

POLICY TITLE	WIRELESS CAPSULE ENDOSCOPY AS A DIAGNOSTIC TECHNIQUE IN DISORDERS OF THE SMALL BOWEL, ESOPHAGUS, AND COLON
POLICY NUMBER	MP-5.033

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I. POLICY

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

- Initial diagnosis in patients with suspected Crohn’s disease without evidence of disease on conventional diagnostic tests such as small-bowel follow-through (SBFT) and upper and lower endoscopy.
- Obscure gastrointestinal (GI) bleeding suspected of being of small bowel origin, as evidenced by prior inconclusive upper and lower gastrointestinal endoscopic studies performed during the current episode of illness.
Note: Obscure GI bleeding is defined as “recurrent or persistent iron-deficiency anemia, positive fecal occult blood test, or visible bleeding with no bleeding source found at original endoscopy.”
- For surveillance of the small bowel in patients with hereditary GI polyposis syndromes, including familial adenomatous polyposis and Peutz-Jeghers syndrome.

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

- Evaluation of the extent of involvement of known Crohn’s disease or ulcerative colitis.
- Evaluation of the esophagus, in patients with gastroesophageal reflux (GERD) or other esophageal pathologies
- Evaluation of other gastrointestinal diseases not presenting with GI bleeding including, but not limited to celiac sprue, irritable bowel syndrome, Lynch syndrome, and small bowel neoplasm
- Evaluation of the colon including, but not limited to, detection of colonic polyps or colon cancer.
- Initial evaluation of patients with acute upper GI bleeding.

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The patency capsule is considered **investigational**, including use to evaluate patency of the gastrointestinal tract before wireless capsule endoscopy.

For the above investigational procedures, there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-reference:

MP- 1.118 Treatment of Barrett’s Esophagus (Cryoablation, Photodynamic Therapy, Radiofrequency Ablation)

II. PRODUCT VARIATIONS

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[N] = No product variation, policy applies as stated

[Y] = Standard product coverage varies from application of this policy, see below

[N] Capital Cares 4 Kids

[N] Indemnity

[N] PPO

[N] SpecialCare

[N] HMO

[N] POS

[Y] SeniorBlue HMO**

[Y] FEP PPO*

[Y] SeniorBlue PPO**

* Refer to FEP Medical Policy Manual MP-6.01.33 Wireless Capsule Endoscopy as a Diagnostic Technique in Disorders of the Small Bowel, Esophagus, and Colon. The FEP Medical Policy manual can be found at:

www.fepblue.org

** Refer to Novitas Solutions Local Coverage Determination (LCD) L34342 Wireless Capsule Endoscopy for indications.

III. DESCRIPTION/BACKGROUND

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Wireless capsule endoscopy is a device intended to visualize portions of the bowel which are not accessible via upper or lower endoscopy, primarily the small bowel. Patients swallow the capsule, and it records images of the intestinal mucosa as it passes through the gastrointestinal (GI) tract. The capsule is collected after being excreted and the images interpreted.

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Wireless capsule endoscopy is performed using the PillCam™ Given® Diagnostic Imaging System (previously called M2A®), which is a disposable imaging capsule manufactured by Given Imaging, Ltd (Norcross, GA). The capsule measures 11 by 30 mm and contains video imaging, self-illumination, and image transmission modules, as well as a battery supply that lasts up to 8 hours. The indwelling camera takes images at a rate of 2 frames per second as peristalsis carries the capsule through the gastrointestinal 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 gauge where the image was taken over the abdomen. Images are then downloaded onto a workstation for viewing and processing.

The device received marketing clearance from the U.S. Food and Drug Administration (FDA) on August 1, 2001, through the 510(k) process. The FDA clearance provides for the capsule's use "along with – not as a replacement for – other endoscopic and radiologic evaluations of the small bowel." The FDA clarified that the "capsule was not studied in the large intestine." On July 1, 2003, a supplemental 510(k) premarket notification was cleared, and the labeled indications were modified by removing the “adjunctive” use qualification: “the Given® Diagnostic System is intended for visualization of the small bowel mucosa. It may be used as a tool in the detection of abnormalities of the small bowel.”

