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

- Initial diagnosis in patients with suspected Crohn disease without evidence of disease on conventional diagnostic tests such as small-bowel follow-through (SBFT) and upper and lower endoscopy.
- In patients with an established diagnosis of Crohn disease, when there are unexpected change(s) in the course of disease or response to treatment, suggesting the initial diagnosis may be incorrect and re-examination may be indicated.
- Suspected small bowel bleeding, as evidenced by prior inconclusive upper and lower gastrointestinal endoscopic studies performed during the current episode of illness.
- For surveillance of the small bowel in patients with hereditary gastrointestinal (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 disease or ulcerative colitis.
- Evaluation of the esophagus, in patients with gastroesophageal reflux (GERD) or other esophageal pathologies.
- Evaluation of other GI diseases not presenting with GI bleeding including, but not limited to celiac sprue, irritable bowel syndrome, Lynch syndrome, portal hypertensive enteropathy, small bowel neoplasm and unexplained chronic abdominal pain.
- 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.

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 Endoscopic Radiofrequency Ablation or Cryoablation for Barrett’s Esophagus

II. PRODUCT VARIATIONS

This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

BlueJourney HMO*  BlueJourney PPO*  FEP PPO**

*Refer to Novitas Solutions Local Coverage Determination (LCD) L35089, Wireless Capsule Endoscopy.


III. DESCRIPTION/BACKGROUND

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. 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 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 gauge where the image was taken over the abdomen. Images are then downloaded onto a workstation for viewing and processing.

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 esophagus associated with 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.

**Regulatory Status**

On August 1, 2001, the PillCam™ Given® Diagnostic Imaging System (Given Imaging) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. FDA clearance provides for the capsule's use "along with – not as a replacement for – other endoscopic and radiologic evaluations of the small bowel." 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 FDA in June 2007, the PillCam ESO2 Capsule. In September 2007, the Olympus Capsule Endoscope System was cleared for marketing by FDA 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 2006, the Given AGILE™ patency system was also cleared by FDA through the 510(k) process. 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 before 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 to 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 without symptoms (abdominal pain or obstruction) is reported to predict the uncomplicated passage of the wireless capsule.

In 2014, PillCam™ COLON was granted a de novo 510(k) classification by FDA. The new classification applies to devices with low to moderate risk that have no predicate on the market. PillCam™ COLON is intended to visualize the colon in patients who have had an incomplete
colonoscopy due to a technical impossibility and not incomplete evacuation. In 2016, the PillCam™ COLON 2 Capsule Endoscopy System was cleared by FDA through the 510(k) process for the detection of colon polyps in patients after an incomplete colonoscopy with adequate preparation, and a complete evaluation of the colon was not technically possible, and for detection of colon polyps in patients with evidence of GI bleeding of lower GI origin in patients with major risks for colonoscopy or moderate sedation, but who could tolerate a colonoscopy and moderate sedation in the event that a clinically significant colon abnormality was identified on capsule endoscopy.

FDA Product Code: NEZ.

IV. RATIONALE

The most recent update covers the period through October 14, 2016. In general, diagnostic technologies are evaluated on the basis of analytic validity, clinical validity, and clinical utility. For capsule endoscopy, in general, very little evidence exists for most indications regarding analytic validity, which in this case would evaluate concordance between different examinations in the same person and concordance between different examiners. Clinical validity is usually assessed by determining the diagnostic characteristics of the test compared to a reference standard. However, for certain indications (e.g., suspected small bowel bleeding), a specific diagnosis is not being sought but rather a source of bleeding, which could be due to any of several diagnoses. In this situation, an appropriate measure of clinical validity would be diagnostic yield, which is the proportion of examinations for which a diagnosis is achieved. Clinical utility may be determined based on diagnostic yield or sensitivity and specificity if the test improves outcomes or avoids morbidity based on an indirect chain of evidence.

