

Wireless Capsule Endoscopy as a Diagnostic Technique in Disorders of the Small Bowel, Esophagus, and Colon

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Products:	Products: Medicaid	
Application:	All participating hospitals and providers	
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Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under the medical-surgical benefits of the Company's Medicaid products for medically necessary capsule endoscopy procedures.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Highmark Health Options (HHO) – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children Program (DHCP) and Diamond State Health Plan Plus members.

Esophageal Capsule Endoscopy (ECE) – A minimally invasive procedure that uses video capsules with the ability to acquire images from two cameras with high image storing speed of 14-18 frames per second. An ingestion procedure allows for prolonged esophageal transit time and an optimized view of the gastroesophageal junction.

Wireless Capsule Endoscopy (WCE) – An ingestible telemetric gastrointestinal capsule imaging system that is used for visualization of the small bowel mucosa. It is used in the detection of abnormalities of the small bowel, which are not accessible via standard upper gastrointestinal endoscopy and colonoscopy.



Ingestible pH and Pressure-Sensing Capsule – An ingestible wireless device that is equipped with pH, pressure, and temperature sensors (e.g., SmartPill® GI Monitoring System).

Idiopathic Gastroparesis – The most common form of gastroparesis, in which a cause cannot be identified.

Diabetic Gastroparesis – The second most common cause of gastroparesis, in which continued high blood glucose levels damage the vagus nerve.

Postsurgical Gastroparesis – The third most common etiology of gastroparesis, most often the result of a vagotomy or vagus nerve injury.

Gastric Emptying Scintigraphy – A diagnostic test where the individual ingests a radionuclide-labeled standard meal, and then images are taken at 0, 1, 2, and 4 hours postprandial in order to measure how much of the meal has passed beyond the stomach. A typical threshold to indicate abnormal gastric emptying is more than 10% of the meal remaining at 4 hours after ingestion.

PROCEDURE

Prior authorization is required.

WCE of the small bowel may be considered medically necessary for the following indications:

- Suspected small bowel bleeding; or
- Initial diagnosis in individuals with suspected Crohn's disease; or
- In individuals with an established diagnosis of Crohn's disease, when there are unexpected change(s) in the course of disease or response to treatment, suggesting the initial diagnosis may be incorrect and reexamination may be indicated; or
- For surveillance of the small bowel in individuals with hereditary GI polyposis syndromes, including familial adenomatous polyposis and Peutz-Jeghers syndrome; or
- For evaluation of individuals with suspected undefined enteropathies to help direct/guide device assisted enteroscopy; or
 - Individuals with enteropathies who are unable to undergo esphagogastroduodenoscopy (EGD) with biopsy; or;
- For evaluation of individuals with suspected celiac disease with a positive serology and a
- For re-evaluation of individuals with celiac disease who remain symptomatic despite treatment and there is no suspected or confirmed gastro-intestinal (GI) obstruction, stricture, or fistulae; or
- For screening or surveillance of esophageal varices in cirrhotic individuals 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; or
- For evaluation of known or suspected small bowel tumors.
- Persistent or unexplained iron deficiency anemia suspected to be due to GI bleeding.

The following indications for WCE are considered experimental/investigational and therefore non-covered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature, include but are not limited to:

- Evaluation of other GI diseases and conditions not presenting with GI bleeding, including but not limited to:
 - o Use in evaluating the stomach; or
 - o Duodenal lymphocytosis; or





- o Lynch syndrome (risk for hereditary nonpolyposis colorectal cancer); or
- Portal hypertensive enteropathy or gastropathy; or
- Unexplained chronic abdominal pain; or
- o Use for evaluating intussusception; or
- Use for follow-up of individuals with known small bowel disease other than Crohn's disease; or
- Evaluation of the colon, including but not limited to, detection of colonic polyps or colon cancer; or
- o Initial evaluation of individuals with acute upper GI bleeding; or
- Use for evaluating diseases involving the esophagus other than esophageal varices; or
- Use in confirming pathology identified by other diagnostic means.
- Evaluation of individuals with evidence of lower GI bleeding and major risks for colonoscopy or moderate sedation; or
- Evaluation of individuals following incomplete colonoscopy; or
- Evaluation of the esophagus, in individuals with gastroesophageal reflux or Barrett's esophagus.