In November 2004, the device received FDA clearance for the following labeled indication: “the Given® Diagnostic System with the PillCam™ ESO Capsule is intended for the visualization of esophageal mucosa.” A new model was cleared by the FDA in June 2007, the PillCam ES02 Capsule. In September 2007, the FDA cleared the Olympus Capsule Endoscope System through the 510(k) process for “visualization of the small intestine mucosa.” More recent versions of both these systems also incorporate a blood indicator feature to assist with rapid screening of intestinal lesions with bleeding potential.

In the small bowel, the capsule camera has been most frequently proposed as a technique to identify the source of obscure intestinal bleeding, although recently there has been interest in exploring its use in patients with inflammatory bowel disease. Alternative diagnostic techniques include barium studies or small intestinal endoscopy. In the esophagus, the capsule camera has been proposed as a screening technique for Barrett’s esophagus associated with gastroesophageal reflux disease (GERD). Evaluation of the esophagus requires limited transit time, and it is estimated that the test takes 20 minutes to perform. Alternative techniques include upper endoscopy.

In 2006, the FDA also provided clearance for the Given AGILE patency system. This system is an accessory to the PillCam video capsule and, according to FDA material, is intended to verify adequate patency of the GI tract prior to administration of the PillCam in patients with known or suspected strictures. This capsule is of similar size to the endoscopy capsule but is made of lactose and barium and dissolves within 30–100 hours of entering the GI tract. It carries a tracer material that can be detected by a scanning device. Excretion of the intact capsule

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without symptoms (abdominal pain or obstruction) is reported to predict the uncomplicated passage of the wireless capsule

IV. RATIONALE

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This policy is updated periodically with a literature review of the MEDLINE database. The most recent update covers the period of June 2012 through June 2013.

Literature Review

Obscure GI Bleeding

Obscure gastrointestinal (GI) bleeding is defined as bleeding from the GI tract that persists or recurs without an obvious etiology after imaging with upper and lower endoscopy and radiologic evaluation of the small bowel. Obscure GI bleeding is often detected by fecal occult blood testing performed for colon cancer screening, and the presence of anemia consistent with persistent blood loss. (1) Without anemia, further testing beyond upper and lower endoscopy is not warranted. Most obscure GI bleeding is due to lesions in the esophagus, stomach, and colon; 5% are due to lesions in the small intestine. Causes of obscure bleeding in the small intestine include angiodysplasia (70–80%), tumor (5–10%), and other causes (10–25%) including those related to medication, infections (tuberculosis), Crohn’s disease, Meckel’s diverticulum, Zollinger-Ellison, vasculitis, radiation enteritis, jejunal diverticula, and chronic mesenteric ischemia. (2) In patients older than age 60 years, angiodysplasia is the most likely cause, while in those younger than age 50 years, a small bowel tumor would be the most likely cause of bleeding. (3)

A 2007 position statement by the American Gastroenterological Association (AGA) states that capsule endoscopy should be the third test after upper and lower endoscopy in the evaluation of obscure GI bleeding. (1) Evidence cited in the accompanying technical review caused them to revise prior position statements in which other tests, such as bleeding scans, angiography, repeat endoscopy, enteroscopy, and enteroclysis were recommended, depending on the presence or absence of active bleeding. (4) The arguments supporting the utility of capsule endoscopy are based on several lines of evidence. Capsule endoscopy appears to have higher sensitivity of locating bleeding lesions compared to other diagnostic techniques, when diagnostic yields are compared. The technical review summarizes 10 studies in which capsule endoscopy was compared with push enteroscopy in the same patients. Capsule endoscopy located a source of bleeding in between 25-55% more patients than push enteroscopy. (4) One study by Hartmann et al. compared the findings of capsule endoscopy to what might be considered the gold standard for localizing bleeding, intraoperative endoscopy. (5) Capsule endoscopy was 95% sensitive in locating bleeding and was able to localize bleeding in a few cases in which intraoperative endoscopy was not able to. In a study by Pennazio et al. in which long term follow-up was used

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as the reference standard, capsule endoscopy was 89% sensitive and 95% specific in 56 patients in whom a confirmed diagnosis was obtained. (6) A “true” reference standard for obscure GI bleeding is, in fact, difficult or impossible to achieve, as the bleeding source may resolve and invasive techniques such as surgery cannot be justifiably used.

A 2012 systematic review and meta-analysis by Koulaouzidis et al. evaluated 24 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.

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.

Section Summary. There are a large number of uncontrolled studies that evaluate the use of capsule endoscopy in the evaluation of patients with occult GI bleeding. These studies are consistent in reporting that a substantial proportion of patients receive a definitive diagnosis following this test when there are few if any other diagnostic options. A 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.

