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Medical Policy Manual

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

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Wireless capsule endoscopy (WCE) is a noninvasive, diagnostic test used to locate the source of obscure gastrointestinal (GI) bleeding and identify the cause of other GI disorders. WCE is performed using a miniature disposable video-imaging capsule. The capsule measures approximately 11 by 30 mm, contains video imaging, self-illumination, image transmission modules, and a battery supply that lasts for up to 8 hours. After the video capsule is swallowed, the indwelling camera takes images as peristalsis carries the capsule through the GI tract. The average transit time from ingestion to evacuation is 24 hours. The device uses wireless radio transmission to send the images to a receiving recorder device that the patient wears around the waist. This receiving device also contains some localizing antennae sensors that can roughly gage where the image was taken over the abdomen. Images are then downloaded onto a workstation for viewing and processing.

The source of GI bleeding may be identified nonsurgically using a variety of radiological or endoscopic techniques. However, a bleeding source may remain unclear even after all conventional diagnostic tests (such as upper endoscopy, colonoscopy, oral contrast small bowel radiographic studies, tagged red blood cell scintigraphy, or angiography) have been performed. In the small bowel, the capsule camera has been most frequently proposed as a technique to identify the source of obscure intestinal bleeding, defined as

recurrent or persistent iron-deficiency anemia, positive fecal occult blood test, or visible bleeding with no bleeding source found at original endoscopy. There has also been interest in exploring use of the capsule camera in patients with inflammatory bowel disease.

Due to the risk of capsule retention, WCE is contraindicated in patients with suspected small bowel strictures. Retention of a capsule above an intestinal stenosis may necessitate removal either endoscopically or surgically.[1]

Regulatory Status

WCE devices with U.S. Food and Drug Administration (FDA) 510(k) approval include:

- PillCam® SB (Given Imaging; Duluth, GA), for detecting small bowel abnormalities;
- PillCam®ESO (Given Imaging; Duluth, GA), for visualizing the esophagus; and
- Olympus Capsule Endoscope System (Olympus America, Inc., Allentown, PA), for visualization of small intestine mucosa.

WCE devices with U.S. Food and Drug Administration (FDA) class II approval include:

- PillCam® COLON (Given Imaging; Duluth, GA), for visualization of the colon after an incomplete optical colonoscopy.

Additionally, the Given AGILE™ Patency System has U.S. FDA 510(k) approval. This system is designed to determine which patients with known or suspected intestinal strictures can safely ingest a PillCam video capsule.

MEDICAL POLICY CRITERIA

I. Wireless capsule endoscopy of the small bowel may be considered **medically necessary** for the following indications:

   A. Obscure gastrointestinal (GI) bleeding* suspected to be of small bowel origin as evidenced by prior inconclusive upper and lower gastrointestinal endoscopy.

      ** Obscure GI bleeding: recurrent or persistent iron-deficiency anemia, positive fecal occult blood test, or visible bleeding with no bleeding source found at original endoscopy.*

   B. Suspected Crohn's disease without evidence of disease on conventional diagnostic tests. Conventional tests may include one or more of the following: small bowel follow-through, upper and lower endoscopy, MR enterography or CT enterography.

II. Other indications of wireless capsule endoscopy are considered **investigational**, including but not limited to:

   A. Evaluation of the extent of involvement of known Crohn’s disease or ulcerative colitis.

   B. Evaluation of the esophagus, including, but not limited to gastroesophageal reflux (GERD) or other esophageal pathologies

   C. Evaluation of other gastrointestinal diseases not presenting with GI bleeding including, but not limited to, Celiac Sprue, irritable bowel syndrome, and small bowel neoplasm

D. Evaluation of the colon including, but not limited to, detection of colonic polyps or colon cancer.

E. For surveillance of the small bowel in patients with hereditary GI syndromes, including familial adenomatous polyposis, Peutz-Jeghers syndrome, Lynch syndrome and Juvenile Polyposis syndrome.

F. Evaluation of acute upper GI bleeding.

III. The patency capsule is considered **investigational** for all indications, including but not limited to evaluation of the patency of the gastrointestinal tract before wireless capsule endoscopy.

SCIENTIFIC EVIDENCE[2]

The published literature reports on the use of wireless capsule endoscopy (WCE) as a diagnostic tool for a variety of indications, including obscure GI bleeding, esophageal disorders, small bowel diseases other than obscure GI bleeding, and evaluation of the colon.