SUSPECTED SMALL BOWEL BLEEDING

Suspected small bowel bleeding, previously referred to as obscure gastrointestinal (GI) tract 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. Suspected small bowel bleeding is often detected by fecal occult blood testing performed for colon cancer screening, and the presence of anemia consistent with persistent blood loss.\(^1\) 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 disease (CD), Meckel diverticulum, Zollinger-Ellison syndrome, 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) indicated that capsule endoscopy should be the third test after upper and lower endoscopy in the evaluation of obscure GI bleeding. Evidence cited in the accompanying technical review caused the AGA to revise prior position statements in which other tests (e.g., bleeding scans, angiography, repeat endoscopy, enteroscopy, enteroclysis) were recommended, depending on the presence or absence of active bleeding. 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 than other diagnostic techniques, when diagnostic yields are compared. The technical review summarized 10 studies comparing capsule endoscopy with push enteroscopy in the same patients. Capsule endoscopy located a source of bleeding in 25% to 55% more patients than push enteroscopy. One study by Hartmann et al compared the findings of capsule endoscopy with what might be considered the criterion standard for localizing bleeding, intraoperative endoscopy. Capsule endoscopy was 95% sensitive in locating bleeding and was able to localize bleeding in a few cases in which intraoperative endoscopy was not. In a study by Pennazio et al in which long-term follow-up was used as the reference standard, capsule endoscopy was 89% sensitive and 95% specific in 56 patients for whom a confirmed diagnosis was obtained. A “true” reference standard for obscure GI bleeding is, in fact, difficult or impossible to achieve, because the bleeding source may resolve and invasive techniques (e.g., 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 from previous diagnostic evaluations including upper and lower endoscopy. Selected studies included 1960 patients, 1194 (60.9%) of whom 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% to 52%). Almost 50% of the diagnostic yield was for small bowel angioectasia. In a subset of 4 studies focused on patients with iron-deficiency anemia (n=264 [13.47%]), the pooled diagnostic yield with capsule endoscopy was 66.6% (95% CI, 61.0% to 72.3%) and included more vascular, inflammatory, and mass/tumor lesions.

In 2012, Leung et al reported on 60 consecutive patients with acute melena or hematochezia who were randomized to immediate capsule endoscopy or mesenteric angiography in a 1:1 ratio after nondiagnostic endoscopy and colonoscopy. Capsule endoscopy had a significantly higher diagnostic yield (53.3%) than angiography (20.0%; p=0.016). The cumulative risk of rebleeding in the angiography and capsule endoscopy group was 33.3% and 16.7%, respectively (p=0.10). After a mean follow-up of 48.5 months, further transfusion, hospitalization for rebleeding, and mortality did not differ significantly between the groups.

**Section Summary: Suspected Small Bowel Bleeding**

A large number of uncontrolled studies have evaluated use of capsule endoscopy in the evaluation of patients with suspected small bowel bleeding. These studies have consistently
reported that a substantial proportion of patients receive a definitive diagnosis following this test when there are few 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. Capsule endoscopy appears to locate the source of bleeding at least as well as other diagnostic methods and direct treatment to the source of bleeding.

**ACUTE UPPER GI TRACT BLEEDING**

In 2016, Sung et al reported on a prospective randomized controlled trial (RCT) to evaluate the use of capsule endoscopy in the emergency department for patients with suspected upper GI bleeding. Capsule endoscopy was used to determine whether patients would be admitted to the hospital or sent home, versus an alternative strategy of admitting all patients. Eligible patients presented with signs and/or symptoms of acute upper GI bleeding but were without hemodynamic shock or conditions likely to preclude use of the capsule endoscope. Seventy-one patients were randomized to capsule endoscopy in the emergency department (n=37), followed by monitoring for upper GI bleeding, or standard care (n=34), which included mandatory hospital admission. Seven capsule endoscopy patients with active bleeding or endoscopic findings were admitted, with the remainder discharged home. There were no deaths or morbid outcomes in either group, indicating that capsule endoscopy could result in equivalent patient outcomes with many patients safely avoiding emergency hospitalization.

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

**Section Summary: Acute Upper GI Tract Bleeding**

Use of capsule endoscopy in the emergency department setting for suspected upper GI bleeding is based on efficiency (avoiding hospitalization, avoiding immediate endoscopy). Further controlled studies are needed to further assess the impact of capsule endoscopy on health outcomes compared with standard management. Patients should be followed to their ultimate diagnosis to determine whether use of capsule endoscopy versus other triage strategies or immediate endoscopy results in lower health care resource utilization.
CROHN DISEASE

Diagnosis of CD

CD is an inflammatory disease involving the small intestine that 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 CD. There is no single criterion standard diagnostic test for CD; rather, 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.

Despite difficulties in evaluating the clinical value of capsule endoscopy to assess suspected CD, findings tend to indicate that, compared with other diagnostic modalities, capsule endoscopy has an equivalent or higher yield of positive findings. A 2009 international consensus statement found 7 studies comparing capsule endoscopy with small bowel follow-through (SBFT), 1 study comparing capsule endoscopy with magnetic resonance imaging (MRI), and 4 studies comparing capsule endoscopy with computed tomography (CT) scan. Conclusions reached indicated that capsule endoscopy may be superior to these alternative diagnostic tests.