Acute upper GI bleeding

Three 2013 studies with small cohorts of patients (n = 25-83) have reported on the use of capsule endoscopy before upper endoscopy for acute GI bleeding, in order to triage and/or risk stratify patients in the emergency department or hospital. (9-11) The studies report that capsule endoscopy provides useful information in a substantial proportion of patients, such as identifying gross bleeding, inflammatory lesions and stratifying patients into high or low risk categories. 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

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further assess the impact of capsule endoscopy on health outcomes compared to standard management.

Suspected Crohn’s Disease

Crohn’s disease is an inflammatory disease of the small intestine. It is usually diagnosed with small bowel imaging studies and ileocolonoscopy. When these studies are negative or equivocal, capsule endoscopy has been proposed as a method for identifying Crohn’s disease. However, there is no single gold standard diagnostic test for Crohn’s disease; the diagnosis is based on a constellation of findings. Thus it is difficult to determine the diagnostic characteristics of various tests used to diagnose the condition and difficult to determine a single comparator diagnostic test to capsule endoscopy. An international consensus from 2009 stated that there are no validated diagnostic criteria for interpreting capsule endoscopy for a diagnosis of Crohn’s disease, thus, possibly explaining the variability of the diagnostic performance of capsule endoscopy. (12)

Nonetheless, despite the difficulties in evaluating the clinical value of capsule endoscopy in assessing suspected Crohn’s disease, findings tend to indicate that, compared with other diagnostic modalities, capsule endoscopy has an equivalent or higher yield of positive findings. An international consensus statement found 7 studies comparing capsule endoscopy to small-bowel follow-through (SBFT), 1 study comparing capsule endoscopy to magnetic resonance imaging (MRI), and 4 studies comparing capsule endoscopy to computed tomography (CT) scan. (12) The conclusion statements stated that capsule endoscopy may be superior to these alternative diagnostic tests.

The role of capsule endoscopy in established Crohn’s disease is less certain. An international consensus statement states that radiographic imaging should take precedence over capsule endoscopy because of the capability to detect obstructive strictures, extraluminal and transmural disease. (12) The consensus statement identifies some studies in which capsule endoscopy had a higher percentage of positive findings than alternative tests in patients with established Crohn’s disease, but it is not clear how these findings correlated with either symptoms or the outcome of therapeutic intervention.

Section summary. 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 may not perform as well as other modalities for diagnosing complications of Crohn’s disease.

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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 on the same day. (13) The authors reported capsule endoscopy sensitivity and specificity to detect active colonic inflammation was 89% (95% CI 80 – 95) and 75% (95% CI 51 - 90), respectively. The positive and negative predictive values were 93% (95% CI 84 - 97) and 65% (95% CI 43 - 83), respectively. It does not appear to be an adequate alternative method of assessing disease activity.

Suspected 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 obtained 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.

A meta-analysis by El-Matary et al. compared the diagnostic performance of capsule endoscopy to a reference standard of duodenal biopsy. (14) 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. (15) 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. Given the less than 90% sensitivity of capsule endoscopy for celiac disease, it does not appear to be an adequate alternative method of making an initial diagnosis.

The role of capsule endoscopy in unconfirmed, nonresponsive or established celiac disease has little evidence to assess. One study evaluated 47 patients with complicated celiac disease and found unexpected additional findings in 60% of patients, most of which were ulcerations. (16) However, the definition of “complicated” celiac disease included other factors such as evidence of blood loss, itself an indication for capsule endoscopy. The impact on patient management and outcomes is unclear.

In a 2013 study by Kurien and colleagues, 62 patients with an equivocal diagnosis of celiac disease and 69 patients with confirmed celiac disease who were unresponsive to standard treatment were evaluated with capsule endoscopy. (17) Results were combined with HLA typing and response to gluten challenge, with the final diagnosis made by three expert physicians who were provided with the information from all three sources. The main outcome was the increase in

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diagnostic yield after capsule endoscopy combined with the other tests. The diagnostic yield was greatest in cases with anti-body negative villous atrophy where a diagnosis of celiac disease (or Crohn’s disease) was made in 9 of 32 patients (28%). In 8 of the 69 (12%) nonresponsive celiac disease patients, capsule endoscopy identified 2 cases of enteropathy-associated lymphoma, 4 type 1 refractory disease cases, 1 fibroepithelial polyp, and 1 case of ulcerative jejunitis. This study is limited by the lack of control groups and small sample size, in addition to the use of other tests in conjunction with capsule endoscopy for the ascertainment of a final diagnosis.