Obscure Gastrointestinal Bleeding

Technology Assessment, Meta-Analysis and Systematic Reviews

- The February 2003 BlueCross BlueShield Association (BCBSA) Technology Evaluation Center (TEC) Assessment addressed the clinical applications of WCE in patients with obscure GI tract bleeding suspected of being of small bowel origin.[3] The evidence included 3 published studies totaling 124 patients.[4-6] Obscure GI bleeding of small bowel origin is an infrequent condition and the availability of subjects for investigation is limited. However, the evidence was determined to be sufficient to permit conclusions concerning the effect of WCE on health outcomes in this specific population. WCE improved net health outcomes when used to identify a source of bleeding in patients with obscure digestive tract bleeding suspected to be of small-bowel origin.

- In 2012, Koulaouzidis et al. conducted a systematic review and meta-analysis evaluating 24 retrospective studies on capsule endoscopy performed after negative findings on previous diagnostic evaluations including upper and lower endoscopy.[7] Included in the studies were a total of 1,960 patients of which 1,194 (60.9%) had iron-deficiency anemia. The pooled per-patient diagnostic yield of all 24 studies, evaluated by a random-effects model, was 47% (95% confidence interval [CI], 42%-52%). Almost 50% of the diagnostic yield was for small bowel angioectasia. In a subset of 4 studies focused only on patients with iron-deficiency anemia (n = 264, 13.47%), the pooled diagnostic yield with capsule endoscopy was 66.6% (95% CI, 61.0%-72.3%) and included more vascular, inflammatory and mass/tumor lesions. The authors concluded that WCE was beneficial in identifying the cause of bleeding in patients with previous negative findings; however, the authors also noted that study heterogeneity, retrospective design and selection bias were limitations of this review.

Randomized Controlled Trials (RCTs)

In 2012, Leung and colleagues reported on 60 consecutive patients with acute melena or hematochezia who were randomized to receive either immediate capsule endoscopy or mesenteric angiography in a 1:1 ratio after nondiagnostic endoscopy and colonoscopy.[8] Capsule endoscopy had a significantly higher diagnostic yield than angiography (53.3% vs. 20.0%, p = 0.016). The cumulative risk of re-bleeding in the angiography and capsule endoscopy group was 33.3% and 16.7%, respectively (p = 0.10, log-rank test). After a mean follow-up of 48.5 months, further transfusion, hospitalization for re-bleeding, and mortality were not significantly different between the two groups.

Conclusion

There are a large number of uncontrolled studies that evaluate the use of capsule endoscopy in the evaluation of patients with occult GI bleeding.[5,9-15] These studies support the conclusions reached in the February 2003 TEC Assessment and are consistent in reporting that a definitive diagnosis is obtained in a substantial proportion of cases when few diagnostic options remain. The 2012 meta-analysis of 24 studies estimated that the diagnostic yield in this patient population was approximately half of the included patients, and was higher in patients with documented iron deficiency anemia. Therefore, WCE may be considered a diagnostic option in patients with obscure gastrointestinal bleeding of the small bowel when upper and lower endoscopy is inconclusive.

Acute Upper Gastrointestinal Bleeding

Evidence regarding WCE in cases of acute upper GI bleeding consist of 3 small cohorts studies (n = 25-83) which reported on the use of capsule endoscopy in order to triage and/or risk stratify patients in the emergency department or hospital.[16-18] The studies reported that capsule endoscopy provided information on the identification of gross bleeding, inflammatory lesions and risk stratification. However, the yield of capsule endoscopy in localizing the bleeding source was lower than for esophagogastroduodenoscopy, which is the standard initial evaluation for acute upper GI bleeding. For this reason, it is unlikely that capsule endoscopy can take the place of upper endoscopy for initial evaluation of acute upper GI bleeding. Controlled studies are needed to further assess the impact of WCE on health outcomes compared to standard diagnostic techniques.

Crohn's Disease

Suspected Crohn's Disease

The December 2003 BCBSA TEC Assessment addressed the clinical applications of WCE in patients with small-bowel disease other than obscure GI tract bleeding.[19] Three studies were identified that examined the use of WCE for initial diagnosis of Crohn's disease.[20-22] These studies provided consistent evidence that WCE may identify Crohn's lesions when other conventional tests are negative. Subsequent studies reported similar outcomes.[13,23-25]

Established Crohn's Disease

Several small studies explored the role of WCE to determine the extent of Crohn's disease in patients in whom the diagnosis was already established:[26-29]

- In one prospective case series of 31 patients, WCE identified additional areas of Crohn's disease that were not identified by enteroclysis.[26] However, it is unclear how knowledge regarding the extent of involvement would direct patient management.

