Subject: Capsule Endoscopy

Background: Capsule endoscopy (CE), also called wireless capsule endoscopy (WCE) is a noninvasive procedure in which a swallowable, multivitamin-sized capsule (containing a miniaturized video camera, light, and transmitter) takes a video recording of the mucosal lining of the esophagus and/or small bowel as it moves through the gastrointestinal (GI) tract.

Policy and Coverage Criteria:

Harvard Pilgrim Health Care (HPHC) considers capsule endoscopy utilizing a U.S. Food and Drug Administration (FDA)-approved device as reasonable and medically necessary when the procedure is performed once for any episode of illness and documentation confirms ANY of the following:

- Evaluation of malignant or benign carcinoid tumors of the small intestine or suspected small bowel tumors not adequately characterized by standard endoscopic and imaging techniques, including but not limited to upper GI endoscopy, colonoscopy, push enteroscopy, nuclear imaging, or radiological procedures, OR
- Investigation of GI bleeding, suspected to be of small bowel origin, who have had upper and lower gastrointestinal endoscopies (EGD and colonoscopy) during the current episode of illness that have failed to identify a bleeding source, OR
- Evaluation of undiagnosed malabsorptive syndromes with prior history of negative small bowel biopsy (suspected celiac), OR
- Initial diagnosis in member with suspected Crohn's disease when conventional treatments have failed, OR
- Re-evaluation of persons with Crohn's disease who remain symptomatic throughout treatment, suggesting erroneous diagnosis and re-examination may be required, OR
- Evaluation of members with hamartomatous polyposis syndromes effecting the small bowel (Peutz-Jeghers syndrome), OR
- Evaluation for and surveillance of esophageal varices when member has portal hypertension and cirrhosis with significantly compromised liver function when sedation and anesthesia necessary for EGD is contraindicated

Exclusions:

Harvard Pilgrim Health Care (HPHC) considers capsule endoscopy as experimental/investigational for all other indications. In addition, HPHC does not cover:

- Cytosponge™ Cell Collection Device
- Evaluation of gastrointestinal diseases (e.g. irritable bowel syndrome, unexplained chronic abdominal pain) with no evidence of GI bleeding
- Evaluation of the colon, such as detection of polyps or colorectal cancer (e.g. Pillcam® COLON)
- Patency capsule (AGILE™ Patency System)
- Repeat use to determine surgical effectiveness
- SmartPill™ GI Monitoring System

Supporting Information:

Wireless capsule endoscopy is a noninvasive technology intended to deliver diagnostic imaging of the small intestine, a site that has been difficult to visualize. Magnification through capsule endoscopy allows visualization of individual villi and these devices may aid in evaluation of suspected small bowel bleeding in adults, evaluation of those with suspected Crohn's Disease, along with other indications.

Cytosponge is a novel, minimally invasive, non-endoscopic esophageal sampling device. Januszewicz et al. 2019 performed patient-level reviews of five prospective trials assessing the efficacy of Cytosponge in individuals with reflux disease, Barrett's esophagus (BE) and eosinophilic esophagitis (EoE) in primary and secondary care. In total, 2,672 procedures were performed between 2008 and 2017 with two adverse events related to the device – a minor pharyngeal bleed and a detachment. The results showed to be promising. However, the authors noted prior to implementation in clinical practice, additional randomized trial data is required to fully evaluate the safety, acceptability and diagnostic yield of Cytosponge.

Segarajasingam et al. (2015) conducted a randomized trial to compare video capsule endoscopy (VCE) with push enteroscopy in 79 individuals with obscure gastrointestinal bleeding (OGIB) and negative esophagogastroduodenoscopy (EGD) and colonoscopies. VCE had greater diagnostic yield, especially in the small bowel. More VCE-identified lesions were rated possible or certain causes of bleeding. The authors concluded that a VCE-first approach had a significant diagnostic advantage over push endoscopy-first in individuals with OGIB. Lewis and Swain (2002) studied 21 individuals with obscure GI bleeding who underwent CE. The results of CE examinations were compared with push enteroscopy findings. A bleeding site was found in 11 of 20 individuals during CE with a yield of 55%, whereas, push enteroscopy only yielded 30%. CE identified a distal source of bleeding in five of 14 individuals who had normal push enteroscopic examinations. The authors concluded that the results demonstrate that CE provides excellent visualization of the small intestine, is well tolerated by individuals, and is safe.