In 2016, Choi et al reported on a meta-analysis of studies on the effectiveness of capsule endoscopy compared to other diagnostic modalities in patients with small bowel CD. Reviewers selected 24 studies, which included patients with both suspected and established CD, and compared capsule endoscopy with a range of alternative diagnostic modalities, including SBFT, enteroclysis (a conventional fluoroscopic technique not widely used due to invasiveness, time-intensiveness, and associated discomfort for the patient), CT enterography, and magnetic resonance enterography (MRE). For patients with suspected CD, the diagnostic yield of capsule endoscopy (66%) was higher than that of SBFT (21.3%; weighted incremental yield [IYw], 0.44; 95% confidence interval [CI], 0.29 to 0.59, I²=30%). The diagnostic yield of capsule endoscopy was not significantly higher than that of CT enterography (72.5% for endoscopy vs 22.5% for CT enterography; IYw=0.36; 95% CI, 0.18 to 0.90; I²=68%) or that of MRE (85.7% for endoscopy vs 100% for MRE; IYw = -0.16; 95% CI, -0.63 to 0.32; I²=44%). The reference standards varied for the included studies, so quantitative data were not synthesized for diagnostic accuracy. In pooled analysis, in patients with suspected CD, the sensitivity and specificity of capsule endoscopy ranged from 89.6% to 92.0% and 100%, respectively.

Established Diagnosis of CD

The role of capsule endoscopy in an established diagnosis CD is less certain. An international consensus statement indicated that radiographic imaging should take precedence over capsule endoscopy because of the capability to detect obstructive strictures as well as extraluminal and transmural disease. The consensus statement identified some studies in which capsule endoscopy had a higher percentage of positive findings than alternative tests in patients with established CD, but it is not clear how these findings correlated with either symptoms or
outcomes of therapeutic intervention. A 2013 European consensus statement indicated magnetic resonance enterography (MRE) or CT enterography is usually preferred to capsule endoscopy in known CD patients.\textsuperscript{15} The 2013 consensus also indicated capsule endoscopy should be limited in patients with CD to the evaluation of unexplained symptoms, unexplained iron deficiency, or obscure GI bleeding after other investigations are inconclusive.

In 2015, D’Haens et al reported on a multicenter pilot study to validate the second-generation colon capsule endoscopy recordings against optical colonoscopy for evaluating colonic ulcerations in 40 patients with active CD.\textsuperscript{16} Patients with clinically and biochemically active CD who had indication for optical colonoscopy underwent colon capsule endoscopy with scoring of disease activity using the Simple Endoscopic Score for Crohn’s Disease (SES-CD) and the Crohn’s Disease Endoscopic Index of Severity (CDEIS). Colon capsule endoscopy scoring results were validated against optical colonoscopy results. For the CDEIS, agreement between the 2 modalities was high (intraclass correlation coefficient [ICC], 0.65; 95% CI, 0.43 to 0.80). For the SES-CD, agreement between the 2 modalities was moderate (ICC=0.50; 95% CI, 0.24 to 0.70). For a random subset of 20 recordings, the interobserver variability for colon capsule endoscopy readings was calculated. For the CDEIS and SES-CD, the between-reader ICCs were 0.67 (95% CI, 0.35 to 0.86) and 0.66 (95% CI, 0.32 to 0.85), respectively.

**Section Summary: Crohn Disease**

For patients with suspected CD of the small bowel who cannot be diagnosed by other modalities, capsule endoscopy can confirm the diagnosis in a substantial number of patients. The diagnostic yield in the available studies varies, but is likely superior to alternative tests such as CT or MRI scanning.

**ULCERATIVE COLITIS**

Ulcerative colitis is an inflammatory disease of the large intestine. It is usually diagnosed by colonoscopy and biopsy. Capsule endoscopy has been proposed as an alternative method for assessing the extent and severity of disease activity in those with known ulcerative colitis. Sung et al evaluated 100 patients with suspected or known ulcerative colitis using capsule endoscopy and colonoscopy performed on the same day.\textsuperscript{17} They reported capsule endoscopy sensitivity and specificity to detect active colonic inflammation were 89% (95% CI, 80% to 95%) and 75% (95% CI, 51% to 90%), respectively. The positive (PPV) and negative predictive values (NPV) were 93% (95% CI, 84% to 97%) and 65% (95% CI, 43% to 83%), respectively.

San Juan-Acosta et al (2014) evaluated 42 patients with known ulcerative colitis using capsule endoscopy and colonoscopy to assess disease activity.\textsuperscript{18} Results were expressed with \( \kappa \) coefficients. There was a good correlation between colon capsule endoscopy and colonoscopy in disease severity (\( \kappa=0.79; \) 95% CI, 0.62 to 0.96) and extent of inflammation (\( \kappa=0.71; \) 95% CI, 0.52 to 0.90). In 3 patients, inflammation was seen in the terminal ileum, leading to a change in diagnosis to ileocolonic CD. Although the correspondence between the 2 methods was
reasonably good, it is uncertain whether management changes based on one or the other test would result in similar or different patient outcomes.

