

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 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 the Agile patency capsule because it is considered **experimental, investigational or 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

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.

REFERENCES:

- Ratko TA, Bini EJ, et. al. "A review of capsule endoscopy". Journal of Clinical Outcomes Management. 10(5):273-277, May 2003.
- Costamagna G, Shah SK, et. al. "A prospective trial comparing small bowel radiographs and video capsule endoscopy for suspected small bowel disease.", Gastroenterology. 123(4):999-1005, Oct. 2002.
- Lewis BS, Swain P. "Capsule endoscopy in the evaluation of patients with suspected small intestine bleeding: Results of a pilot study." Gastrointestinal Endoscopy. 56(3):349-353. Sept. 2002.
- Eil C, Remke S, May A, Helou L, Henrich R, Mayer G. "The first prospective controlled trial comparing wireless capsule endoscopy with push enteroscopy in chronic gastrointestinal bleeding". Endoscopy 34(9):685-689. Sept. 2002.
- Appleyard M, Fireman Z, et. al. "A randomized trial comparing wireless capsule endoscopy with push enteroscopy for the detection of small-bowel lesions". Gastroenterology. 119(6):1431-1438. Dec. 2000.
- Fireman Z, Mahajna E, et. al. "Diagnosing small bowel Crohn's disease with wireless capsule endoscopy". Gut. 52(3):390-392. Mar. 2003.
- Scapa E, Jacob H, et. al. " Initial experience of wireless capsule endoscopy for evaluating occult gastrointestinal bleeding and suspected small bowel pathology". American Journal of Gastroenterology. 97(11):2776-2779. Nov. 2002.
- ECRI, Target Report #819, Capsule Endoscopy. November 2002. Accessed June 4, 2003.
- Hayes Inc. Online, Hayes Alert, Update on Capsule Endoscopy. 6(5). May 2003. Accessed June 4, 2003. This policy will be revised as necessary and reviewed no less than annually.
- Geisinger Technology Assessment Committee, TAC Triage Group review. Wireless Capsule Endoscopy. June 2003.
- Geisinger Technology Assessment Committee, Wireless Capsule Endoscopy, Jan.14, 2004.
- Mitchell SH, Schaefer DC, Dubagunta S., "A new view of occult and obscure gastrointestinal bleeding", American Family Physician 69(4):875-881. Feb. 15, 2004.

American Gastroenterological Association medical position statement: Evaluation and management of occult and obscure gastrointestinal bleeding. *Gastroenterology* 118:201, 2000.

ECRI Target (database online). Capsule Endoscopy of the esophagus. Plymouth Meeting(Pa): ECRI; January 2006.

American Society for Gastrointestinal Endoscopy. ASGE Technology Status Evaluation Report: wireless capsule endoscopy. *Gastrointest Endosc* 2006;63(4):539-545.

Bailey AA, Debinski HS, Appleyard MN, Remedios ML, Hooper JE, Walsh Aj, Selby WS. Diagnosis and outcome of small bowel tumors found by capsule endoscopy: A three-center Australian experience. *Am J Gastroenterol* 2006;101:2237-2243.

Cheifetz AS, Kornbluth AA, Legnani P, Schmelkin I, Brown A, Lichtiger S, Lewis BS. The risk of retention of the capsule endoscope in patients with known or suspected Crohn's Disease. *Am J Gastroenterol* 2006;101:2218-2222.

Zhang WQ, Yan GZ, Yu LZ, Yang XQ. Non-invasive measurement of pan-colonic pressure over a whole digestive cycle: Clinical application of a capsule-style manometric system. *World J Gastroenterol* 2006 December 21;12(47):7690-7694.

Zhang WQ, Yang GZ, Ye DD, Chen CW. Simultaneous assessment of the intraluminal pressure and transit time of the colon using a telemetry technique. *Physiol Meas.* 2007 Feb;28(2):141-8.

ECRI Institute. HTAIS Custom Hotline Response (online). SmartPill GI Monitoring System for Assessing Gastric Motility. ECRI Institute. Current as of 02/02/07.