WCE not meeting the criteria as indicated in this policy is considered experimental/investigational and therefore non-covered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

The patency capsule, including use to evaluate patency of the GI tract before WCE is considered experimental/investigational and therefore noncovered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

POST-PAYMENT AUDIT STATEMENT

The medical record should include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

PLACE OF SERVICE

Wireless endoscopy is typically an outpatient procedure which is only eligible for coverage as an inpatient procedure in special circumstances, including, but not limited to, the presence of a co-morbid condition that would require monitoring in a more controlled environment such as the inpatient setting.

CODING REQUIREMENTS

CPT Code	Description
91110	Gastrointestinal tract imaging, intraluminal (e.g., Capsule endoscopy), esophagus through ileum, with physician interpretation and report.
91111	Gastrointestinal tract imagine, intraluminal (e.g. Capsule endoscopy), esophagus with interpretation and report.
91113	Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), colon, with interpretation and report

Medical Policy



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91299
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Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report.

Covered Diagnosis Codes for Procedure Codes 91110 and 91111

C17.0	C17.1	C17.2	C17.3	C17.8
C17.9	C78.4	C7A.010	C7A.011	C7A.012
C7A.019	D13.2	D13.30	D13.39	D37.2
D3A.010	D3A.011	D3A.012	D3A.019	D50.0
D50.1	D50.8	D50.9	185.00	185.10
I85.11	K20.0	K22.0	K22.10	K22.11
K22.4	K22.5	K22.6	K22.81	K22.82
K22.89	K22.9	K23	K31.A0	K31.A11
K31.A12	K31.A13	K31.A14	K31.A15	K31.A19
K31.A21	K31.A22	K31.A29	K50.00	K50.011
K50.012	K50.013	K50.014	K50.018	K50.019
K50.10	K50.111	K50.112	K50.113	K50.114
K50.118	K50.119	K50.80	K50.811	K50.812
K50.813	K50.814	K50.818	K50.819	K50.90
K50.911	K50.912	K50.913	K50.914	K50.918
K50.919	K51.00	K51.011	K51.012	K51.013
K51.014	K51.018	K51.019	K51.20	K51.211
K51.212	K51.213	K51.214	K51.218	K51.219
K51.30	K51.311	K51.312	K51.313	K51.314
K51.318	K51.319	K51.80	K51.811	K51.812
K51.813	K51.814	K51.818	K51.819	K51.90
K51.911	K51.912	K51.913	K51.914	K51.918
K51.919	K52.3	K58.0	K58.1	K58.2
K58.8	K58.9	K90.0	K92.0	K92.1
K92.2	Q85.8	Q85.9	Z84.89	

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

SUMMARY OF LITERATURE

The American College of Gastroenterology (ACG) - 2013



The ACG (2013) issued guidelines on the diagnosis and management of celiac disease. The guidelines recommended that capsule endoscopy (CE) not be used for initial diagnosis, except for patients with positive celiac-specific serology who are unwilling or unable to undergo upper endoscopy with biopsy.

CE should be considered for the evaluation of small bowel mucosa in patients with complicated Crohn disease.

The ACG (2018) updated its guidelines on the management of CD in adults. It makes two recommendations specific to video capsule endoscopy:

- "Video capsule endoscopy (VCE) is a useful adjunct in the diagnosis of patients with small bowel Crohn's disease in patients in whom there is a high index of suspicion of disease."
- "Patients with obstructive symptoms should have small bowel imaging and/or patency capsule evaluation before VCE to decrease risk of capsule retention."

These recommendations are based on multiple studies. Capsule endoscopy was found to be "superior to small bowel barium studies, computed tomography enterography (CTE) and ileocolonoscopy in patients with suspected CD, with incremental yield of diagnosis of 32%, 47%, and 22%, respectively ... Capsule endoscopy has a high negative predictive value of 96%."

"However, some studies have questioned the specificity of capsule endoscopy findings for CD, and to date there is no consensus as to exactly which capsule endoscopy findings constitute a diagnosis of CD."

The ACG (2015) issued guidelines on the diagnosis and management of small bowel bleeding (including using "small bowel bleeding" to replace "obscure GI [gastrointestinal] bleeding," which should be reserved for patients in whom a source of bleeding cannot be identified anywhere in the GI tract).

References

Cave D. Wireless video capsule endoscopy. UpToDate. Updated 2017.

Suryakanth R. The role of endoscopy in the management of suspected small-bowel bleeding. Gastrointest Endosc. 2017;85(1):22-31.

Sung J. Use of capsule endoscopy in the emergency department as a triage of patients with GI bleeding. Clin Endosc. 2016;84(6):907-913.

Hayes, Inc. Hayes Health Technology Brief. Wireless Capsule Systems for Diagnosis of Gastroparesis and Monitoring of Gastrointestinal Motility. Lansdale, PA: Hayes, Inc.; 01/19/2021.