Oliva et al (2014) evaluated 30 patients with known ulcerative colitis with both capsule endoscopy and colonoscopy to assess disease activity.\(^{19}\) The reference standard for disease activity was a Matts score greater than 6 as judged by colonoscopy. The sensitivity of capsule endoscopy was 96\% (95\% CI, 79\% to 99\%) and specificity was 100\% (95\% CI, 61\% to 100\%). The PPV and NPV of second-generation colon capsule endoscopy were 100\% (95\% CI, 85\% to 100\%) and 85\% (95\% CI, 49\% to 97\%), respectively. Although the 2 methods had high concordance at this cutoff level of disease in this study, patient outcomes linked to these assessments of disease activity cannot be determined.

Section Summary: Ulcerative Colitis
Effects of capsule endoscopy findings on patient management need to be assessed to determine whether capsule endoscopy findings result in meaningful changes in management that improve outcomes compared to clinical management alone or assessment of disease activity with colonoscopy.

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 criterion 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, assessing the extent of disease, and in evaluation of celiac disease unresponsive to treatment.

A meta-analysis by El-Matary et al compared the diagnostic performance of capsule endoscopy with a reference standard of duodenal biopsy.\(^{20}\) 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 with biopsy, summarizing 6 studies (total N=166 subjects).\(^{21}\) 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 the 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 nonresponsive celiac disease has been evaluated in only a few studies. One case series by Culliford et al evaluated 47 patients with complicated celiac disease and found unexpected additional findings in 60\% of patients, most of which were ulcerations.\(^{22}\) 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 et al, 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. Results were combined with human leukocyte antigen typing and response to gluten challenge, with the final diagnosis made by 3 expert physicians who received the information from all 3 sources. The main outcome was the increase in diagnostic yield after capsule endoscopy combined with the other tests. The diagnostic yield was greatest in cases with antibody negative villous atrophy where a diagnosis of celiac disease (or CD) was made in 9 (28%) of 32 patients. In 8 (12%) of the 69 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 was limited by the small sample size and use of other tests in conjunction with capsule endoscopy to ascertain a final diagnosis.

Section Summary: Suspected Celiac Disease
In cases where the diagnosis of celiac disease is equivocal, capsule endoscopy can sometimes reveal 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. Case series of patients with unresponsive celiac disease undergoing capsule endoscopy have shown some yield of actionable diagnoses which have the potential to improve patient outcomes. Larger studies are needed to better determine the diagnostic yield of capsule endoscopy in these patients.

ESOPHAGEAL DISORDERS
Capsule endoscopy has the capability to visualize several types of esophageal conditions. It could substitute for traditional upper endoscopy for several indications and may have the advantage of comfort and convenience. However, interventional procedures and biopsies cannot be performed with capsule endoscopy. Capsule endoscopy could triage patients for endoscopy if either the sensitivity or the specificity is high. Traditional endoscopy could then be performed on the appropriate group to determine false positives or false negatives, having spared the group with a high PPV an endoscopy procedure.

Most studies have shown that capsule endoscopy has inferior diagnostic characteristics compared with traditional upper endoscopy for a variety of esophageal conditions. A meta-analysis of 9 studies comparing capsule endoscopy with traditional endoscopy for detecting esophageal varices calculated a sensitivity of 83% and specificity of 85%. Another meta-analysis of 9 studies comparing capsule endoscopy with traditional endoscopy for detecting Barrett esophagus showed a sensitivity and specificity of 77% and 86%, respectively. Because neither the sensitivity nor the specificity of the test approached a high value, the test cannot substitute for traditional endoscopy nor can it be used to triage patients to endoscopy.
COLON CANCER SCREENING
Capsule endoscopy has been investigated as a method of colon cancer screening. The test may detect precancerous polyps or cancerous lesions. Several studies have assessed the accuracy of capsule endoscopy for detection of colonic lesions.

In 2016, Spada et al reported on a systematic review and meta-analysis of the diagnostic accuracy of capsule endoscopy for detecting colorectal polyps with stratified results for first- and second-generation capsules. Across the 14 eligible studies, the indications for endoscopy included colorectal cancer screening (n=1261 [47%]), postpolypectomy surveillance or family history of colorectal cancer (n=636 [24%]), symptoms suggestive of cancer and/or fecal occult blood test positivity (n=619 [23%]), positive imaging tests (n=136 [5%]), or other indication (24 [1%]). Characteristics of the systematic review and its main findings are summarized in Tables 1 and 2, respectively.