An official statement of the European Society of Gastrointestinal Endoscopy (ESGE, 2015), reviewed and endorsed by the British Society of Gastroenterology (BSG), addresses the roles of small-bowel capsule endoscopy and device-assisted enteroscopy for diagnosis and treatment of small-bowel disorders. ESGE recommends small- bowel VCE as the first-line investigation in individuals with obscure GI bleeding. In individuals with overt obscure GI bleeding, ESGE recommends performing small-bowel CE as soon as possible after the bleeding episode, optimally within 14 days, in order to maximize the diagnostic yield. In those with suspected Crohn's disease and negative ileocolonoscopic findings, ESGE recommends small-bowel CE as the initial diagnostic modality for investigating the small bowel, in the absence of obstructive symptoms or known stenosis. ESGE does not recommend routine small-bowel imaging or the use of the PillCam patency capsule prior to CE. In individuals with unremarkable or nondiagnostic findings from cross-sectional imaging of the small bowel, ESGE recommends small-bowel CE as a subsequent investigation, if deemed to influence individual management.

Studies indicate capsule endoscopy (CE) may be an acceptable tool for the diagnosis of celiac disease. A 2013 review by Ianiro et al. noted the indications for CE in the use of diagnosis and follow up of celiac disease are growing. Mustafa et al. (2013) also highlighted CE's role as an important diagnostic tool in celiac disease.

A 2011 review by Lui and Kaffes explored the evidence on the diagnosis and investigation of obscure gastrointestinal bleeding (OGIB). In their report they noted the latest systematic review of 227 articles on capsule endoscopy (CE) revealed OGIB was the most common indication, with 66% of individuals undergoing the procedure. Factors such as performing CE within two weeks of a bleeding episode increase the yield of the examination. The authors also noted that CE has consistently been shown to be superior to push enteroscopy

and small bowel radiography in detecting small bowel lesions.

Calabrese et al. (2011) retrospectively evaluated medical records for individuals who underwent capsule endoscopy (CE) for obscure gastrointestinal bleeding (OGIB) from May 2006 to May 2011. Records were reviewed to determine the type of OGIB (occult, overt), CE results and complications, and timing of CE with respect to onset of bleeding. Out of 346 individuals investigated, 71.1% had some lesion detected. 206 individuals (59.5%) had definite lesions detected that could unequivocally explain the bleeding. Small bowel angiodysplasia, ulcer/erosions secondary to Crohn's disease, non-steroidal anti-inflammatory agent use, and neoplasms were the commonest lesions detected. Given the results of their experience, the authors found CE to be safe, comfortable and effective, with a high rate of accuracy for diagnosing OGIB.

Atlas et al. (2011) looked at the utility of capsule endoscopy (CE) in non-responsive Celiac. The authors performed a case-control study on 42 individuals with non-responsive Celiac and 84 age and sex matched disease-free controls who underwent CE. The main outcome measurement was diagnostic accuracy of CE for the detection of mucosal abnormalities in non-responsive CD. Results found macroscopic features of villous atrophy detected in 13 out of 42 celiac individuals compared with none among the controls. Overall sensitivity and specificity of CE for the detection of any degree of villous atrophy as graded by histology were 56% and 85%, respectively. The authors found CE can detect severe complications in individuals with nonresponsive celiac.

A 2011 review by Lucendo and Guagnozzi analyzing the literature around small bowel capsule endoscopy (CE) in Crohn's found the technology to be in important advance in the diagnosis of small bowel diseases. Diagnostic yield of CE in Crohn's disease increases when findings are interpreted within a suitable clinical and analytical context.

Chavalitdhamrong et al. (2011) reported capsule endoscopy (CE) findings in individuals with GER symptoms. Reflux esophagitis was diagnosed via CE in 50.5% of individuals. 2.4% of individuals were tagged with suspected Barrett's esophagus. The authors noted esophageal CE is valuable as an alternative screening tool for diagnosing Barrett's esophagus.

Petruzziello et al. (2010) found capsule endoscopy (CE) allowed for the detection of previously unknown upper small bowel lesions in a high proportion of individuals with a previous diagnosis of Crohn's disease involving the distal ileum. 64 individuals underwent CE; 32 with Celiac Disease of the distal ileum and 32 controls with iron-deficiency anemia or diarrhea. CE detected proximal small bowel lesions in 16 of 32 individuals (14 aphthoid ulcers, two deep ulcers, one stricture), which appeared to be unrelated to clinical parameters.

Dionisio et al. (2010) conducted a literature analysis of studies comparing the diagnostic yield of capsule endoscopy (CE) with other modalities in individuals with Crohn's Disease. Other modalities included push enteroscopy, colonoscopy with ileoscopy, SB radiography, computed tomography enterography (CTE), and magnetic resonance enterography (MRE). The authors concluded through their analysis that CE is superior to the other modalities included in the comparison in individuals with suspected Crohn's disease. CE was also a more effective diagnostic tool in established Crohn's disease individuals compared with SB radiography, CTE, and push enteroscopy.