Van de Bruaene c, Hindryckx P, De Looze D, et al. The predictive value of negative capsule endoscopy for the indication of obscure gastrointestinal bleeding: No reassurance in the long term. Acta GastroEnterologica Belgica [serial online]. 2016;79(4):405-413.

Choi M, Lim S, Choi MG, Shim KN, Lee SH. Effectiveness of capsule endoscopy compared with other diagnostic modalities in patients with small bowel Crohn's disease: A meta-analysis. Gut Liver. 2017;11(1):62–72.

Kopylov U, Yung DE, Engel T, et al. Diagnostic yield of capsule endoscopy versus magnetic resonance enterography and small bowel contrast ultrasound in the evaluation of small bowel Chrohn's disease: Systematic review and meta-analysis. Dig Liver Dis. 2017;49(8):854-863.

Shi HY, Chan FKL, Higashimori A, et al. A prospective study on second-generation colon capsule endoscopy to detect mucosal lesions and disease activity in ulcerative colitis (with video).



Gastrointest Endosc. 2017;86(6):1139-1146.

McCarty TR, Afinogenova Y, Njei B. Use of wireless capsule endoscopy for the diagnosis and grading of esophageal varices in patients with portal hypertension: A systematic review and metaanalysis. J Clin Gastroenterol. 2017;51(2):174–182.

Sung JJ, Tang RS, Ching JY, et al. Use of capsule endoscopy in the emergency department as a triage of patients with GI bleeding. Gastrointest Endosc. 2016;84(6):907-913.

Spada C, Pasha SF, Gross SA, et al. Accuracy of first- and second-generation colon capsules in endoscopic detection of colorectal polyps: A systematic review and meta-analysis. Clin Gastroenterol Hepatol. 2016;14(11):1533-1543.

Morgan DR, Malik PR, Romeo DP, Rex DK. Initial US evaluation of second-generation capsule colonoscopy for detecting colon polyps. BMJ Open Gastroenterol. 2016;3(1):e000089.

Parodi A, Vanbiervliet G, Hassan C, et al. Colon capsule endoscopy to screen for colorectal neoplasia in those with family histories of colorectal cancer. Gastrointest Endosc. 2018;87(3):695-704.

Enns R, Hookey L, Armstron D, et al. Clinical practice guidelines for the use of video capsule endoscopy. Gastroenterol. 2017;152(3):497-514.

ASGE Standards of Practice Committee. The role of endoscopy in the management of suspected smallbowel bleeding. Gastrointest Endosc. 2017;85(1):22-31.

US Preventative Services Task Force. Screening for colorectal cancer: US Preventative Services Task Force recommendation statement. JAMA. 2016;315(23):2564-2575.

Hayes, Inc. Hayes Health Technology Assessment. Colon capsule endoscopy for colorectal cancer screening, diagnosis, and surveillance. Lansdale, PA: Hayes, Inc.; 11/25/2019.

Rex DK, Boland CR, Dominitz JA, et al. Colorectal cancer screening: Recommendations for physicians and patients from the U.S. Multi-Society Task Force on colorectal cancer. Gastroenterol. 2017;153(1):307-323.

Johnston CA, Yung DE, Joshi A, Plevris JN, et al. Small bowel malignancy in patients undergoing capsule endoscopy at a tertiary care academic center: Case series and review of the literature. Endosc Int Open. 2017;5(6):E463.

Cheung DY, Kim JS, Shim KN, Choi MG, Korean Gut Image Study Group. The usefulness of capsule endoscopy for small bowel tumors. Clin Endosc. 2016;49(1):21.

Esaki M, Matsumoto T, Ohmiya N, et al. Capsule endoscopy findings for the diagnosis of Crohn's disease: A nationwide case–control study. J Gastroenterol. 2019;54(3):249-60. Fabiola F, Federica G, Francesca V, et al. Applications of wireless capsule endoscopy in pediatric age: An update. Acta Biomed. 2018;89(Suppl 9):40.

Lichtenstein GR, Loftus EV, Isaacs KL et al. ACG clinical guideline: Management of Crohn's disease in adults. Am. J. Gastroenterol. 2018;113(4).

Nemeth A, Kopylov U, Koulaouzidis A, et al. Use of patency capsule in patients with established Crohn's disease. Endoscopy. 2016;48(04):373-9.



Lamb CA, Kennedy NA, Raine T, et al. British Society of Gastroenterology consensus guidelines on the management of inflammatory bowel disease in adults. Gut. 2019;68(Suppl 3): s1-06.

