Medical Policy Reference Manual
Medical Policy

7.01.076 Wireless Capsule Endoscopy (Enteral Camera)

Original MPC Approval: 04/17/2002
Last Review: 01/01/2023
Last Revision: 01/01/2023

Description

The American Gastroenterological Association states that obscure gastrointestinal (GI) bleeding, defined as persistent or recurrent bleeding of unknown origin from within the GI tract, can be difficult to diagnose and manage. Patients may present with iron-deficiency anemia, positive fecal occult blood test, or visible bleeding, which may arise from vascular malformation, tumor(s), angiodysplasias, or telangiectasias in the small bowel. Patients may have undergone numerous diagnostic tests, including upper GI series, nuclear scans, CT scans and endoscopies with inconclusive results. Although direct vision endoscopic examination and therapy is very effective, endoscopy is limited in that it is not possible to examine the entire length of the small intestine with conventional push endoscopy technique.

Wireless capsule endoscopy is a technique that uses a miniature digital camera to visualize the entire length of the small intestine. The system consists of a tiny disposable camera unit, a sensor unit with recording device, and computer analysis software. The patient swallows the camera unit with water in the physician's office as one would take a medication or vitamin capsule. The camera has its own light source, and as it makes its way through the digestive system it captures over o 50,000 images, before its internal battery is exhausted. The images are transmitted via the sensor unit to the recording unit, which the patient wears on a belt around the waist. The camera is eventually excreted in the stool and disposed of, and the patient returns the recording unit to the physician, who downloads the data into a computer. A software program then processes the data into a video stream of the patient's small intestine. Drawbacks of capsule endoscopy consist of lack of control as the device moves through the digestive system and an inability to obtain tissue samples (biopsies) or perform suction during the exam. (Akpunonu, B., et al, 2022).

Accepted and established applications of the enteral camera include evaluation of patients with obscure bleeding from the small bowel, initial diagnosis of patients with suspected Crohn's disease, and surveillance of patients with hereditary polyposis syndromes. Other lower GI system applications have been proposed, such as further evaluation of patients diagnosed with Crohn's disease, and evaluation of GI disorders not associated with bleeding, such as celiac sprue, irritable bowel syndrome, and small bowel neoplasms. Recently, a modification of the original enteral camera system was developed for use in evaluating disorders of the esophagus, such as gastroesophageal reflux disease (GERD), esophagitis, Barrett's esophagus, and esophageal varices.

Policy

Wireless capsule endoscopy is considered **medically necessary** for the following indications:

- to investigate obscure gastrointestinal bleeding suspected of being of small bowel origin.
- Crohn’s disease, known or suspected, when there is no clinical suspicion or radiologic evidence of significant stricture
- for surveillance of the small bowel in patients with hereditary GI polyposis syndromes, including familial adenomatous polyposis and Peutz-Jeghers syndrome
- to evaluate other gastrointestinal diseases not presenting with gastrointestinal bleeding, such as celiac sprue, irritable bowel syndrome or small bowel neoplasm.
- Esophageal varices, suspected, in presence of confirmed Cirrhosis and esophagogastroduodenoscopy (EGD) is not an option

Except for esophageal varices because of cirrhosis, wireless capsule endoscopy for the esophagus is considered experimental / investigational because it does not meet TEC criteria #2-5.

Wireless capsule colonoscopy is considered **experimental / investigational** when used to evaluate the colon, including detection of colon polyps or colon cancer as it does not meet TEC criteria #2-5

The patency capsule is considered **experimental / investigational**, including use to evaluate patency of the gastrointestinal tract before wireless capsule endoscopy as it does not meet TEC criteria # 2-5.

Wireless capsule endoscopy is considered **not medically necessary** in patients with full or partial intestinal obstructions or a history of or known/current intestinal strictures.

Policy Guidelines

Experimental/Investigational

The term "experimental/investigational" describes services or supplies that are in the developmental stage and are in the process of human or animal testing. Services or supplies that do not meet all 5 of the criteria listed below adopted by the BlueCross BlueShield Association (BCBSA) Medical Policy Services (MPS) Assessment Criteria (formerly known as the TEC Criteria or “Technology Evaluation Center” criteria are deemed to be experimental/investigational):

1. The technology* must have final approval from the appropriate U.S. government regulatory bodies; and
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes; and
3. The technology must improve the net health outcome; and
4. The technology must be as beneficial as any established alternatives; and
5. The improvement must be attainable outside the investigational settings.

* Technology includes drugs, devices, processes, systems, or techniques

Rationale:

1. The technology* must have final approval from the appropriate U.S. government regulatory bodies:

The M2A® (Given Imaging, Ltd.) camera and accompanying signal receiver and software were originally given 510(k) market clearance by the FDA in August 2001 as an adjunctive evaluation method for detecting small bowel abnormalities in persons with unexplained or recurrent GI bleeding where conventional endoscopy or other diagnostic tests failed to locate the origin of the bleeding. In July of 2003 the FDA approved labeling as a first-line method for detecting small bowel abnormalities, and in October of 2003 the device was granted an additional labeling for use in patients aged 10-18 years. The FDA granted a new 510(k) clearance for the PillCam™ ESO with the Given Diagnostic System® in October of 2004 for visualization of the esophageal mucosa, and a month later a modified PillCam™ SB capable of producing 14 frames per second received 510(k) clearance. In 2006, the FDA provided clearance for the Given AGILE® patency system which is intended to verify adequate patency of the GI tract prior to administration of the wireless capsule for endoscopy. This capsule is of similar size to the endoscopy capsule but is made of lactose and barium and carries a tracer material that can be detected by a scanning device. Excretion of the intact capsule without symptoms (abdominal pain or obstruction) is reported to predict the uncomplicated passage of the wireless capsule. If not excreted, the capsule dissolves within 30-100 hours of entering the GI tract. Colon capsule endoscopy is approved by the US Food and Drug Administration (FDA) for use only in patients who had an incomplete colonoscopy, not as a screening option by itself.

