recorded and transmitted to the data recorder as the capsule camera travels through the gastrointestinal tract, propelled by peristalsis. The capsule is excreted approximately 8-72 hours after ingestion and is discarded.

SmartPill® GI Monitoring System is an ingestible capsule which is thought to sense and record pH and pressure measurements from the entire length of the gastrointestinal tract in order to evaluate members with suspected delayed gastric emptying. These measurements are used to then determine gastric emptying time (GET), total transit time (TTT), and combined small-large bowel transit time (SLBTT). In addition, the pressure contraction patterns from the antrum and duodenum are used to calculate motility indices.

INDICATIONS:

Capsule Endoscopy:

For Commercial Medicare and Medicaid Business Segment:

Wireless capsule endoscopy may be considered **medically** necessary, as a diagnostic imaging tool, in the following clinical circumstances:

- **Occult Gastrointestinal Bleeding**
Limited to members who have undergone upper gastrointestinal (GI) endoscopy, colonoscopy and small bowel imaging studies and these tests have failed to reveal a source of bleeding. The bleeding must be of a nature that there is documentation of anemia secondary to the loss of blood.
- **Small Bowel Neoplasm**
Limited to the detection of neoplasms of the small bowel in members who are symptomatic for a neoplasm (e.g., GI bleeding, partial bowel obstruction) and when the diagnosis has not been confirmed by upper GI endoscopy, colonoscopy, push enteroscopy, and nuclear imaging or radiologic procedures.
- **Crohn's Disease**
Limited to members who are symptomatic for Crohn's disease (e.g., diarrhea, GI bleeding, abdominal pain) and who have undergone complete lower GI studies (e.g. Colonoscopy or barium enema), and an upper GI with small bowel follow-through and the testing has failed to reveal the source of the symptoms.
- **GI polyposis syndromes**
Surveillance of the small bowel in members with hereditary small bowel polyposis syndromes, including familial adenomatous polyposis and Peutz-Jeghers syndrome.
- **Celiac Disease**
Known celiac disease and unexplained symptoms (e.g. bloating, diarrhea, abdominal pain, weight loss, distension, evidence of malabsorption) despite treatment defined as 6 months of a gluten-free diet.
- **Anemia** with associated iron deficiency that is suspected to be of small bowel origin, when colon and upper gastrointestinal tract evaluations have been completed and have been ruled out as a source of bleeding.

For Medicaid Business Segment:

Evaluation of Celiac Disease for individuals with a negative biopsy and when the diagnosis has not been confirmed by upper GI endoscopy, push enteroscopy, colonoscopy, nuclear imaging or radiological procedures.

LIMITATIONS:

- The device must be FDA approved
- Capsule endoscopy is contraindicated in persons with known or suspected gastrointestinal obstruction, strictures, or fistulae

Colon Capsule Endoscopy:

For Medicare Business Segment

For diagnostic and/or surveillance purposes, Colon Capsule Endoscopy (CCE) is medically necessary when EITHER of the following criteria are met:

1. 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; or
2. 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

LIMITATION:

CCE is not a Medicare Benefit option for colorectal cancer screening.

For Medicaid Business segment:

There is no coverage for this technology for the Medicaid business segment. Consideration through the Program Exception process may be requested if there is a clinical contraindication to the alternative diagnostic standards of care

SmartPill® GI Monitoring System

For Commercial and Medicare Business segments;

SmartPill® GI Monitoring System may be considered medically necessary, as a diagnostic imaging tool when **all of the following** criteria are met:

1. To measure pressure, pH, transit time and temperature and assess gastric emptying time, colonic transit time, whole gut transit time in the evaluation of members with either:
 - chronic constipation; **or**
 - gastric dysmotility/ gastroparesis; **or**
 - evaluation of small bowel motility
- and**
2. The absence of **any** of the following:
 - intestinal stricture
 - Inflammatory bowel disease
 - pacemaker

For Medicaid Business segment:

There is no coverage for this technology for the Medicaid business segment. Consideration through the Program Exception process may be requested if there is a clinical contraindication to the alternative diagnostic standards of care.

EXCLUSIONS:

Wireless capsule endoscopy is not intended for use as a gastrointestinal cancer-screening tool. This use is considered **Unproven** and Not Medically Necessary and is **NOT COVERED**.

Wireless capsule endoscopy is Not Medically Necessary and **NOT COVERED** for the confirmation of lesions or pathology normally within the reach of upper or lower endoscopes (lesions proximal to the ligament of Treitz or distal to the ileum)

The Plan does **NOT** provide coverage for the use of magnetically-controlled wireless capsule (eg, NaviCam®) endoscopy is considered **Unproven** and Not Medically Necessary and is **NOT COVERED** for all indications including but not limited to the evaluation of patients with unexplained upper abdominal complaints. Although the device is FDA approved, there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this testing on health outcomes

The Plan does NOT provide coverage for the use of the Agile patency capsule because it is considered **unproven** for evaluating patency of the gastrointestinal tract before wireless capsule endoscopy, and for all other indications. Although the device is FDA approved, there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this testing on health outcomes.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in **MP 15 - Experimental Investigational or Unproven Services or Treatment**.

Medicaid Business Segment:

Any requests for services that do not meet criteria set in the PARP may be evaluated on a case by case basis.

CODING ASSOCIATED WITH: Wireless Capsule Endoscopy

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

HCPCS/CPT Codes

- 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
- A9268 Programmer for transient, orally ingested capsule
- A9269 Programmable, transient, orally ingested capsule, for use with external programmer, per month
- 0651T Magnetically controlled capsule endoscopy, esophagus through stomach, including intraprocedural positioning of capsule, with interpretation and report

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

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This policy will be revised as necessary and reviewed no less than annually.

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This policy will be revised as necessary and reviewed no less than annually

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Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

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