Mitselos IV, Katsanos KH, Tsianos EV, Eliakim R, et al. Clinical use of patency capsule: A comprehensive review of the literature. Inflamm Bowel Dis. 2018;24(11):2339-47.

Römmele C, Brueckner J, Messmann H, Gölder SK. Clinical experience with the PillCam patency capsule prior to video capsule endoscopy: A real-world experience. Gastroenterol Res Pract. 2016;2016.

Kopylov U, Nemeth A, Cebrian A, et al. Symptomatic retention of the patency capsule: A multicenter real life case series. Endosc Int Open. 2016;4(9): E964.

Bruining DH, Oliva S, Fleisher MR, Fischer M, Fletcher JG; BLINK study group. Panenteric capsule endoscopy versus ileocolonoscopy plus magnetic resonance enterography in Crohn's disease: A multicentre, prospective study. BMJ Open Gastroenterol. 2020;7(1):e000365.

Kjølhede T, Ølholm AM, Kaalby L, Kidholm K, Qvist N, Baatrup G. Diagnostic accuracy of capsule endoscopy compared with colonoscopy for polyp detection: Systematic review and metaanalyses. Endoscopy. 2021;53(7):713-721.

ASGE Standards of Practice Committee, Gurudu SR, Bruining DH, Acosta RD, Eloubeidi MA, Faulx AL, et al. The role of endoscopy in the management of suspected small-bowel bleeding. Gastrointest Endosc. 2017;85(1):22-31.

Strate LL, Gralnek IM. ACG clinical guideline: Management of patients with acute lower gastrointestinal bleeding. Am J Gastroenterol. 2016;111(4):459-74.

Awadie H, Bourke MJ. When colonoscopy fails... Refer, repeat, and succeed. GE Port J Gastroenterol. 2018;25(6):279-281.

Chetcuti Zammit S, Sidhu R. Capsule endoscopy - Recent developments and future directions. Expert Rev Gastroenterol Hepatol. 2021;15(2):127-137.

Spada C, Hassan C, Bellini D, Burling D, Cappello G, Carretero C, et al. Imaging alternatives to colonoscopy: CT colonography and colon capsule. European Society of Gastrointestinal Endoscopy (ESGE) and European Society of Gastrointestinal and Abdominal Radiology (ESGAR) guideline - Update 2020. Endoscopy. 2020;52(12):1127-1141.

Offman J, Fitzgerald RC. Alternatives to traditional per-oral endoscopy for screening. Gastrointest Endosc Clin N Am. 2017;27(3):379-396.

Krishna Chandar A, Sharma A, Chak A. Novel screening alternatives for barrett esophagus. Gastroenterol Hepatol (N Y). 2020;16(5):238-245.

Hayes, Inc. Hayes Evidence Analysis Research Brief. Use of a patency capsule to verify small bowel patency prior to capsule endoscopy. Lansdale, PA: Hayes, Inc.; 05/17/2021.

Hayes, Inc. Hayes Health Technology Assessment. Capsule endoscopy for the diagnosis of small bowel crohn's disease. Lansdale, PA: Hayes, Inc.; 03/23/2017.

Nakamura M, Kawashima H, Ishigami M, Fujishiro M. Indications and limitations associated with the patency capsule prior to capsule endoscopy. Intern Med. 2021.

Nakamura M, Watanabe K, Ohmiya N, Hirai F, Omori T, et al.; J-POP study group. Tag-less





patency capsule for suspected small bowel stenosis: Nationwide multicenter prospective study in Japan. Dig Endosc. 2021;33(1):151-161.

Watanabe K, Ohmiya N, Nakamura M, Fujiwara Y. A prospective study evaluating the clinical utility of the tag-less patency capsule with extended time for confirming functional patency. Digestion. 2021;102(2):180-187.

Yamamoto H, Ogata H, Matsumoto T, Ohmiya N, Ohtsuka K, et al. Clinical practice guideline for enteroscopy. Dig Endosc. 2017;29(5):519-546.

Sawada T, Nakamura M, Watanabe O, Yamamura T, et al. Clinical factors related to falsepositive rates of patency capsule examination. Therap Adv Gastroenterol. 2017;10(8):589-598.

POLICY UPDATE HISTORY

08/19/2021	Approved in Medical Policy Committee	
01/27/2022	Revised and approved in Medical Policy Committee	
02/2022	Approved in QI/UM	
02/22/2023	Annual review; approved in Medical Policy Committee	
02/28/2023	Approved in QI/UM	