2. The scientific evidence must permit conclusions concerning the effect on health outcomes:

The PillCam™ ESO is a design of the capsule endoscopy product that was developed specifically for use in identifying pathologies in the lower esophagus, such as varices, Barrett's metaplasia, esophagitis, and gastroesophageal reflux disease. Currently the evidence for use of the esophageal capsule is limited. Because esophagoscopy (ES) is a well-established, widespread, and fairly simple procedure, studies have tended to focus on comparing results obtained with esophageal CE to those obtained endoscopically. Eliakim and colleagues have documented three studies since 2004, with blinding of observers to results obtained by ES. Within these study designs, sensitivities tend to run in the 92% range and 95% specificity range for CE, with overall better than 90% concordance with results from ES. A study by Schnoll-Sussman and colleagues, however, reported results that were not nearly so impressive in a cohort study of 53 patients with long-standing GERD in an evaluation for Barrett's esophagus. Compared with conventional ES, the sensitivity was 67%, specificity 75%. These studies for the most part are considered preliminary and the role for esophageal CE remains to be defined. CE by its nature only provides a means for visualization, whereas ES allows the operator to perform biopsy or therapeutic interventions. MCG (2021) reports that research outcomes for capsule endoscopy for Barrett’s esophagus do not adequately address net benefit and further high quality studies are needed.

Hayes Evolving Evidence (2022) reports research is limited and comprised of poor and very poor quality retrospective studies. High quality research such as double-blind RCTs or meta-analyses are needed to assess effect on health outcomes.

3. The technology must improve the net health outcome:

For patients with disorders of the esophagus other than varices in patients with previously diagnosed cirrhosis for whom conventional endoscopy is not an option, there is insufficient evidence to permit conclusions regarding patient outcomes (MCG 2021). Therefore, it is not possible to determine whether net health outcomes are improved. High quality research is needed to assess that data from wireless capsule endoscopy studies has a beneficial impact on health outcomes for persons with GI motility disorders. Multiple small studies that demonstrate the role of capsule endoscopy for measuring gastrointestinal motility have yet to provide clearly defined outcomes (Hayes 2021). MCG also recommends further research on capsule endoscopy for gastrointestinal motility as available evidence is of low quality and does not adequately address net benefit (MCG, 2021). Available research outcomes for wireless capsule endoscopy as a diagnostic and treatment management tool for ulcerative colitis does not provide evidence of net benefit and available studies are considered very low quality. Larger studies are needed to assess clinical validity. (MCG, 2021). Research outcomes for wireless capsule endoscopy for colorectal polyps do not clearly provide proof of net benefit as data from studies is considered lacking and recommendations from clinical guidelines are not strong (MCG, 2021). NCCN (2022), reports that wireless capsule endoscopy is an emerging diagnostic tool which has improving accuracy for colorectal cancer diagnosis but still remains inconsistent in polyp detection with ranges from 24% to 74% diagnosed. For follow-up after incomplete colonoscopy, available research for wireless capsule endoscopy is from small, low-quality studies plagued with inconsistency such as lack of standardization and follow-up data. Additional high-quality research in the form of blinded RCTs and meta-analyses that compare capsule endoscopy with radiologic imaging or conventional endoscopic modalities are recommended to confirm wireless capsule endoscopy's effectiveness and patient suitability. (MCG, 2021)

4. The technology must be as effective as any established alternatives:

The most recent studies have demonstrated CE to be superior to techniques such as push endoscopy and enteroclysis as diagnostic methodologies in obscure gastrointestinal bleeding and Crohn's disease. For celiac disease, there is preliminary evidence that CE may be used to identify conditions such as villous atrophy and mucosal fissures in complicated cases, but the role of CE for this condition has not yet been established, and that endoscopy and biopsy remain the standard treatment approach. For conditions of the esophagus, there is preliminary evidence that CE can identify these conditions, but there is as yet inadequate evidence that it is at least as effective as the current standard esophagoscopy. USPSTF 2021 guidelines do not recommend CE as a screening tool for colon cancer, stating limited available research on CE for this indication and the availability of proven alternatives such as direct visualization (colonoscopy) and stool DNA tests. Current research on CE for screening of colon cancer fails to provide reliable outcomes as a screening tool compared to alternative procedures like conventional colonoscopy or computed tomography of the colon. Concerns in reported data include incomplete visual evaluation of colon by CE. Further studies comprised of high-quality research that include long term data on mortality/morbidity are necessary to fully assess CE as an alternative to established exams for colorectal cancer screening. (Hayes, 2019). Hayes Health Technology Assessment (2021) relays that more research is needed to assess wireless capsule endoscopy comparisons to established testing for GI Motility disorders. While the American Gastroenterologic Association provides a recommendation for a patency capsule in individuals with known or suspected strictures of the small bowel, this is a conditional recommendation with very low quality of evidence for efficacy and low-quality evidence for safety. The AGA notes: "Therefore, the consensus group suggested that in patients with obstructive symptomatology, imaging should be performed before CE. In patients with negative imaging, most investigators will not use a patency capsule. In patients with abnormalities, suggesting a high risk of capsule retention, patency capsules can be considered although some recent data have questioned their benefit." (AGA, 2017).