Coding:

Codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible.

CPT® Codes	Description
91110	Gastrointestinal tract imaging, intraluminal (e.g. capsule endoscopy), esophagus through ileum, with physician interpretation and report

Non-covered Code

CPT® Codes	Description
91112	Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report

Medically Necessary ICD-10 Codes with 91110

ICD-10 Codes	Description
A18.32	Tuberculous Enteritis
A18.83	Tuberculosis of Digestive Tract Organs, not elsewhere classified
C7A.010	Malignant carcinoid tumor of the duodenum
C7A.011	Malignant carcinoid tumor of the jejunum
C7A.012	Malignant carcinoid tumor of the ileum
C7A.019	Malignant carcinoid tumor of the small intestine, unspecified portion
C17.0	Malignant Neoplasm of Duodenum
C17.1	Malignant Neoplasm of Jejunum
C17.2	Malignant Neoplasm of Ileum
C17.3	Meckel's Diverticulum, Malignant
C17.8	Malignant Neoplasm of Overlapping Sites of Small Intestine
C17.9	Malignant Neoplasm of Small Intestine, Unspecified
C78.4	Secondary Malignant Neoplasm of Small Intestine
D01.49	Carcinoma in Situ of Other Parts of Intestine
D13.2	Benign neoplasm of duodenum
D13.30	Benign neoplasm of unspecified part of small intestine
D13.39	Benign neoplasm of other parts of small intestine
D3A.010	Benign carcinoid tumor of the duodenum
D3A.011	Benign carcinoid tumor of the jejunum
D3A.012	Benign carcinoid tumor of the ileum
D3A.019	Benign carcinoid tumor of the small intestine, unspecified portion
D37.2	Neoplasm of Uncertain Behavior of Small Intestine
D50.0	Iron deficiency anemia secondary to blood loss (chronic)
D50.8	Other iron deficiency anemias
D50.9	Iron deficiency anemia, unspecified
K31.811	Angiodysplasia of Stomach and Duodenum with Bleeding
K31.82	Dieulafoy Lesion (Hemorrhagic) of Stomach and Duodenum
K50.00	Crohn's disease of small intestine without complications
K50.011	Crohn's disease of small intestine with rectal bleeding
K50.012	Crohn's disease of small intestine with intestinal obstruction
K50.013	Crohn's disease of small intestine with fistula
K50.014	Crohn's disease of small intestine with abscess

HPHC policies are based on medical science, and written for the majority of people with a given condition.

Coverage described in this policy is standard under most HPHC plans. Specific benefits may vary by product and/or employer group. Please reference appropriate member materials (e.g., Benefit Handbook, Certificate of Coverage) for member-specific benefit information.

K50.018	Crohn's disease of small intestine with other complication
K50.019	Crohn's disease of small intestine with unspecified complications
K50.811	Crohn's disease of both small and large intestine with rectal bleeding
K50.813	Crohn's disease of both small and large intestine with fistula
K50.814	Crohn's disease of both small and large intestine with abscess
K50.818	Crohn's disease of both small and large intestine with other complication
K50.819	Crohn's disease of both small and large intestine with unspecified complications
K50.90	Crohn's disease, unspecified, without complications
K50.911	Crohn's disease, unspecified, with rectal bleeding
K50.912	Crohn's disease, unspecified, with intestinal obstruction
K50.913	Crohn's disease, unspecified, with fistula
K50.914	Crohn's disease, unspecified, with abscess
K50.918	Crohn's disease, unspecified, with other complication
K50.919	Crohn's disease, unspecified, with unspecified complications
K52.0	Gastroenteritis and Colitis Due to Radiation
K52.3	Indeterminate Colitis
K52.831	Collagenous Colitis
K52.832	Lymphocytic Colitis
K52.838	Other Microscopic Colitis
K52.839	Microscopic Colitis, Unspecified
K52.89	Other Specified Noninfective Gastroenteritis and Colitis
K52.9	Noninfective Gastroenteritis and Colitis, Unspecified
K55.1	Chronic Vascular Disorders of Intestine
K57.00	Diverticulitis of Small Intestine with Perforation and Abscess without Bleeding
K57.01	Diverticulitis of Small Intestine with Perforation and Abscess with Bleeding
K57.10	Diverticulosis of Small Intestine without Perforation or Abscess without Bleeding
K57.11	Diverticulosis of Small Intestine without Perforation or Abscess with Bleeding
K57.12	Diverticulitis Of Small Intestine Without Perforation Or Abscess Without Bleeding
K57.13	Diverticulitis Of Small Intestine Without Perforation Or Abscess With Bleeding
K57.41	Diverticulitis Of Both Small And Large Intestine With Perforation And Abscess With Bleeding
K57.51	Diverticulosis Of Both Small And Large Intestine Without Perforation Or Abscess With Bleeding
K57.53	Diverticulitis Of Both Small And Large Intestine Without Perforation Or Abscess With Bleeding
K63.3	Ulcer Of Intestine
K63.81	Dieulafoy Lesion Of Intestine
K70.30	Alcoholic cirrhosis of liver without ascites
K70.31	Alcoholic cirrhosis of liver with ascites
K71.7	Toxic liver disease with fibrosis and cirrhosis of liver
K74.69	Other cirrhosis of liver
K90.0	Celiac Disease
K90.1	Tropical Sprue
K90.2	Blind Loop Syndrome, Not Elsewhere Classified
K90.81	Whipple's Disease