Section summary. In cases where the diagnosis of celiac disease is equivocal, capsule endoscopy can sometimes uncover 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

Capsule endoscopy has the capability of visualizing several types of esophageal conditions. It could potentially substitute for traditional upper endoscopy for several indications and may have an advantage of comfort and convenience. However, interventional procedures and biopsies cannot be performed.

Most studies have shown that capsule endoscopy has inferior diagnostic characteristics compared to traditional upper endoscopy for a variety of esophageal conditions. A meta-analysis of 9 studies comparing capsule endoscopy to traditional endoscopy for detecting esophageal varices calculated a sensitivity of 83% and specificity of 85%. (18) Another meta-analysis of 9 studies comparing capsule endoscopy to traditional endoscopy for detecting Barrett’s esophagus showed a sensitivity and specificity of 77% and 86%, respectively. (19) The sensitivity of the test is not good enough to substitute for endoscopy.

Colon Cancer Screening

Capsule endoscopy has been investigated as a method of colon cancer screening. The test may detect precancerous polyps or actual cancer. Several studies have assessed the accuracy of capsule endoscopy for detection of colonic lesions. In the largest study of 328 patients, the sensitivity of capsule endoscopy was 64% for polyps 6 mm or larger, 73% for advanced adenoma, and 74% for cancer. (20) Other smaller studies show the sensitivity of capsule endoscopy for various types of lesions to be less than 80%. (21-23) A meta-analysis by Spada et al. of 8 studies enrolling 837 patients showed a sensitivity of 71% for polyps of any size and a specificity of 75%. (24) 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. 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

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frequently than colonoscopy. The specificity of the test is not optimal either, meaning that patients will undergo unnecessary follow-up colonoscopy.

Hereditary GI Polyposis Syndromes

Persons with familial adenomatous polyposis and Peutz-Jeghers syndrome are at genetically high risk of small bowel polyps and tumors. Mata and colleagues studied the role of capsule endoscopy in 24 patients with hereditary GI polyposis syndromes, including familial adenomatous polyposis (n=20) or Peutz-Jeghers syndrome (n=4). (25) Compared to barium studies using small bowel enteroclysis, capsule endoscopy identified 4 additional patients with small bowel polyps, which were subsequently removed with endoscopic polypectomy. Another study by Brown et al. in 19 patients showed a greater number of polyps identified with capsule endoscopy than with barium follow-through examinations. (26) Although these studies are small, they demonstrate that capsule endoscopy can identify additional lesions in persons with disease syndromes at high risk for such lesions.

There is a small amount of evidence on use of capsule endoscopy for small bowel screening in Lynch syndrome. (27) This data is insufficient to determine the prevalence and/or natural history of small bowel polyps in patients with Lynch syndrome. In addition, surveillance of the small bowel is not generally recommended as a routine intervention for patients with Lynch syndrome. For this reason, it is not possible to determine whether capsule endoscopy improves outcomes for patients with Lynch syndrome.

Patency Capsule

Contraindications to the use of capsule endoscopy include; known or suspected obstruction or stricture, Zenker’s diverticulum, intestinal pseudo-obstruction and motility disorders. Certain patients with known or suspected strictures of the small bowel may be at risk of retaining the capsule. Surgical removal may be necessary. There are limited data on the performance of the patency capsules proposed as a technique to evaluate patients with known or suspected strictures prior to using the wireless capsule endoscopy system. The capsule could be used either to eliminate certain patients who are considered low risk for capsule retention to further increase the safety of capsule endoscopy or to select patients at high risk for capsule retention who would otherwise not undergo capsule endoscopy. In either scenario, it needs to be determined whether the change in diagnostic strategy and ultimate treatment was ultimately improved as a consequence of either being selected or de-selected to have a capsule endoscopy.