5. The improvement must be attainable outside the investigational settings:

An improvement outside of investigational settings has not been adequately established for capsule patency testing, wireless capsule endoscopy as a diagnostic test or management for esophageal disease except as noted in medically necessary statement, ulcerative colitis, gastric motility, screening for colon cancer, or colon cancer diagnosis.

Update 2022:
A search of the peer-reviewed literature was performed from the period of January 2020 through September 2022. Findings in the recent literature expand the medically necessary indications to include esophageal varices, suspected, in presence of confirmed Cirrhosis and esophagogastroduodenoscopy is not an option and modified Crohn's disease to Crohn's disease known or suspected, when there is no clinical suspicion or radiologic evidence of significant stricture.

Additionally, research supports wireless capsule endoscopy as not medically necessary in patients with full or partial intestinal obstructions or a history of or known/current intestinal strictures.

Update 2020:
A search of the peer-reviewed literature was performed from the period of January 2018 through January 2020. Findings in the recent literature do not change the medically necessary indications for the use of wireless capsule endoscopy. Therefore, the policy statement remains unchanged.

Update 2017:
A search of the peer-reviewed literature was performed from October 2015 through December 2017. Findings in the literature do not change the medically necessary indications for the use of wireless capsule endoscopy. Therefore, the policy is unchanged.

Update 2015:
A search of the peer-reviewed literature was performed from October 2013 through October 2015. In February 2014, the PillCam COLON was granted a de novo 510(k) classification by the FDA. The new classification applies to devices with low to moderate risk that have no predicate device on the market. PillCam COLON is intended to visualize the colon in patients who have had an incomplete optical colonoscopy with adequate preparation and a complete evaluation of the colon was not technically possible.

Studies evaluating capsule endoscopy for colon cancer screening have almost all enrolled patients with a clinical indication for colonoscopy rather than as a screening test. In 2015, Rex et al found that for detecting polyps greater than 6 mm, capsule colonoscopy had an 81% sensitivity and a 93% specificity when optical colonoscopy was used as the gold standard. For polyps greater than 10 mm, the sensitivity was 80% and the specificity was 97%. Currently, the studies show there is a lower sensitivity and specificity for colon polyp detection using capsule colonoscopy than the gold standard, colonoscopy. The current evidence has not established roles for the PillCam COLON outside of the investigational settings. The policy statements remain unchanged.

Update 2013:
A search of the peer-reviewed literature was performed from June 2011 through September 2013. Based on the current literature, the medically necessary indications have been expanded for other gastrointestinal disorders. Evaluation of disorders of the esophagus using wireless capsule endoscopy remains experimental / investigational.

Update 2011:
A search of the peer-reviewed literature was performed from May 2009 through May 2011. Findings in the literature do not change the medically necessary indications for the use of wireless capsule endoscopy. Therefore, the policy is unchanged.

Update 2009:
Disorders of the esophagus:

Assessment of CE for evaluation of esophageal disorders requires comparison of its diagnostic performance with that of conventional esophagoscopy. Endoscopy is often recommended in patients with chronic GERD in order to rule out Barrett's esophagus, which is associated with GERD and may be a premalignant condition. Capsule endoscopy using the PillCamESO™ system would be an alternative to conventional endoscopy. Potentially, patients with a negative capsule study could avoid a more invasive endoscopy, whereas those with positive findings from a CE would undergo conventional esophagoscopy with biopsy. In this type of setting, the negative predictive value of CE would be a key factor. At the present time, the body of evidence supporting the use of CE for the esophagus is limited. Most of the studies are small; all are prospective in nature, and most of them are comparative studies that compared CE with upper endoscopy (EGD). Although the data from these small, feasibility-type studies is promising, the data is not adequate to permit conclusions regarding health outcomes or establish a protocol for selecting GERD patients for capsule examination versus EGD.

The small studies to date suggest that CE is a safe procedure. Reported complications include retention of the capsule in the esophagus in two cases. The European Society of Gastrointestinal Endoscopy (ESGE) in a 2006 guideline states that larger prospective studies are needed to clarify the role of CE for esophageal disorders. The American Society for Gastrointestinal Endoscopy take a similar position in a 2006 guideline. Patient selection criteria have not yet been defined for capsule endoscopy.

Patency capsule:

1. The technology must have final approval from the appropriate U.S. government regulatory bodies:

The FDA gave marketing clearance under the 510(k) process for Given Imaging's AGILE® Patency System in May of 2006 as an accessory to the PillCam™ video endoscopy system. The patency system consists of the biodegradable capsule, handheld scanner, and a TesTag interference scanner.