- A study evaluated the effectiveness of treatment for Crohn's disease by using wireless capsule endoscopy before and after therapy.[27] The authors reported only one of three endoscopic outcomes improved with treatment and clinical response did not seem to correlate with mucosal healing.

Additional small case series or retrospective studies reporting on WCE in established Crohn's disease have been published.[30-32] Due to methodological limitations, these studies do not allow conclusions concerning the clinical utility of WCE in established Crohn's disease.

Conclusion

For patients with suspected Crohn's disease of the small bowel, who are unable to be diagnosed by other modalities, capsule endoscopy can confirm the diagnosis in a substantial number of patients. The diagnostic yield in the available studies is variable, but is likely superior to alternative tests such as CT or MRI scanning. The evidence on monitoring of Crohn's disease is less definitive, and it is unclear how the use of WCE would improve patient management or health outcomes compared to other modalities for diagnosing complications of Crohn's disease.

Ulcerative Colitis

Ulcerative colitis is an inflammatory disease of the large intestine. It is usually diagnosed with colonoscopy and biopsy. Capsule endoscopy has been proposed as an alternative method for assessing the extent and severity of disease activity in known ulcerative colitis. Sung and colleagues evaluated 100 patients with suspected or known ulcerative colitis using capsule endoscopy and colonoscopy performed the same day.[33] The authors reported on the sensitivity 89% (95% CI 80 – 95) and specificity 75% (95% CI 51 - 90), of capsule endoscopy to detect active colonic inflammation. The positive and negative predictive values were 93% (95% CI 84 - 97) and 65% (95% CI 43 - 83), respectively. However, a direct comparison of colonoscopy was not performed as part of this study precluding conclusions regarding the use of WCE as an alternative method of assessing ulcerative colitis disease activity.

Celiac Disease

Celiac disease or gluten-sensitive enteropathy is an immune-mediated condition of the small intestine. Serologic markers of the disease have good sensitivity and specificity, but the gold standard for diagnosis of celiac disease is obtained through small-bowel biopsies acquired during endoscopy. Capsule endoscopy has been evaluated as an alternative method of diagnosing celiac disease or in assessing the extent of disease to improve management of patients.

Suspected Celiac Disease

- A meta-analysis by El-Matary et al. compared the diagnostic performance of capsule endoscopy to a reference standard of duodenal biopsy.[34] The pooled analysis of 3 studies showed a sensitivity of 83% and a specificity of 98%.
- Another meta-analysis by Rokkas and Niv. also compared the diagnostic performance of capsule endoscopy to biopsy, summarizing 6 studies that evaluated a total of 166 subjects.[35] The overall pooled sensitivity was 89% and the specificity was 95%. Capsule endoscopy was able to detect involvement of intestines beyond the duodenum; however, the clinical significance of detecting further extent of celiac disease is uncertain.
- In a study of 43 consecutive patients with symptoms of celiac disease, WCE was compared to duodenal histology as the gold standard for diagnosing celiac disease. Authors found WCE had

a sensitivity and specificity of 87.5% and 90.9% respectively; however, the clinical utility of WCE was not shown to be better than the standard of care for diagnosing celiac disease.[36]

- Given the less than 90% sensitivity of capsule endoscopy for celiac disease, WCE does not appear to be an adequate alternative method of making an initial diagnosis.

Established Celiac Disease

The evidence on the role of capsule endoscopy in established celiac disease is limited to a small case series and one comparative nonrandomized study which do not provide sufficiently reliable evidence concerning the clinical utility of WCE in established celiac disease.[37,38]

Conclusion

In cases where the diagnosis of celiac disease is equivocal, capsule endoscopy mayuncover morphologic changes in the small bowel consistent with celiac disease. However, it is unlikely that the appearance of small bowel on capsule endoscopy is itself sufficient to make a definitive diagnosis of celiac disease. Small bowel biopsy, celiac serologies, and HLA typing remain the standard tests for confirming celiac disease, and have a higher sensitivity and specificity for this purpose.

Esophageal Conditions

Direct imaging of the small bowel with an endoscope is limited, and thus WCE of the small bowel occupies a unique niche. In contrast, esophageal endoscopy, which also offers the opportunity for biopsy, is a routinely performed procedure. Therefore, assessment of WCE of the esophagus requires comparison of its diagnostic performance with the gold standard of conventional endoscopy.