These improvements would need to be weighed against any complications due to the use of the patency capsule. The published studies are small and do not provide comparative data about the incremental value of this capsule over standard clinical evaluation. Also, in some series, administration of the patency capsule has produced symptoms requiring hospitalization and even surgery. In a series from Europe, Delvaux et al. reported on findings in 22 patients with

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suspected intestinal stricture, 15 of whom had Crohn’s disease. (28) In this study, at 30 hours after ingestion, the patency capsule was detected in 17 patients (72.3 %). In all patients in whom the capsule was blocked in the small intestine, the stenosis had been suspected on computed tomography (CT) scan or small-bowel follow-through. In 3 patients, the delay in progression of the patency capsule led to cancellation of capsule endoscopy. In 3 patients, the patency capsule induced a symptomatic intestinal occlusion, which resolved spontaneously in 1 and required emergency surgery in 2. The authors commented that the current technical development of the patency capsule limits its use in clinical practice, as it did not detect stenoses undiagnosed by CT or small-bowel follow-through, and the start of dissolution at 40 hours after ingestion is too slow to prevent episodes of intestinal occlusion. They also comment that a careful interview eliciting the patient's history and symptoms remains the most useful indicator with regard to suspicion of an intestinal stenosis. In another study from Europe, Spada et al. reported on findings in 27 patients, 24 with Crohn’s disease. (29) In this study, 25 patients (92.6%) retrieved the patency capsule in the stools. Six patients complained of abdominal pain, 4 of whom excreted a nonintact capsule, and hospitalization was required in 1 patient due to occlusive syndrome.

Several studies show that patients who had uncomplicated passage of the patency capsule subsequently underwent uncomplicated capsule endoscopy. (30-32) These patients often had significant findings on capsule endoscopy. (30, 31) However, it is difficult to determine whether the findings of capsule endoscopy in these patients improved their outcomes beyond any alternate test regimen that could have been done. In 1 of these studies, 3 of 106 patients had severe adverse events, including 1 patient who required surgery. (30) The overall balance of harm and benefit of using the patency capsule cannot be determined from the existing studies.

Ongoing Clinical Trials

A search of ClinicalTrials.gov on July 15, 2013 identified 2 active randomized clinical trials on wireless capsule endoscopy. In NCT00694954 capsule endoscopy will be compared to the standard of care for suspected occult/obscure intestinal bleeding in patients with iron deficiency anemia after negative gastroscopy and colonoscopy. In NCT 01557101 adherence to screening recommendations in patients with first degree relatives with colorectal cancer will be compared in colon capsule endoscopy vs. optical colonoscopy. Capsule endoscopy is being evaluated for assessment of acute upper gastrointestinal hemorrhage in the emergency department in NCT01371591.

Summary

Wireless capsule is a device that allows visualization of intestinal mucosa that is not accessible by traditional upper or lower endoscopy. It has been most extensively studied in patients with obscure GI bleeding. For this population, the evidence demonstrates that capsule endoscopy can identify a bleeding source in a substantial number of patients who are unable to be diagnosed by other methods, with a low incidence of adverse events. Since there are no other options for

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diagnosing obscure small bowel bleeding in patients who have negative upper and lower endoscopy, this technique will likely improve health outcomes by directing specific treatment when a bleeding source is identified. Therefore wireless capsule endoscopy may be considered medically necessary for the evaluation of obscure GI bleeding. Similarly, for patients with suspected small bowel Crohn’s disease and for patients with familial polyposis syndromes who require surveillance of the small bowel, other methods are not available for visualizing the small bowel. Although the performance characteristics of the capsule for these indications are uncertain, it is likely to improve health outcomes by identifying some cases of these disorders and directing specific treatment. Therefore, wireless capsule endoscopy may be considered medically necessary for these indications.

For other conditions, including acute upper GI bleeding, determining the extent of involvement in Crohn’s disease, ulcerative colitis, celiac disease, esophageal conditions, Lynch syndrome, colon cancer screening, and for determination of patency of the GI tract, the evidence is not sufficient to conclude that health outcomes are improved. For some of these conditions, e.g., esophageal conditions and colon cancer screening, other modalities are available that are superior to capsule endoscopy. For other conditions, e.g., determining the extent of Crohn’s disease, the accuracy of the device needs to be established prior to determining whether outcomes are improved. For these reasons, wireless capsule endoscopy is considered investigational for these indications.

Practice Guidelines and Position Statements

A 2007 position statement by the American Gastroenterological Association (AGA) (1) 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.