2. The scientific evidence must permit conclusions concerning the effect on health outcomes:
Evidence for the patency capsule derives from a few small, uncontrolled feasibility-type studies, most involving patients who were candidates for VCE but who had known presence of small bowel strictures as determined by small bowel enteroclysis, small bowel follow-through or CT scan. Spada et al (2005) enrolled 34 such patients. 30 capsules were egested, 20 of which were intact, over a range of time from 5 to 439 hours. The authors offered VCE only to patients who passed an intact capsule within 72 hours; 10 VCE's were performed within this group. Boivin and colleagues (2005) conducted a small study (n=22) of patients with known or suspected strictures. Of this group, one patient required emergency surgery for a small bowel obstruction caused by a lodged patency capsule. 16 capsules were excreted intact, and in 5 the capsule dissolved before excretion. Another small study (n=22) by Delvaux involved ingestion of the patency capsule, with 20 successfully passing the capsule intact. The other two required emergency surgery. 16 patients subsequently underwent VCE successfully. A single-institution experience review by Postgate and colleagues (2008) noted that in a few cases, location was incorrectly assessed radiographically, leading to video capsule retention and surgery in one case. The authors note that capsule location can be difficult.

Results from these small studies suggest that the AGILE® patency system can identify patients suitable for VCE imaging even with clinical evidence of intestinal strictures. In the above studies, 59%-77% of the patients who would have been excluded from VCE were deemed eligible for VCE based on the capsule patency test. However, patency testing does place the patient at risk for bowel obstruction that may require emergency surgery. There were few such events in these studies, but the studies were limited by sample size, lack of randomization or controls, and single-center status. In addition, the data assumes that if a patency capsule is successfully passed, that successful passage of a capsule will always occur. There is too little data to make that assumption. Therefore, the evidence does not permit conclusions regarding patient outcomes, as the question of safety has not been fully addressed.

3. The technology must improve the net health outcome:

4. The technology must be as effective as any established alternatives:
As previously noted, the patency capsule is not without risk. In the small studies, few patients required surgery for capsule-related bowel obstruction. It is not known, however what the real risks are because of the very small sample sizes tested. The American Society for Gastrointestinal Endoscopy (ASGE) in a published 2006 guideline, states that information about the patency capsule is limited, and that due to complications associated with its use, improvements in the capsule were required before it could be approved for use in the United States. A 2006 guideline from the European Society for Gastrointestinal Endoscopy (ESGE) states that the safety and efficacy of the patency capsule have been questioned since the capsule may exacerbate stenosis, requiring surgical intervention.

Endoscopic methods such as the double-balloon small bowel endoscope have been developed that allow examination of the entire length of the small intestine. There have been no comparison studies to determine whether the patency capsule is at least as safe and efficacious, nor has there been a determination whether the potential benefits of VCE outweigh the risks associated with the use of the patency capsule in patients with known or suspected intestinal obstructions.

5. The improvement must be attainable outside the investigational settings:
Whether a net improvement in health outcomes is attainable outside the investigational settings cannot be determined by the available evidence at this time.

Benefit Applications
NOTE: For FEP business check the member's contract for benefits.

Provider Guidelines
This procedure is commonly performed when prior studies such as upper and lower gastrointestinal endoscopic studies are inconclusive.

This procedure can be reported as an office or outpatient hospital procedure only. Benefits are not provided for this service in an ambulatory surgery center as it is not a surgical procedure. If the service is provided in an outpatient hospital facility and the physician does the interpretation and report only, the facility should report the technical

component and the physician should report the professional component. If the entire procedure is done in the physician's office, use the appropriate code without a modifier.

CPT® is medically necessary only when used with ICD10 ™ diagnosis codes I85.10-I85.11 when EGD is not an option in patients with cirrhosis.

ICD 10™ diagnosis code D12.6 (Benign neoplasm of colon, unspecified) is for small bowel surveillance of patients with hereditary GI polyposis syndromes, including familial adenomatous polyposis and Peutz-Jeghers syndrome.

Cross References to Related Policies and Procedures

1.02.002	Amino Acid-Based Elemental Formulas for Treatment of Malabsorption Disorders, Policy
2.01.004	Hyperbaric Oxygen Therapy, Policy
2.03.007	Photodynamic Therapy, Policy
2.03.010	Archived Genetic Testing for Inherited Susceptibility to Colon Cancer, Policy
2.03.011A	Screening for Colorectal Cancer, Procedure
5.01.005	ARCHIVED Botulinum Toxin, Policy
6.01.032	Positron Emission Tomography (PET), Policy
7.01.129	Peroral Endoscopic Myotomy (POEM) for Esophageal Achalasia, Policy
7.01.097	Gastric Electrical Stimulation, Policy
11.01.041	Archived KRAS Mutation Analysis in Metastatic Colorectal Cancer, Policy
11.01.073	Genetic Testing, Policy

References

The following were among the resources reviewed and considered in developing this policy. By reviewing and considering the resources, CareFirst does not in any way endorse the contents thereof nor assume any liability or responsibility in connection therewith. The opinions and conclusions of the authors of these resources are their own and may or may not be in agreement with those of CareFirst.