ECRI Institute. Windows on Medical Technology – Capsule Endoscopy for Diagnosis of Obscure Small-bowel bleeding. ECRI Institute (online) 2007.

Abell TL, Camilleri M, Donohoe K, Hasler WL, Lin HC, et al. American Neurogastroenterology and Motility Society and the Society of Nuclear Medicine. Consensus recommendations for gastric emptying scintigraphy: a joint report of the American Neurogastroenterology and Motility Society and the Society of Nuclear Medicine. *J Nucl Med Technol.* 2008 Mar;36(1):44-54. Epub 2008 Feb 20.

US Food and Drug Administration (FDA). Center for Devices and Radiological Health. 510(k) Summary. K053639: Given® AGILE Patency System; premarket approval letter. [FDA Web site]. 05/08/06.

Spada C, Shah SK, Riccioni ME, et al. Video capsule endoscopy in patients with known or suspected small bowel stricture previously tested with the dissolving patency capsule. *J Clin Gastroenterol.* 2007;41(6):576-582.

Herrerias JM, Leighton JA, Costamagna G, et al. Agile patency system eliminates risk of capsule retention in patients with known intestinal strictures who undergo capsule endoscopy. *Gastrointest Endosc.* 2008;67(6):902-909.

Postgate AJ, Burling D, et al. Safety, Reliability, and Limitations of the Given Patency Capsule in Patients at Risk of Capsule Retention: A 3-Year Technical Review. *Dig Dis Sci* (2008) 53:2732–2738

ECRI Institute. HTAIS Hotline. Capsule endoscopy for the diagnosis of obscure small bowel bleeding. 10/14/10

Hayes Inc. Capsule Endoscopy for Diagnostic Imaging of the Small Bowel. Published Jan 13, 2008. Updated Jan 21, 2011.

Redondo-Cerezo E, Sánchez-Capilla AD, De La Torre-Rubio P, De Teresa J. Wireless capsule endoscopy: perspectives beyond gastrointestinal bleeding. *World J Gastroenterol.* 2014 Nov 14;20(42):15664-73.

Neumann H, Fry LC, Nägel A, Neurath MF. Wireless capsule endoscopy of the small intestine: a review with future directions. *Curr Opin Gastroenterol.* 2014 Sep;30(5):463-71.

Yung DE. Capsule endoscopy, magnetic resonance enterography, and small bowel ultrasound for evaluation of postoperative recurrence in Crohn's disease: systematic review and meta-analysis. *Inflamm Bowel Dis.* 2017;24(1):93-100.

Enns R. Clinical Practice Guidelines for the Use of Video Capsule Endoscopy. *Gastroenterol.* 2017;152:497-514.

Kuo, B, McCallum, RW, Koch, KL, et al. Comparison of gastric emptying of a nondigestible capsule to a radio-labelled meal in healthy and gastroparetic subjects. *Aliment Pharmacol Ther.* 2008 Jan 15;27(2):186-96.

Maqbool, S, Parkman, HP, Friedenberg, FK. Wireless capsule motility: comparison of the SmartPill GI monitoring system with scintigraphy for measuring whole gut transit. *Dig Dis Sci.* 2009 Oct;54(10):2167-74.

Camilleri, M, Thorne, NK, Ringel, Y, et al. Wireless pH-motility capsule for colonic transit: prospective comparison with radiopaque markers in chronic constipation. *Neurogastroenterol Motil.* 2010 Aug;22(8):874-82, e233.

Diaz Tartera, HO, Webb, DL, Al-Saffar, AK, et al. Validation of SmartPill(R) wireless motility capsule for gastrointestinal transit time: Intra-subject variability, software accuracy and comparison with video capsule endoscopy. *Neurogastroenterol Motil.* 2017 Oct;29(10):1-9.