An international consensus panel from 2009 (12) published guidelines on the use of wireless capsule endoscopy for inflammatory bowel disease (IBD). These guidelines included the following statements about evaluation of Crohn’s disease:

- Small bowel capsule endoscopy is able to identify mucosal lesions compatible with Crohn’s disease in some patients in whom conventional endoscopic and small-bowel radiographic imaging modalities have been nondiagnostic.
- A diagnosis of Crohn’s disease should not be based on the appearances at capsule endoscopy alone.

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- A normal capsule endoscopy has a high negative predictive value for active small-bowel Crohn’s disease.
- For patients with established Crohn’s disease, small bowel capsule endoscopy is better at identifying small-bowel mucosal lesions than barium and may be better than CT or MR enterography or enteroclysis, but the clinical significance of this potential difference remains to be defined.
- There are no validated diagnostic criteria for small bowel capsule endoscopy for the diagnosis of Crohn’s disease.

European guidelines for quality assurance in colorectal cancer screening and diagnosis, originally published in 2010, indicate capsule endoscopy is not recommended for screening for colorectal cancer. (33) These guidelines indicate studies have shown capsule endoscopy to be inferior to colonoscopy in diagnostic performance.

V. DEFINITIONS

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ANEMIA is a reduction in the amount of circulating red blood cells. Generally, a person is considered anemic when their hemoglobin levels are more than two standard deviations below the mean level of the laboratory. Various factors, such as bleeding, vitamin or mineral deficiencies or a decrease in red blood cell production can cause anemia.

ENDOSCOPY refers to inspection of body organs or cavities by use of an endoscope.

510 (K) is a premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA). Applicants must compare their 510(k) device to one or more similar devices currently on the U.S. market and make and support their substantial equivalency claims.

PERISTALSIS refers to the progressive wavelike movement that occurs involuntarily in hollow tubes of the body, especially the alimentary canal.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member’s individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member’s benefit information or contact Capital for benefit information.

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VII. DISCLAIMER

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Capital’s medical policies are developed to assist in administering a member’s benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member’s benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

CPT Codes®								
91110								

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Investigational; therefore not covered:

CPT Codes®								
91111								

ICD-9-CM Diagnosis Code*	Description
211.2	Benign neoplasm of other parts of digestive system; duodenum, jejunum, and ileum (small intestine NOS)
555.0 – 555.9	Regional enteritis, code range
556.9	Unspecified ulcerative colitis
578.0 – 578.9	Gastrointestinal hemorrhage, code range
759.6	Other hamartoses, not otherwise specified (includes Peutz-Jeghers syndrome)

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

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The following ICD-10 diagnosis codes will be effective October 1, 2014:

ICD-10-CM Diagnosis Code*	Description
D13.2 – D13.39	Benign neoplasm of other and unspecified parts of the small intestine code range
K50.00 – K50.919	Crohn’s disease (regional enteritis) code range
K51.90- K51.919	Ulcerative Colitis code range
K92.0 – K92.2	Hematemesis and gastrointestinal hemorrhage, unspecified code range
Q85.0 0 – Q85.9	Phakomatoses, not elsewhere classified (includes Peutz-Jegher’s syndrome) code range

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

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X. POLICY HISTORY

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MP 5.033	CAC 5/27/03
	CAC 6/24/03
	CAC 9/28/04
	CAC 9/27/05
	CAC 11/28/06
	CAC 5/27/08
	CAC 9/29/09 Requirements for small bowel follow through as a pre-requisite removed from the policy. Information added to the description regarding the Given AGILE patency system and new PillCam models.
	CAC 11/30/10 Consensus Review
	CAC 4/24/12 Title changed to match BCBSA. (Formerly Wireless Capsule Endoscopy. Wording changes do not alter coverage criteria. Added definition of obscure GI bleeding as a note. Patency capsule remains investigational
	CAC 6/4/13 Consensus review. No code changes.
	CAC 9/24/13 Minor review. Added evaluation of extent of known ulcerative colitis, evaluation of Lynch syndrome and initial evaluation of initial episode of acute upper GI bleeding as investigational indications. Added the statement “performed during the current episode of illness” to the second medically necessary bullet “Obscure gastrointestinal (GI) bleeding suspected of being of small bowel origin, as evidenced by prior inconclusive upper and lower gastrointestinal endoscopic studies”. Added rationale section and FEP variation referencing the FEP manual. Administrative code review complete.
	CAC 3/25/14 Consensus. No change to policy statements. References reviewed.
	3/27/14 New LCD for Novitas in effect

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