K92.0	Hematemesis
K92.1	Melena
K92.2	Gastrointestinal hemorrhage, unspecified
K92.81	Gastrointestinal Mucositis (Ulcerative)
Q43.0	Meckel's Diverticulum (Displaced) (Hypertrophic)
Q85.8	Other phakomatoses, not elsewhere classified
Q85.9	Phakomatosis, unspecified

Billing Guidelines:

Member's medical records must document that services are medically necessary for the care provided. Harvard Pilgrim Health Care maintains the right to audit the services provided to our members, regardless of the participation status of the provider. All documentation must be available to HPHC upon request. Failure to produce the requested information may result in denial or retraction of payment.

References:

1. Calabrese, C., Liquori, G., Gionchetti, P., Rizzello, R., et al. Obscure gastrointestinal bleeding: single center experience of capsule endoscopy. Intern Emerg Med. 2011 Sept 29.
2. Capsule Endoscopy for the Diagnosis of Small Bowel Crohn's Disease. Hayesinc.com/subscribers [via
3. Capsule Endoscopy of the Diagnosis of Small Bowel Disease in Children. Hayesinc.com/subscribers [via subscription only]. Accessed October 28, 2020.
4. Capsule Endoscopy of the Small Bowel for Oscure Gastrointestinal Bleeding. Hayesinc.com/subscribers [via subscription only]. Accessed October 28, 2020.
5. Chavalitdhamrong, D., Chen, GC., Roth, BE., et al. Esophageal capsule endoscopy for evaluation of patients with chronic gastroesophageal reflux systems: findings and its imagine quality. Dis Esophagus 2011; June 10.
6. Cheung D, Kim J, Shim K, Choi M. The Usefulness of Capsule Endoscopy for Small Bowel Tumors. Clin Endosc. 2016;49(1):21-25. doi:10.5946/ce.2016.49.1.21.
7. Colli A, Gana J, Turner D et al. Capsule endoscopy for the diagnosis of oesophageal varices in people with chronic liver disease or portal vein thrombosis. Cochrane Database of Systematic Reviews. 2014. doi:10.1002/14651858.cd008760.pub2.
8. Diagnosis and staging of small bowel neoplasms. Uptodate.com/login [via subscription only]. Accessed October 28, 2020.
9. Diagnosis of celiac disease. Uptodate.com/login [via subscription only]. Accessed October 28, 2020.
10. Dionisio, PM., Gurudu, SR., Leighton, JA., Leontiadis, GI., Fleischer, DE., Hara, AK., Heigh, RI., Shiff, AD., Sharma, VK. Capsule endoscopy has a significantly higher diagnostic yield in patients with suspected and established small-bowel Crohn's disease: a meta-analysis. Am J Gastroenterol. 2010; 105(6):1240-8.
11. Doherty, GA., Moss, AC., Chiefetz, AS. Capsule endoscopy for small-bowel evaluation in Crohn's disease.
12. Dye, CE., Gaffney, RR., Dykes, TM., Moyer, MT. Endoscopic and radiographic evaluation of the small bowel in 2012. Am J Med. 2012; 125(12): 1228.e1-1228.e12.
13. Evaluation of occult gastrointestinal bleeding. Uptodate.com/login [via subscription only]. Accessed October 27, 2020.
14. Figueiredo, P., Almeida, N., Lopes, S., Dugue, G., et al. Small bowel capsule endoscopy in patients with Gastro Endosc. 2011; 74(1): 167-175.
15. Gerson LB, Fidler JL, Cave DR, Leighton JA. ACG Clinical Guideline: Diagnosis and management of small bowel bleeding.Am J Gastroenterol. 2015; 110(9):1265-1288.
16. Herescbach, D., Leray, E., d"halluin, PN., et al. Diagnostic accuracy of esophageal capsule endoscopy versus conventional upper digestive endoscopy for suspected esophageal squamous cell carcinoma. Endoscopy.