Akpunonu, B., et al (2022). Capsule endoscopy in gastrointestinal disease: Evaluation, diagnosis, and treatment. Cleveland Clinic journal of medicine, 89(4), 200–211. https://doi.org/10.3949/ccjm.89a.20061

Alexander, J., Leighton, J. (2009). Capsule endoscopy and balloon-assisted endoscopy: competing or complementary technologies in the evaluation of small bowel disease: *Current Opinion in Gastroenterology,* 25(5):433-7.

American Gastroenterological Association medical position statement: evaluation and management of occult and obscure gastrointestinal bleeding (2000), January). *Gastroenterology* 118, 197-200.

Appleyard, M., Glukhovsky, A., Swain, P. (2001). Wireless capsule diagnostic endoscopy for recurrent small-bowel bleeding. *New England Journal of Medicine* 344, 232-3.

Appleyard, M., Fireman, Z., Glukhovsky, A. et al (2000). A randomized trial comparing wireless capsule endoscopy with push enteroscopy for the detection small bowel lesions. *Gastroenterology* 119., 1431-8.

Baichi, M.M., Arifuddin, R.M., Mantry, P.S. (2006). What we have learned from 5 cases of permanent capsule retention. *Gastrointestinal Endoscopy* 64, 283-7.

Bhardwaj, A., Hollenbeak, C., Pooran, N. et al (2009, June). A meta-analysis of the diagnostic accuracy of esophageal capsule endoscopy for Barrett's esophagus in patients with gastroesophageal reflux disease. *American Journal of Gastroenterology*. 104(6):1533-9.

Boivin, M.L., Lochs, H., Voderholzer, W.A. (2005). Does passage of a patency capsule indicate small-bowel patency? A prospective clinical trial. *Endoscopy*37, 808-15.

Bradbury, J. (2000). Journey to the centre of the body. *The Lancet* 356, 2074.

Bruining, D. H. et al (2020). Panenteric capsule endoscopy versus ileocolonoscopy plus magnetic resonance enterography in Crohn's disease: a multicentre, prospective study. BMJ open gastroenterology, 7(1), e000365. https://doi.org/10.1136/bmjgast-2019-000365

Cave, David. (2018, April). Evaluation of suspected small bowel bleeding (formerly obscure gastrointestinal bleeding). *UpToDate*. Retrieved from the World Wide Web on December 30, 2019 from https://www.uptodate.com/contents/evaluation-of-suspected-small-bowel-bleeding-formerly-obscure-gastrointestinal-bleeding?search=Evaluation%20of%20suspected%20small%20bowel%20bleeding%20(formerly%20obscure%20gastrointestinal%20bleeding)&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1

Cave, David. (2019, January). Wireless video capsule endoscopy. *UpToDate*. Retrieved from the World Wide Web on December 30, 2019 from https://www.uptodate.com/contents/wireless-video-capsule-endoscopy?search=PillCam%20Colon%202%20system&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1

Cheifetz, A.S., Kornbluth, A.A., Legnani, P. et al (2006). The risk of retention of the capsule endoscope in patients with known or suspected Crohn's disease. *American Journal of Gastroenterology* Jul 18 [E-Pub]

Cheifetz, A.S., Lewis, B.S. (2006). Capsule endoscopy retention: Is it a complication? *Journal of Clinical Gastroenterology* 40, 688-91.

Cobrin, G.M., Pittman, R.H., Lewis, B.S. (2006). Increased diagnostic yield of small bowel tumors with capsule endoscopy. *Cancer* 107, 22-7.

Colli, A., Gana, J.C., Turner, D., Yap, J., Adams-Webber, T., Ling, S.C. Casazza, G. (2014, October). Capsule endoscopy for the diagnosis of esophageal varices in people with chronic liver disease or portal vein thrombosis. *Cochrane Database Systematic Review*, 10:CD008760. Doi: 10.1002/14651858.CD008760.

Collin, P., Rondonotti, E., Lundin, K.E., Spada, C., Keuchel, M., Kaukinen, K., et al. (2012, February). Video capsule endoscopy in celiac disease: current clinical practice. *J Dig Dis.,*13(2):94-9.

Cortegoso Valdivia, P. et al (2022). Indications, Detection, Completion and Retention Rates of Capsule Endoscopy in Two Decades of Use: A Systematic Review and Meta-Analysis. Diagnostics (Basel, Switzerland), 12(5), 1105. https://doi.org/10.3390/diagnostics12051105

Culliford, A., Daly, J., Diamond, B., et al (2005). The value of wireless capsule endoscopy in patients with complicated celiac disease. *Gastrointestinal Endoscopy* 62, 55-61.
Delvaux, M., Ben Soussan, E., Laurant, V. et al (2005). Clinical evaluation of the use of the M2A patency capsule system before a capsule endoscopy procedure, in patients with known or suspected intestinal stenosis. *Endoscopy* 37, 801-7.

Eisen, G.M., Eliakim, R., Zaman, A. et al (2006). The accuracy of PillCam ESO capsule endoscopy versus conventional upper endoscopy for the diagnosis of esophageal varices: a prospective three-center pilot study. *Endoscopy* 38, 31-5.

Eliakim, R., Sharma, V.K., Yassin, K. et al (2005). A prospective study of the diagnostic accuracy of PillCam ESO esophageal capsule endoscopy versus conventional upper endoscopy in patients with chronic gastroesophageal reflux disease. *Journal of Clinical Gastroenterology* 39, 572-8.