<table>
<thead>
<tr>
<th>Table 1. Colon Cancer Screening Systematic Review Characteristics</th>
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<td><strong>Study (Year)</strong></td>
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CCE: colon capsule endoscopy.

<table>
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<tr>
<th>Table 2. Summary of Colon Cancer Screening Results for Capsule Endoscopy (Spada et al)</th>
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<tr>
<td><strong>Analysis</strong></td>
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<tr>
<td>Random-effects model for ≥10 mm polyps</td>
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AUC: area under the curve; CCE: colon capsule endoscopy; CI: confidence interval; DOR: diagnostic odds ratio; NLR: negative likelihood ratio; NR: not reported; PLR: positive likelihood ratio; Sens: sensitivity; Spec: specificity.

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There were no missed cancers (n=11) in the series using second-generation capsule endoscopy (per patient sensitivity, 100%). In series using first-generation capsule endoscopy, 6 of 26 proven cancers were missed on capsule endoscopy (per patient sensitivity, 77%).

Other recent studies by Saito et al (2015) and Morgan et al (2016) have evaluated the diagnostic characteristics of capsule endoscopy, using subsequently performed colonoscopy as the reference standard. In the study by Saito et al, of 66 evaluable patients, per-patient sensitivity for detection of polyps was 94% (95% CI, 88.2% to 99.7%). In the study by Morgan et al, for lesions 10 mm or larger, sensitivity of capsule endoscopy was 100% (95% CI, 56.1% to 100%), with a specificity of 93.0% (95% CI, 79.9% to 98.2%). For lesions 6 mm or larger, sensitivity was 93.3% (95% CI, 66.0% to 99.7%) and the specificity was 80.0% (95% CI, 62.5% to 90.9%).

Section Summary: Colon Cancer Screening
Studies of diagnostic characteristics alone are not sufficient evidence to determine efficacy of capsule endoscopy for colon cancer screening. Because diagnostic performance is worse than standard colonoscopy, capsule endoscopy would need to be performed more frequently than standard colonoscopy to potentially have comparable efficacy. Without direct evidence of efficacy in a clinical trial of colon cancer screening using capsule endoscopy, modeling studies using established mathematical models of colon precursor incidence and progression to cancer could provide estimates of efficacy in preventing colon cancer mortality. Studies of capsule endoscopy in screening populations are necessary to determine the diagnostic characteristics of the test in this setting.

HEREDITARY GI POLYPOSIS SYNDROMES
Persons with familial adenomatous polyposis and Peutz-Jeghers syndrome are genetically at high risk of small bowel polyps and tumors. Mata et al 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). Compared with barium studies using small bowel enteroclysis, capsule endoscopy identified 4 additional patients with small bowel polyps, which were subsequently removed with endoscopic polypectomy. A study by Brown et al in 19 patients showed a greater number of polyps identified with capsule endoscopy than with barium follow-through examinations. Urquhart et al compared capsule endoscopy with MRE in 20 patients with Peutz-Jeghers syndrome. Capsule endoscopy identified more polyps 10 mm or larger (47 polyps) than MRE (14 polyps; p=0.02). However, subsequent balloon enteroscopy in 12 patients showed poor correlation of findings between techniques, with a 100% PPV of finding a polyp on balloon enteroscopy with MRE versus 60% for capsule endoscopy. Although these studies were small, they demonstrated that capsule endoscopy can identify additional lesions compared to other diagnostic methods in persons with disease syndromes at high risk for such lesions.
The lifetime risk of small bowel cancer in Lynch syndrome has been estimated at 5%. Although not extremely high, this risk is greatly increased compared to the general population. There are a few case series of the prevalence of neoplastic lesions in asymptomatic patients in patients with Lynch syndrome. In the study by Saurin et al (2010), 35 asymptomatic patients with Lynch syndrome underwent capsule endoscopy. Small bowel neoplasms were diagnosed in 3 (8.6%) patients (1 adenocarcinoma, 2 adenomas with low-grade dysplasia). In a larger study by Haanstra et al (2015), 200 patients with Lynch syndrome underwent capsule endoscopy. Small bowel neoplasia was detected in the duodenum in 2 patients (1 adenocarcinoma, 1 adenoma). These lesions would have been in the reach of a gastroduodenoscope.

Section Summary: Hereditary GI Polyposis Syndromes
Although these studies show at least a low prevalence of small bowel neoplasms, these data are insufficient to determine whether screening with capsule endoscopy would improve patient outcomes. Further information on the prevalence and natural history of small bowel polyps in Lynch syndrome patients is necessary. At this time, surveillance of the small bowel is not generally recommended as a routine intervention for patients with Lynch syndrome.