2010; 42(2): 93-7.
17. Hirano, A., Esaki, M., Moriyama, T., et al. Comparison of capsule endoscopy and double balloon endoscopy for the diagnosis of submucosal tumor of the small bowel. Diag Endosc. 2012; 24(4): 287.
18. Ianiro, G., Gasbarrini, A., Cammarota, G. Endoscopic tools for the diagnosis and evaluation of celiac disease. World J Gastroenterol. 2013; 19(46): 8562-70.
19. Januszewicz W, Tan WK, Lehovsky K, et al. Safety and Acceptability of Esophageal Cytosponge Cell Collection Device in a Pooled Analysis of Data From Individual Patients. Clinical Gastroenterology and Hepatology. 2019;17(4). doi:10.1016/j.cgh.2018.07.043.
20. Leighton, JA. The role of endoscopic imaging of the small bowel in clinical practice. Am J Gastroenterol. 2011; 106(1): 27-36.
21. Lidums, I., Cummins, AG., Teo, E. The role of capsule endoscopy in suspected celiac disease patients with positive celiac serology. Dig Dis Sci. 2011; 56(2): 499-505.
22. Lucendo, AJ., Guagnozzi, D. Small bowel video capsule endoscopy in Crohn's disease: what have we learned in the last 10 years? World J Gastrointest Endosc. 2011; 3(2): 23-29.
23. Luján-Sanchis M, Sanchis-Artero L, Larrey-Ruiz L et al. Current role of capsule endoscopy in Crohn's disease.
24. Mustafa, BF., Samaan, M., Langmead, L., Khasraw, M. Small bowel video capsule endoscopy: an overview. Expert Rev Gastroenterlol Hepatol. 2013; 7(4): 323-9.
25. Nakamura M, Hirooka Y, Yamamura T et al. Clinical usefulness of novel tag-less Agile patency capsule prior to capsule endoscopy for patients with suspected small bowel stenosis. Digestive Endoscopy. 2014;27(1):61-66. doi:10.1111/den.12306.
26. Overview of deep small bowel enteroscopy. UpToDate.com/login [via subscription only]. Accessed October 26, 2020.
27. Pennazio, M., Spada, C., Eliakim, R., et al. Small-boawel capsule endoscopy and device-assisted enteroscopy for diagnosis and treatment of small-bowel disorders: European Society of Gastrointestinal Endoscopy (ESGE) Clinical Guideline. Endoscopy. 2015; 47(4):352-86.
28. Petruzziello, C., Onali, S., Calabrese, E., et al. Wireless capsule endoscopy and prximal small bowel lesions in
29. Raghav, K., Overman, MJ. Small bowel adenocarcinomas—existing evidence and evolving paradigms. Nat Rev Clin Oncol. 2013; 10(9): 534-44.
30. Segarajasingam, DS., Hanley, SC., Barkun, AN., Waschke, KA., Burtin, P., Parent, J., Mayrand, S., Fallone, CA., Jobin, G., Seidman, EG., Martel, M. Randomized controlled trial comparing outcomes of video capsule endoscopy with push endoscopy in obscure gastrointestinal bleeding. Can J Gastroenterol Hepatol. 2015; 29(2):85-90.
31. Wireless video capsule endoscopy. Uptodate.com/login [via subscription only]. Accessed October 28, 2020. World Journal of Gastrointestinal Endoscopy. 2016;8(17):572. doi:10.4253/wjge.v8.i17.572.
32. Zagorowicz, ES., Pietrzak, AM., Wronska, E., et al. Small bowel tumors detected and missed during capsule endoscopy: single center experience. World J Gastroenterol. 2013; 19(47): 9043-8.

Summary of Changes:

Date	Changes
11/20	Annual review; criteria refined, supporting information and references updated
12/19	Criteria and coding updated
6/17	References updated, policy coverage criteria and exclusions refined

Approved by Medical Policy Committee: 11/10/20
Approved by Clinical Policy Operational Committee: 6/09; 1/10; 1/12; 1/14; 5/15; 6/17; 12/19; 11/20
Policy Effective Date: 11/30/20
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