Enns, R. A., Hookey, L., Armstrong, D., Bernstein, C. N., Heitman, S. J., et al (2017, February). Clinical Practice Guidelines for the Use of Video Capsule Endoscopy. *Gastroenterology,* doi: 10.1053/j.gastro.2016.12.032.

Feldman, M.D. (2008). PillCam ESO Capsule for the Evaluation of Esophageal Disease: A Technology Assessment. October 15, 2008. San Francisco, CA: California Technology Assessment Forum.

Galmiche, J.P., Sacher-Huvelin, S., Coron, E., Cholet, F., Soussan, E.B., et al, (2008). Screening for esophagitis and Barrett's esophagus with wireless esophageal capsule endoscopy: a multicenter prospective trial in patients with reflux symptoms. *American Journal of Gastroenterology,*103(3):538-45.

Green, P.H., Rubin, M. (2006). Capsule endoscopy in celiac disease: diagnosis and management. *Gastrointestinal Endoscopy Clinics of North America*16, 307-16.

Gupta, A., Postgate, A., Burling, D. et al (2011). A prospective study of MR enterography versus capsule endoscopy for the surveillance of adult patients with Peutz-Jeghers syndrome. *AJR Am J Roentgenol.* 195(1):108-16.

Gutkin, E., Shalomov, A., Hussain, S.A., Kim, S.H., Cortes, R., Gray, S., (2013, May). Pillcam ESO is more accurate than clinical scoring systems in risk stratifying emergency room patients with acute upper gastrointestinal bleeding. *Therap Adv Gastroenterol.,*6(3):193-8.

Hale, M.F., Sidhu, R., McAlindon, M.E. (2014, June). Capsule endoscopy: Current practice and future directions. World Journal of Gastroenterology, Vol 20, Iss 24. Doi: 10.3748/wjg. V20.i24.7752.

Hayes Evidence Analysis Research Brief. (2019, April; 2019, November 25-archived). PillCam COLON 2 System (Medtronic) for colorectal cancer screening. April 23, 2019. Lansdale, PA: Hayes, Inc.

Hayes Evidence Analysis Research Brief. (PillCam Patency Capsule (Medtronic) to Assess Small Bowel Patency. April 26, 2022. Lansdale, PA: Hayes, Inc.

Hayes Health Technology Assessment. (2019, November, 2021, Nove,ber – annual review). Colon capsule endoscopy for colorectal cancer screening, diagnosis, and surveillance. November 25, 2019. Lansdale, PA: Hayes, Inc.

Hayes Medical Technology Brief (2007; update 2009, February; archived 2010, May). AGILE™ Patency System (Given Imaging Ltd.) for Verification of Gastrointestinal Patency Prior to Capsule Endoscopy. February 20, 2007. Lansdale, PA: Hayes, Inc.

Hayes Medical Technology Directory (2011; 2012, December; 2015, January). Capsule Endoscopy for the Diagnosis of Small Bowel Crohn's Disease. December 17. 2011, Lansdale, PA: Hayes, Inc.

Hayes Medical Technology Directory. (2017, March 23; 2019, March -annual review, 2021 – May annual review, 2022 – April archived). Capsule Endoscopy for the Diagnosis of Small Bowel Crohn's Disease. Lansdale, PA: Hayes, Inc.

Hayes Medical Technology Directory (September 2015; 2016, October 27 -archived). Capsule Endoscopy for the Diagnosis of Small Bowel Disease in Children. Lansdale, PA: Hayes, Inc.

Hayes Medical Technology Directory (2008; update 2011, January; updated 2012; archived 2013, February). Capsule Endoscopy for Diagnostic Imaging of the Esophagus. January 3, 2008. Lansdale, PA: Hayes, Inc.

Hayes Medical Technology Directory (2008; update 2011, February). Capsule Endoscopy for Diagnostic Imaging of the Small Bowel. January 13, 2009. Lansdale, PA: Hayes, Inc.

Hayes Medical Technology Directory (2013, June; 2015, May; 2017, May 24- annual review; 2018, July- archived). Capsule Endoscopy of the Small Bowel for Obscure Gastrointestinal Bleeding. June 20, 2013, Lansdale, PA: Hayes, Inc.

Hayes Medical Technology Directory (2003, November). Wireless Capsule Endoscopy. Lansdale, PA: Hayes, Inc.

Hayes Medical Technology Directory. (2017, September; 2018, October-annual review, 2019, October -annual review, 2020, October- annual review, 2021, October-annual review). Wireless Capsule Systems for Diagnosis of Gastroparesis and Monitoring of Gastrointestinal Motility. September 21, 2017. Lansdale, PA: Hayes, Inc.

Hayes Search & Summary. (2016, August 4; 2017, September 04- archived). Capsule Endoscopy (CE) of the Small Bowel in Adults with Familial Adenomatous Polyposis (FAP). Lansdale, PA: Hayes, Inc.

Health Quality Ontario. Colon capsule endoscopy for the detection of colorectal polyps: an evidence-based analysis. Ont Health Technol Assess Ser [Internet]. 2015 July; 15(14):1-39 Available from: http://www.hqontario.ca/evidence/publications-and-ohtac-recommendations/ontario-health-technology-assessment-series/eba-colon-capsule-endoscopy.