Barrett's Esophagus

One proposed indication for the capsule camera is detection of Barrett's esophagus, considered a premalignant condition associated with gastroesophageal reflux disease (GERD). Conventional endoscopy is often recommended in patients with longstanding symptoms of GERD or in patients requiring pharmacologic therapy to control GERD symptoms in order to rule out Barrett's esophagus. This is a high volume indication for conventional endoscopy, given the high prevalence of GERD. WCE offers a potential alternative to endoscopy; those patients with a negative study could potentially forego conventional endoscopy. In this setting, the negative predictive value of WCE is the key diagnostic parameter. Patients who are found to have suggestive findings of Barrett's esophagus will require a confirmatory conventional endoscopy with biopsy.

There is limited published literature regarding the diagnostic performance of esophageal capsule endoscopy.

- In 2005, Eliakim evaluated 106 patients (93 with GERD and 13 with Barrett esophagus) with WCE followed by standard endoscopy as the gold standard.[39] A blinded adjudication committee reviewed all discrepant findings. The authors reported a sensitivity of 92% (61 of 66) and specificity of 95%.

- Lin and colleagues reported results of a prospective blinded (without adjudication) study of WCE compared with conventional endoscopy for Barrett's esophagus in 66 screening and 24 surveillance patients.[40] This study reported a sensitivity of 67% (14 of 21) and specificity of

84%.

- One analysis pooled the results of 9 studies (n=618) and found a pooled sensitivity of 77% and a pooled specificity of 86%.[41]

- Several small, individual studies showed a moderate sensitivity for esophageal lesions in the 60% to 80% range.[42,43]

Additional studies of diagnostic validity of esophageal WCE have been published as well.[44] However, given the differences in the findings of these studies and the range of sensitivities, as well as methodological limitations, additional studies of this technique are needed.

Other Esophageal Disorders

Studies evaluating the use of WCE for varies esophageal disorders consist primarily of case series have not shown WCE to be superior to standard of care techniques in the evaluation of esophageal diseases.[45-48] In addition, these studies report issues with interoperator agreement, unpredictable esophageal transit times, poor image quality, and significant failure rates with up to 6% of patients unable to swallow the capsule.[49-51]

Conclusion

Current evidence is insufficient regarding the use of WCE to diagnose disease or to improve health outcomes in patients with suspected esophageal disorders. Randomized studies using general screening populations are needed to evaluate the effectiveness of WCE in diagnosing various esophageal conditions compared to standard of care techniques.

Colon Cancer Screening

WCE has been evaluated for detection of polyps and cancer in comparison with conventional optical colonoscopy, which is the gold standard for colorectal cancer screening. A meta-analysis by Spada et al. of 8 studies enrolling 837 patients undergoing capsule endoscopy showed a sensitivity of 71% for polyps of any size and a specificity of 75%.[52] Almost all the existing studies evaluating capsule endoscopy for detecting colonic lesions have been done on patients with a clinical indication for colonoscopy rather than a screening population. Spada et al., conducted a follow-up study of the second-generation capsule endoscopy system in 109 patients and reported that compared with conventional colonoscopy, the WCE sensitivity for polyps 6 mm was 84% and for polyps 10 mm or larger 88%, with specificities of 64% and 95% respectively.[53] This study was relatively small, and had heterogeneous study population consisting of nonconsecutive patients. Other, smaller studies (n= 41-91) show the sensitivity of capsule endoscopy for various types of lesions to be less than 80%.[54-56] Based on the low sensitivity for colonic polyps, capsule endoscopy is unlikely to be an effective screening test for colon cancer unless it is repeated more frequently than colonoscopy. The specificity of the test is not optimal either, meaning that patients will undergo unnecessary follow-up colonoscopy.

Currently, there are no established guidelines for routine small bowel screening in the general population.[57,58] Several studies evaluated WCE in comparison to other techniques for visualizing the small bowel, however, studies were limited by small sample size, lack of randomization, and short-term follow-up, all of which preclude conclusions regarding the optimal screening method for small bowel examination.[59-67] Additionally, results from these studies were mixed.