PORTAL HYPERTENSIVE ENTEROPATHY
Patients with liver cirrhosis and portal hypertension can develop portal hypertensive enteropathy, which may lead to GI bleeding. Capsule endoscopy has been considered as a diagnostic tool for portal hypertensive enteropathy. A Cochrane systematic review on the use of capsule endoscopy for the diagnosis of esophageal varices was published in 2014. This analysis included 16 studies of adults with cirrhosis. All patients underwent capsule endoscopy followed by esophagogastroduodenoscopy. Most studies were judged at high risk for bias. On pooled analysis, the sensitivity of capsule endoscopy was 84.8% (95% CI, 77.3% to 90.2%) and the specificity was 84.3% (95% CI, 73.1% to 91.4%). A subset analysis of studies that were at low risk for bias reported a sensitivity of 79.7% (95% CI, 73.1% to 85.0%) and a specificity of 86.1% (95% CI, 64.5% to 95.5%). Because neither the sensitivity nor specificity is high for identifying esophageal varices, capsule endoscopy could not be used instead of esophagogastroduodenoscopy nor could it be used to triage patients to esophagogastroduodenoscopy. Based on these diagnostic characteristics, the test does not appear to have clinical utility.

Jeon et al evaluated capsule endoscopy registry data for 45 patients with cirrhosis and portal hypertension. Capsule endoscopy identified angiodysplasias and varices in 55.7% and 38.9% of portal hypertensive enteropathy patients (n=18) versus 7.4% and 0% in patients without portal hypertensive enteropathy (n=27), respectively (p=0.001 in both). Active bleeding did not differ significantly but was found in 16.6% of portal hypertensive enteropathy patients versus 3.7% of patients without portal hypertensive enteropathy. Without a comparison group, this case series cannot be used to determine how alternative methods would perform in identifying important pathology.
Section Summary: Portal Hypertensive Enteropathy
Capsule endoscopy has been used to diagnose portal hypertensive enteropathy. A systematic review of studies of its diagnostic performance for this purpose reported limited sensitivity and specificity.

UNEXPLAINED CHRONIC ABDOMINAL PAIN
Capsule endoscopy has been proposed as a diagnostic tool for unexplained chronic abdominal pain. Xue et al reported on a systematic review of 21 studies (total N=1520 patients) evaluating capsule endoscopy for unexplained chronic abdominal pain. The pooled diagnostic yield was 20.9% (95% CI, 15.9% to 25.9%). The most commonly identified findings were inflammatory lesions (78.3%) and tumors (9.0%). Studies in the review were highly heterogeneous. Limitations in interpreting the findings included retrospective study designs, different durations of abdominal pain, and use of different tests before capsule endoscopy.

In a study not included in the systematic review, Yang et al (2014) reported on a case series evaluating 243 patients with capsule endoscopy for unexplained chronic abdominal pain. The diagnostic yield of capsule endoscopy was 23.0%. Identified findings included 19 (7.8%) patients with CD, 15 (6.2%) with enteritis, 11 (4.5%) with idiopathic intestinal lymphangiectasia, 5 (2.1%) with uncinaria, 5 (2.1%) with abnormal transit time and other findings (e.g., small bowel tumor, ascariasis, anaphylactoid purpura).

Section Summary: Unexplained Chronic Abdominal Pain
While capsule endoscopy may have yielded a diagnosis for unexplained chronic abdominal pain in a fair proportion of these patients, the sequence and chronology of testing and treatment recommended before capsule endoscopy needs to be defined to determine whether capsule endoscopy was necessary to diagnose the condition.

PATENCY CAPSULE
Contraindications to the use of capsule endoscopy include known or suspected obstruction or stricture, Zenker 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. The patency capsule is proposed as a technique to evaluate patients with known or suspected strictures before using the wireless capsule endoscopy system. The capsule could be to select patients for capsule endoscopy instead of assessing clinical risk factors. It needs to be determined whether the change in diagnostic strategy and ultimate treatment improved as a consequence of either being selected or deselected to have a capsule endoscopy.

The use of the patency capsule has some risk itself. Published studies are small and do not provide comparative data on the incremental value of this capsule over standard clinical evaluation. 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 suspected intestinal stricture, 15 of whom had CD. In this study, at 30 hours after ingestion, the patency capsule was detected in 17 (72.3%) patients. In all patients in whom the capsule was blocked in the small intestine, the stenosis had been suspected on 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, because 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 commented that a careful interview eliciting the patient's history and symptoms remains the most useful indicator for suspicion of an intestinal stenosis. In another European study, Spada et al reported on findings for 27 patients, 24 with CD. In this study, 25 (92.6%) patients retrieved the patency capsule in their 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 have shown that patients who had uncomplicated passage of the patency capsule subsequently underwent uncomplicated capsule endoscopy. These patients often had significant findings on capsule endoscopy. However, it is difficult to determine whether the findings of capsule endoscopy in these patients improved their outcomes beyond any alternative testing 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.