Arora, Z, Parungao, JM, Lopez, R, Heinlein, C, Santisi, J, Birgisson, S. Clinical utility of wireless motility capsule in patients with suspected multiregional gastrointestinal dysmotility. *Dig Dis Sci.* 2015 May;60(5):1350-7.

Kuo, B, Maneerattanaporn, M, Lee, AA, et al. Generalized transit delay on wireless motility capsule testing in patients with clinical suspicion of gastroparesis, small intestinal dysmotility, or slow transit constipation. *Dig Dis Sci.* 2011 Oct;56(10):2928-38.

Rao, SS, Mysore, K, Attaluri, A, Valestin, J. Diagnostic utility of wireless motility capsule in gastrointestinal dysmotility. *Journal of clinical gastroenterology.* 2011 Sep;45(8):684-90.

Stein E, Burger Z, Hutless S, et al. Wireless Motility Capsule Versus Other Diagnostic Technologies for Evaluating Gastroparesis and Constipation: A Comparative Effectiveness Review. Agency for Healthcare Research and Quality (US); 2013 May

Farmer AD, Scott SM, Hobson AR. Gastrointestinal motility revisited: The wireless motility capsule. *United European Gastroenterology J.* 2013;1(6):413-421.

Fox MR, Kahrilas PJ, Roman S, et al. Clinical measurement of gastrointestinal motility and function: who, when and which test? *Nature Reviews: Gastroenterology & Hepatology* 2018;15:568-579.

EI-Matary W, Huynh H, Vandermeer B. Diagnostic characteristics of given video capsule endoscopy in diagnosis of celiac disease: A meta-analysis. *J Laparoendosc Adv Surg Tech A.* 2009;19(6):815-820

Rokkas T, Niv Y. The role of video capsule endoscopy in the diagnosis of celiac disease: A meta-analysis. *Eur J Gastroenterol Hepatol.* 2012;24(3):303-308

Pennsylvania Department of Human Services. Technology Assessment Group Coverage Decisions. Managed Care Operations Memorandum: OPS # 03/2009-007; Wireless Capsule Endoscopy (Small Bowel) Option #2.

Pennsylvania Department of Human Services. Technology Assessment Group Coverage Decisions. Managed Care Operations Memorandum: OPS # 05/2010-009; Wireless Capsule Endoscopy (Colon). Option #4.

Pennsylvania Department of Human Services. Technology Assessment Group Coverage Decisions. Managed Care Operations Memorandum: OPS #02/2012-020; Smart Pill. Option #4.

Novitas Solutions, Inc. Local Coverage Determination (LCD): Colon Capsule Endoscopy (CCE) (L38807).

Singh K, Zubair A, Prindle A, et al. Diagnostic yield of capsule endoscopy for small bowel arteriovenous malformations in patients with hereditary hemorrhagic telangiectasia: A systematic review and meta-analysis. *Endosc Int Open.* 2019;7(2):E282-E289

Eliakim R, Yablecovitch D, Lahat A, et al. A novel PillCam Crohn's Capsule Score (Eliakim Score) for quantification of mucosal inflammation in Crohn's disease. *United European Gastroenterol J.* 2020;8(5):544-551

Lai H-S, Wang X-K, Cai J-Q, et al. Standing-type magnetically guided capsule endoscopy versus gastroscopy for gastric examination: multicenter blinded comparative trial. *Dig Endosc.* 2020;32(4):557-564.

Mollers T, Schwab M, Gildein L, et al. Second-generation colon capsule endoscopy for detection of colorectal polyps: Systematic review and meta-analysis of clinical trials. *Endosc Int Open*. 2021;9(4):E562-E57

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

Devised: 8/03

Revised: 5/04; 5/07; 5/09(wording), 5/10 (ref), 4/11 (exclusion, refs), 7/19 (added coverage for Smart-Pill); 7/21 (add indications, CCE); 7/22 (add indication)

Reviewed: 5/05;5/06, 5/08, 9/12, 9/13, 2/14, 3/15, 3/16, 2/17, 2/18, 2/19, 7/20, 7/23

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

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>

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.