Hereditary Gastrointestinal (GI) *Polyposis* Syndromes

Persons with familial adenomatous polyposis (FAP) and Peutz-Jeghers syndrome (PJS) are at increased risk of small bowel polyps and tumors. The lifetime risk for small bowel cancer in patients with PJS is estimated to be 13%.[58] The risk for small bowel cancer in FAP patients is increased; however, the exact incidence of small bowel polyps in this population is unknown.[68] WCE has been proposed as a method to identify additional lesions in patients with disease syndromes at high risk for small bowel lesions. The literature for this indication in patients with PJS and FAP is limited to small (n=4-32) [69-73], non-randomized[69-73] studies which lack comparison groups or long-term follow-up, thereby limiting conclusions regarding how well WCE may perform against alternative screening methods.

Limited evidence from clinical trials suggests that WCE may help to identify small bowel polyps in polyposis patients, but this finding has not been consistent, and methodologic limitations preclude definitive conclusions on this question. High-quality evidence is lacking comparing the use of WCE to other methods of small bowel screening, and as a result, there is uncertainty as to which methods are preferred in these specific populations. It is also uncertain whether patient outcomes are improved with the detection of small bowel polyps with WCE.

Hereditary Gastrointestinal (GI) *Non-Polyposis* Syndromes

Lynch mutation carriers have an estimated 4% lifetime risk for small-bowel cancer.[74] To date, small bowel surveillance has not been incorporated into screening guideline recommendations.[58] In part, this may have been due to an inability of previous diagnostic tests to successfully visualize the small bowel, making small bowel surveillance improbable. Although diagnostic testing technology of the small bowel has improved, it is uncertain which screening test is preferred and, more specifically, questions remain as to whether small bowel surveillance will impact clinical management and change treatment decisions for Lynch syndrome patients. To date, current evidence regarding WCE in patients with Lynch syndrome consists of a single prospective, blinded study[75] which was limited by small sample size and lack of comparison to the other methods of small bowel surveillance. Therefore the evidence is insufficient regarding the efficacy of WCE in patients with hereditary gastrointestinal non-polyposis syndromes.

Other Small Bowel Conditions

WCE was investigated as a diagnostic approach for acute intestinal graft-versus-host disease,[76] unexplained abdominal pain,[77] and irritable bowel syndrome.[78] However, small study populations and observational and/or retrospective study designs limit reliability of reported study findings.

Given® Patency Capsule System for Patients at High Risk of Wireless Capsule Retention

The patency capsule has been proposed for 2 indications:

- To eliminate certain patients who are considered low-risk for capsule retention in order to further increase the safety of capsule endoscopy, or
- To select patients at high risk for capsule retention, who without the test might be considered to have contraindications for capsule endoscopy.

In either scenario, it needs to be determined whether the change in diagnostic and treatment strategy is ultimately improved as a consequence of either being selected or de-selected to have a capsule endoscopy. These improvements need to be weighed against any complications due to the use of the patency capsule.

There are limited data on the performance of the patency capsule.[1,79-87] The published studies are small and do not provide comparative data about the incremental value of this capsule over standard clinical evaluation. In addition, safety concerns have been reported.

- Several studies showed that patients who had uncomplicated passage of the patency capsule subsequently underwent uncomplicated WCE[84-86] These patients often had significant findings on capsule endoscopy. However, it is difficult to determine whether the yield of capsule endoscopy in these patients improved their outcomes beyond any alternate test regimen that could have been performed.

- Several case series reported severe adverse events resulting in the need for hospitalization and emergency surgery.[81,83,84]

Clinical Practice Guidelines

American Gastroenterological Association (AGA)[88]

A 2007 position statement by the AGA states the following concerning obscure GI bleeding and capsule endoscopy:

- Evaluation of the patient with obscure GI bleeding is dependent on the extent of the bleeding and the age of the patient.
- Patients with occult GI blood loss and no anemia most likely do not require evaluation beyond colonoscopy unless upper tract symptoms are present.
- Patients with occult GI blood loss and iron deficiency anemia and negative workup on esophagogastroduodenoscopy (EGD) and colonoscopy need comprehensive evaluation, including capsule endoscopy to identify an intestinal bleeding lesion.

Small Bowel Screening

- Once all the findings on standard examinations (EGD and colonoscopy) are negative, the small bowel may be assumed to be the source of blood loss and capsule endoscopy should be the third test in the evaluation of patients with GI bleeding.
- In the patient with active bleeding, capsule endoscopy can confirm the small bowel as the site of bleeding, providing a location.