Khan, M.I., Johnston, M., Cunliffe, R., Claydon, A., (2013, February). The role of capsule endoscopy in small bowel pathology: a review of 122 cases. *N Z Med J.,* 126(1369):16-26.

Kopylov U., Yung D.E., Engel T., Vijayan, S., Har- Noy, O., et al. (2017, August). Diagnostic yield of capsule endoscopy versus magnetic resonance enterography and small bowel contrast ultrasound in the evaluation of small bowel Crohn's disease: Systematic review and meta-analysis. *Dig Liver Dis.* Doi: 10.1016/j.dld.2017.04.013.

Koulaouzidis, A., Rondonotti, E., Karargyris, A., (2013, June). Small-bowel capsule endoscopy: a ten-point contemporary view. *World J Gastroenterol.,* 19(24):3726-46.

Lapalus, M.G., Dumortier, J., Fumex, F. et al (2006). Esophageal capsule endoscopy versus esophagogastroduodenoscopy for evaluating portal hypertension: a prospective comparative study of performance and tolerance. *Endoscopy* 38, 36-41.

Lee, S.K., Green, P.H. (2005). Endoscopy in celiac disease. *Current Opinions in Gastroenterology* 21, 589-94.

Lee, N., Elsen, G. (2010, August). 10 years of capsule endoscopy: an update. *Expert Rev Gastroenterol and Hepatol.* 4(4):503-12.

Leighton, J.A., Gralnek, I.M., Cohen, S.A., Toth, E., Cave, D.R., Wolf, D.C., (2013, September). Capsule Endoscopy is Superior to Small-Bowel Follow-Through and Equivalent to Ileocolonoscopy in Suspected Crohn's Disease. *Clin Gastroenterol Hepatol.,* pii: S1542-3565(13)01433-X.

Lewis, B., Swain, P. (2001). Capsule endoscopy in the evaluation of patients with suspected small intestinal bleeding, a blinded analysis: The results of the first clinical trial. *Gastrointestinal Endoscopy* 53, AB70.

Lichtenstein, G. R., Loftus, E. V., Isaacs, K. L., Regueiro, M. D., Gerson, L. B. et al. (2018, April). ACG clinical guideline: management of Crohn's disease in adults

Lin, O.S., Schembre, D.B., Mergener, K., et al (2007). Blinded comparison of esophageal capsule endoscopy versus conventional endoscopy for a diagnosis of Barrett's esophagus in patients with chronic gastroesophageal reflux. *Gastrointestinal Endoscopy*65, 577-83.

Makins, R., Blanshard, C. (2006). Guidelines for capsule endoscopy: diagnoses will be missed. *Alimentary Pharmacology and Therapeutics* 24, 293-7.

Marmo, R., Rotondano, G., Piscopo, R. et al (2005). Meta-analysis: capsule enteroscopy vs. conventional modalities in diagnosis of small bowel diseases. *Alimentary Pharmacology and Therapeutics* 22, 595-604.

Marmo, R., Rotondano, G., Piscopo, R. et al (2005). Capsule endoscopy versus enteroclysis in the detection of small-bowel involvement in Crohn's disease: a prospective trial. *Clinical Gastroenterology and Hepatology* 3, 772-6.

McCarthy, T. R., Afinogenova, Y., Njei, B. (2017, February). Use of Wireless Capsule Endoscopy for the Diagnosis and Grading of Esophageal Varices in Patients with Portal Hypertension: A Systematic Review and Meta-Analysis. *Journal of Clinical Gastroenterology*. Doi: 10.1097/MCG.0000000000000589.

MCG Health. (2021).Capsule Endoscopy. (25th edition). Retrieved from http://www.mcg.com on 10/13/2022.
Meister, T., Heinzow, H.S., Domagk, D., Dortgolz, A., Lenze, F., Ross, M., …Lugerine, A. 2013, December. Colon capsule endoscopy versus standard colonoscopy in assessing disease activity of ulcerative colitis: a prospective trial. Techniques in Coloproctology, 17(6):641-6. doi: 10.1007/s10151-012-0965-8.

Meron, G. (2000). The development of the swallowable video capsule (M2A). *Gastrointestinal Endoscopy* 6, 817-19

Mishkin, D.S., Chuttani, R., Croffie, J. et al (2006). ASGE Technology Status Evaluation Report: Wireless Capsule Endoscopy. *Gastrointestinal Endoscopy* 63, 539-45

Min, S.B., Le-Carlson, M., Singh, N., Nylund, C.M., Gebbia, J., et al. (2013, September). Video Capsule Endoscopy Impacts Decision Making in Pediatric IBD: A Single Tertiary Care Center Experience. *Inflamm Bowel Dis.,*19(10):2139-45.

Mustafa, B.F., Samaan, M., Langmead, L., Khasraw, M., (2013, May). Small bowel video capsule endoscopy: an overview. *Expert Rev Gastroenterol Hepatol.,* 7(4):323-9.

Neumann, H., Fry, L.C., Neurath, M.F., (2013). Review article on current applications and future concepts of capsule endoscopy. *Digestion,*87(2):91-9.