Section Summary: Patency Capsule
The overall balance of harm and benefit of using the patency capsule cannot be determined from the existing studies.

SUMMARY OF EVIDENCE
For individuals who have suspected small bowel bleeding (previously referred to as obscure gastrointestinal [GI] bleeding) who receive wireless capsule endoscopy, the evidence includes numerous case series evaluating patients with a nondiagnostic standard workup. Relevant outcomes are test accuracy, test validity, and other test performance measures. The evidence has demonstrated that capsule endoscopy can identify a bleeding source in a substantial number of patients who cannot be diagnosed by other methods, with a low incidence of adverse events. Because there are few other options for diagnosing obscure small bowel bleeding in patients with negative upper and lower endoscopy, this technique will likely improve health outcomes by directing specific treatment when a bleeding source is identified. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have acute upper GI tract bleeding who receive wireless capsule endoscopy, the evidence includes 1 RCT and several cohort studies. Relevant outcomes are test accuracy, test validity, and other test performance measures. The use of capsule endoscopy in the
emergency department setting for suspected upper GI bleeding is based on efficiency (avoiding hospitalization, avoiding immediate endoscopy). Further controlled studies are needed to further assess the impact of capsule endoscopy on health outcomes compared with standard management. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who suspected small bowel Crohn disease or individuals with an established diagnosis of Crohn disease who receive wireless capsule endoscopy, the evidence includes case series. Relevant outcomes are test accuracy, test validity, and other test performance measures. Although the test performance characteristics and diagnostic yields of the capsule for these indications are uncertain, the diagnostic yields are as good as or better than other diagnostic options, and these data are likely to improve health outcomes by identifying some cases of Crohn disease and directing specific treatment. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have ulcerative colitis, suspected celiac disease, esophageal disorders, hereditary polyposis syndromes, colon cancer screening, portal hypertensive enteropathy, or unexplained chronic abdominal pain, the evidence includes case series and diagnostic accuracy studies. Relevant outcomes are test accuracy, test validity, and other test performance measures. For some of these conditions (e.g., esophageal conditions, colon cancer screening), other available modalities are superior to capsule endoscopy. The diagnostic characteristics of capsule endoscopy are not good enough to substitute for other modalities or to triage patients to other modalities. For other conditions (e.g., determining the extent of Crohn disease), direct evidence of improved outcomes or a strong indirect chain of evidence to improved outcomes is lacking. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are scheduled to undergo capsule endoscopy for known or suspected small bowel stricture who receive a patency capsule, the evidence includes case series. Relevant outcomes are test validity and other test performance measures. The available studies have reported that capsule endoscopy following a successful patency capsule test results in high rates of success with low rates of adverse events. The capsule is also associated with adverse events. Because of the lack of comparative data to other diagnostic strategies, it is not possible to determine whether use of the patency capsule improves net health outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

**PRACTICE GUIDELINES AND POSITION STATEMENTS**

**American College of Gastroenterology**

In 2013, the American College of Gastroenterology (ACG) issued guidelines on the diagnosis and management of celiac disease. The guidelines recommended that capsule endoscopy not be used for initial diagnosis, except for patients with positive celiac–specific serology who are
unwilling or unable to undergo upper endoscopy with biopsy (strong recommendation, moderate level of evidence).

Capsule endoscopy should be considered for the evaluation of small bowel mucosa in patients with complicated Crohn disease (CD; strong recommendation, moderate level of evidence).

ACG issued guidelines in 2009 on the management of CD in adults. The guidelines indicated that use of video capsule endoscopy had been assessed in a prospective blinded evaluation and was shown to be superior in its ability to detect small bowel pathology missed on small bowel radiographic studies and computed tomography (CT) radiographic examinations. However, because there is a risk of capsule retention in up to 13% of patients with CD, which could require surgical intervention, capsule endoscopy is considered to be a contraindication in patients with known small bowel strictures. It was recommended that radiographic studies such as CT enterography, small bowel follow-through, or magnetic resonance imaging be done to assess for the presence of unsuspected bowel strictures before capsule endoscopy. A patency capsule may also be considered.