National Comprehensive Cancer Network (NCCN)[58,89-91]

The 2014 and 2013 NCCN guidelines do not include wireless capsule endoscopy (WCE) for the diagnosis or management of colon, gastric or esophageal cancer. In addition the NCCN guidelines regarding hereditary colorectal cancer syndromes do not include WCE for the surveillance of the small bowel or for syndrome related cancer screening.[92]

Summary

Obscure Gastrointestinal (GI) Bleeding

Due to the infrequency of obscure GI bleeding and the small patient population affected, published outcomes data for wireless capsule endoscopy (WCE) are limited. However, the available evidence suggests that WCE may be helpful in identifying a bleeding source in patients for whom other diagnostic testing is inconclusive. Therefore, WCE may be considered medically necessary when obscure GI bleeding is suspected to be of small bowel origin as evidenced by prior inconclusive upper and lower gastrointestinal endoscopic studies.

Acute Upper Gastrointestinal Bleeding

There is insufficient evidence regarding the benefits of wireless capsule endoscopy (WCE) compared to standard diagnostic techniques in patients with acute upper GI bleeding. Therefore, the use of WCE to diagnose acute upper GI bleeding is considered investigational.

Crohn's Disease

Diagnosis of Crohn's Disease: Studies provide consistent evidence that wireless capsule endoscopy (WCE) may identify Crohn's lesions when other conventional tests are negative. Therefore, WCE of the small bowel may be considered medically necessary for suspected Crohn's disease without evidence of disease on conventional diagnostic tests.

Establishing the Extent of Crohn's Disease: The role of wireless capsule endoscopy (WCE) in determining the extent of Crohn's disease in patients with an established diagnosis has been explored in several small studies; however, these studies have significant methodological limitations and fail to demonstrate the clinical utility of the test (i.e., how knowledge regarding the extent of involvement would direct patient management and impact health outcomes). Therefore WCE to establish the extent of Crohn's disease is considered investigational.

Ulcerative Colitis, Celiac Disease, Small Bowel Neoplasms and Other Small Bowel Conditions

Evidence is of insufficient quantity and quality to determine the relative diagnostic performance of wireless capsule endoscopy (WCE) compared with alternative conventional diagnostic tests or to permit conclusions concerning the effect of using WCE on health outcomes of patients with celiac disease, small bowel neoplasms, or other small bowel diseases. Therefore, WCE is considered investigational for evaluation of gastrointestinal diseases not presenting with GI bleeding, including but not limited to ulcerative colitis, Celiac Sprue, irritable bowel syndrome, and small bowel neoplasm.

Esophagus

The evidence on the diagnostic performance of esophageal wireless capsule endoscopy (WCE) is limited in quality and quantity for all esophageal indications. In addition, the studies report inconsistent findings concerning diagnostic validity of esophageal WCE. Therefore, WCE for evaluation of the esophagus, including, but not limited to, gastroesophageal reflux (GERD) or other gastroesophageal pathologies, is considered investigational.

Evaluation of the Colon

There is insufficient evidence to draw conclusions regarding the diagnostic validity (sensitivity and specificity) of wireless capsule endoscopy (WCE) compared with optical colonoscopy. Large, well-designed randomized controlled trials are necessary in order to establish WCE's impact on patient management and health outcomes. Therefore, WCE is considered investigational for evaluation of the colon including, but not limited to, detection of colonic polyps or colon cancer.

Hereditary Polyposis and Nonpolyposis Syndromes

Current studies do not demonstrate how use of wireless capsule endoscopy (WCE) improves the clinical management and health outcomes of patients with hereditary GI polyposis and nonpolyposis syndromes. Therefore, WCE is considered investigational for surveillance of the small bowel in patients with hereditary GI polyposis and nonpolyposis syndromes, including familial adenomatous polyposis, Peutz-Jeghers syndrome, Lynch syndrome and juvenile polyposis syndrome.

Patency Capsule

The value of the patency capsule as a method to evaluate patients in whom the endoscopy capsule may be retained remains uncertain. A full accounting of outcomes in patients for whom the capsule might be used is not available from the current studies. Overall the balance of harm and benefit of using the patency capsule is mixed and cannot be determined from the existing studies. Therefore, the patency capsule is considered investigational for all indications, including, but not limited to, evaluation of the patency of the gastrointestinal tract before wireless capsule endoscopy.

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CROSS REFERENCES

Ingestible pH and Pressure Capsule, Medicine, Policy No. 117

CODES	NUMBER	DESCRIPTION
CPT	0355T	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), colon, with interpretation and report
	91110	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), esophagus through ileum, with interpretation and report
	91111	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), esophagus with interpretation and report
	91112	Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report
HCPCS	None	