National Comprehensive Cancer Network (NCCN) Guidelines Version 3.2022. Colorectal Cancer Screening. retrieved from https://www.nccn.org/guidelines/guidelines-detail?category=2&id=1429 on 10/13/2022.
Ouahed, J., Shagrani, M., S'nt'anna, A., (2013, March-April). Role of wireless capsule endoscopy in reclassifying inflammatory bowel disease in children. *J Pediatr (Rio J,*89(2):204-9.

Rahmi, G., Samaha, E., Lorenceau-Savale, C., Landi, B., Edery, J., et al., (2013, May). Small bowel polypectomy by double balloon enteroscopy: Correlation with prior capsule endoscopy. *World J Gastrointest Endosc.,*5(5):219-25.

Raju, G., Gerson, L., Das, A. (2007). American Gastroenterological Association (AGA) Institute Technical Review on Obscure Gastrointestinal Bleeding. *Gastroenterology.* 133(5):1697-1717.

Remedios, M.L., Appleyard, M. (2005). Capsule endoscopy: current indications and future prospects. *Internal Medicine Journal* 35, 234-9.

Rex, D.K., Adler S.N., Aisenberg, J., Burch Jr., W.C., Carretero, C., Chowers, Y., ... Waterman, M. (2015, May). Accuracy of capsule colonoscopy in detecting colorectal polyps in a screening population. Gastroenterology, 148(5): 948-957.e2. doi: 10.1053/j.gastro.2015.01.025.

Rey, J.F., (2013, May). The Future of Capsule Endoscopy. *Keio J Med,* retrieved from the world wide web on May 28, 2013 at http://www.ncbi.nlm.nih.gov/pubmed/23708295.

Rokkas, T., Niv, Y., (2012, March). The role of video capsule endoscopy in the diagnosis of celiac disease: a meta-analysis. *Eur J Gastroenterol Hepatol.,*24(3):303-8.

Schwartz, G.D., Barkin, J.S. (2006). Small bowel tumors. *Gastrointestinal Endoscopy Clinics of North America* 16, 267-75.

Seidman, E.G., Dirks, M.H. (2006). Capsule endoscopy in the pediatric patient. *Current Treatment Options in Gastroenterology* 9, 416-22.

Sharma, P., Wani, S., Rastogi A., Bansal, A., Higbee, A., Mathur, S., et al. (2008). The diagnostic accuracy of esophageal capsule endoscopy in patients with gastroesophageal reflux disease and Barr'tt's esophagus: a blinded, prospective study. *American Journal of Gastroenterology,*103(3):525-32

Signorelli, C., Rondonotti, E., Villa, F. et al (2006). Use of the Given Patency System for the screening of patients at high risk for capsule retention. *Digestive and Liver Disease*38, 326-30

Spada, C., Spera, G., Riccioni, M., et al (2005). A novel diagnostic tool for detecting functional patency of the small bowel: The Given patency capsule. *Endoscopy* 37, 793-800.

Stipho, S., Tharalson, E., Hakim, S., Akins, R., Shaukat, M., Ramirez, F.C., (2012, April). String capsule endoscopy for screening and surveillance of esophageal varices in patients with cirrhosis. *J Interv Gastroenterol.,*2(2):54-60.

Triantafyllou, K., Viazis, N., Tsibouris, P., Zackarakis, G., Kalantzis, C., Karamanolis, D.G., Ladas, S.D. (2014, February). Colon capsule endoscopy is feasible to perform after incomplete colonoscopy and guides further workup in clinical practice. *Gastrointestinal Endoscopy*, 79(2): 307-16. doi: 10.1016/j.gie.2013.07.061.

Triester, S.L., Leighton, J.A., Leontiadis, G.L., et al (2006). A meta-analysis of the yield of capsule endoscopy compared to other diagnostic modalities in patients with non-stricturing small bowel Cr'hn's disease. *American Journal of Gastroenterology* 101, 954-64.

Urgesi, R., Riccioni, M.E., Bizzotto, A., Cianci, R., Spada, C., et al. (2012, May-June). Increased diagnostic yield of small bowel tumors with PillCam: the role of capsule endoscopy in the diagnosis and treatment of gastrointestinal stromal tumors (GISTs). Italian single-center experience. *Tumori,*98(3):357-63.

U.S. Food and Drug Administration.

US Preventive Services Task Force, Davidson, K. W., Barry, M. J., Mangione, C. M., Cabana, M., Caughey, A. B., …, & Wong, J. B. (2021). Screening for Colorectal Cancer: US Preventive Services Task Force Recommendation Statement. JAMA, 325(19), 1965–1977. https://doi.org/10.1001/jama.2021.6238

Van Tuyl, S.A., Van Noorden, J.T., Kuipers, E.J., Stolk, M.F. (2006). Results of video capsule endoscopy in 250 patients with suspected small bowel pathology. *Digestive diseases and Sciences 51, 900-5.*

Yamada, A., Wataabe, H., Iwama, T., Obi, S., Omata, M., Koike, K., (2013, June). The prevalence of small intestinal polyps in patients with familial adenomatous polyposis: a prospective capsule endoscopy study. *Fam Cancer.* Retrieved from the world wide web on June 13, 2013 at http://www.ncbi.nlm.nih.gov/pubmed/23743563.

This policy statement relates only to the services or supplies described herein. Coverage will vary from contract to contract and by line of business and should be verified before applying the terms of the policy.