In 2015, ACG issued guidelines on the diagnosis and management of small bowel bleeding (including using “small bowel bleeding” to replace “obscure GI [gastrointestinal] bleeding,” which should be reserved for patients in whom a source of bleeding cannot be identified anywhere in the GI tract). These guidelines made the following statements related to video capsule endoscopy:

- “Video capsule endoscopy (VCE) should be considered as a first-line procedure for SB [small bowel] evaluation after upper and lower GI sources have been excluded, including second-look endoscopy when indicated (strong recommendation, moderate level of evidence).”
- “VCE should be performed before deep enteroscopy to increase diagnostic yield. Initial deep enteroscopy can be considered in cases of massive hemorrhage or when VCE is contraindicated (strong recommendation, high level of evidence).”

American Gastroenterological Association
A 2007 position statement by American Gastroenterological Association indicated the following on obscure GI bleeding and capsule endoscopy:

“Evaluation of the patient with obscure 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 EGD [esophagogastroduodenoscopy] and colonoscopy need comprehensive evaluation, including capsule endoscopy to identify an intestinal bleeding lesion.”
European Crohn’s and Colitis Organisation and Organisation Mondiale d’Endoscopie Digestive

An international consensus panel from 2009 published guidelines on the use of wireless capsule endoscopy for inflammatory bowel disease.13 These guidelines included the following statements about evaluation of CD:

- 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.
- 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 [magnetic resonance] 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 Commission

European guidelines for quality assurance in colorectal cancer screening and diagnosis, published in 2012, indicated capsule endoscopy is not recommended for screening for colorectal cancer.46 These guidelines noted that studies have shown capsule endoscopy is inferior to colonoscopy in diagnostic performance.

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS

The U.S. Preventive Services Task Force published its most recent recommendations for colorectal cancer (CRC) screening in June 2016. CRC screening is recommended starting at age 50 years and continuing until age 75 years (A recommendation). Studies evaluating capsule endoscopy were not included in the evidence reviews in this report.

MEDICARE NATIONAL COVERAGE

There is no national coverage determination (NCD).

ONGOING AND UNPUBLISHED CLINICAL TRIALS

Some currently unpublished trials that might influence this review are listed in Table 3.
V. DEFINITIONS

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

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.
VII. DISCLAIMER

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

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.

Investigational; therefore not covered:

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Covered when medically necessary:

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<thead>
<tr>
<th>ICD-10-CM Diagnosis Codes</th>
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<tr>
<td>D50.0</td>
<td>Iron deficiency anemia secondary to blood loss (chronic)</td>
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<tr>
<td>D50.8</td>
<td>Other iron deficiency anemias</td>
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<td>K50.00</td>
<td>Crohn's disease of small intestine without complications</td>
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<tr>
<td>K50.011</td>
<td>Crohn's disease of small intestine with rectal bleeding</td>
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<tr>
<td>K50.012</td>
<td>Crohn's disease of small intestine with intestinal obstruction</td>
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<td>K50.013</td>
<td>Crohn's disease of small intestine with fistula</td>
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<td>K50.014</td>
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<tr>
<td>K50.018</td>
<td>Crohn's disease of small intestine with other complication</td>
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WIRELESS CAPSULE ENDOSCOPY TO DIAGNOSE DISORDERS OF THE SMALL BOWEL, ESOPHAGUS, AND COLON [FORMERLY 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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<th>ICD-10-CM Diagnosis Codes</th>
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<td>Q85.8</td>
<td>Other phakomatoses, not elsewhere classified</td>
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<td>Z83.71</td>
<td>Family history of colonic polyps</td>
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*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

IX. REFERENCES


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**MEDICAL POLICY**

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**Other Sources**


**X. POLICY HISTORY**

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<tr>
<td></td>
<td>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.</td>
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# MEDICAL POLICY

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**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 revision. 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

**CAC 3/24/15** Minor revision. Added portal hypertensive enteropathy and unexplained chronic abdominal pain to the investigational policy statement. Also added a new medically necessary policy statement in patients with established Crohn disease for unexpected change(s) in course of disease or response to treatment suggesting the initial diagnosis may be incorrect and re-examination may be indicated. Background, references, and rationale updated. Coding reviewed.

**11/2/15** Administrative change. LCD number changed from L34342 to L35089 due to Novitas update to ICD-10.

**CAC 3/29/16** Consensus review. No change to policy statements. Regulatory Status, Rationale and References updated. Coding reviewed.

**Admin Update 1/1/17** Variation reformatting.

**CAC 3/28/17** Consensus review. Title changed to “Wireless Capsule Endoscopy to Diagnose Disorders of the Small Bowel, Esophagus, and Colon.” Verbiage change to the 3rd bullet of the 1st policy statement. “Obscure gastrointestinal bleeding” changed to “Suspected small bowel bleeding.” No change to the intent of the policy statement. Description/Background, Regulatory Status, Rationale and Reference sections updated. Coding reviewed.

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