Wireless Capsule Endoscopy to Diagnose Disorders of the Small Bowel, Esophagus, and Colon

Policy # 00137
Original Effective Date: 01/27/2003
Current Effective Date: 12/20/2017

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider wireless capsule endoscopy (CE) of the small bowel to be **eligible for coverage.**

Patient Selection Criteria
Coverage eligibility for wireless capsule endoscopy (CE) of the small bowel will be considered when any of the following criteria are met:

- Initial diagnosis in patients with suspected Crohn disease (CD) without evidence of disease on conventional diagnostic tests such as small-bowel follow-through (SBFT) and upper and lower endoscopy; or
- In patients with an established diagnosis of Crohn disease (CD), 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; or
- Suspected small bowel bleeding, as evidenced by prior inconclusive upper and lower gastrointestinal (GI) endoscopic studies performed during the current episode of illness or;
- For surveillance of the small bowel in patients with hereditary gastrointestinal (GI) polyposis syndromes, including familial adenomatous polyposis and Peutz-Jeghers syndrome.

When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

The use of wireless capsule endoscopy (CE) of the small bowel when patient selection criteria are not met is considered to be **investigational.***

Based on review of available data, the Company considers other indications of wireless capsule endoscopy (CE), including but not limited to the following, to be **investigational*:**

- Evaluation of the extent of involvement of known Crohn disease (CD) or ulcerative colitis; or
- Evaluation of the esophagus, in patients with gastroesophageal reflux (GERD) or other esophageal pathologies; or

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.

- Evaluation of other gastrointestinal (GI) diseases and conditions not presenting with gastrointestinal (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; or
- Evaluation of the colon, including but not limited to, detection of colonic polyps or colon cancer
- Initial evaluation of patients with acute upper gastrointestinal (GI) bleeding

Based on review of available data, the Company considers the patency capsule, including use to evaluate patency of the gastrointestinal (GI) tract before wireless capsule endoscopy (CE), to be **investigational.***

Policy Guidelines

Obscure gastrointestinal 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.

Background/Overview

WIRELESS CAPSULE ENDOSCOPY

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 localizing antennae sensors that can roughly gage where the image was taken over the abdomen. Images are then downloaded onto a workstation for viewing and processing.

Applications

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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In August 2001, the PillCam Given Diagnostic Imaging System (Given Imaging) was cleared for marketing by the U.S. 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." In 2003, after a supplemental 510(k) premarket notification, the labeled indications were modified by removing the “adjunctive” use qualification: “the Given

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.

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 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 (PillCam™‡ ESO2 Capsule) was cleared by FDA in June 2007. 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 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 cleared by FDA through the 510(k) process. This system is an accessory to the PillCam video capsule and, according to FDA, is intended to verify adequate patency of the GI tract before administration of the PillCam into patients with known or suspected strictures. This capsule is of similar size to the endoscopy capsule but 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 cleared for marketing by FDA through a de novo 510(k) classification. 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 CE.
FDA product code: NEZ.

Centers for Medicare and Medicaid Services (CMS)
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Rationale/Source

Assessment of diagnostic technology typically focuses on 3 categories of evidence: (1) technical reliability (test-retest reliability or interrater reliability); (2) clinical validity (sensitivity, specificity, PPVs and NPVs) in relevant populations of patients; and (3) clinical utility (i.e., demonstration that the diagnostic information can be used to improve patient outcomes).

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.

PATIENTS WITH SUSPECTED GASTROINTESTINAL CONDITIONS

Clinical Context and Test Purpose
The question addressed in this portion of the evidence review is whether there is sufficient evidence that wireless CE leads to improved diagnosis and better health outcomes in patients with suspected GI conditions compared with standard approaches.

The following PICOTS were used to select literature to inform this review.

Patients
The relevant population of interest is patients with suspected GI conditions.

Interventions
The intervention of interest is wireless CE.

Comparators
The comparator of interest is a standard workup without wireless CE and, with or without direct endoscopic procedures or specialized GI imaging.

Outcomes
The outcomes of interest for diagnostic accuracy include test accuracy and test validity (ie, sensitivity, specificity). The primary outcomes of interest for the clinical utility are symptoms and disease status that would change due to patient management decisions following wireless CE.

Timing
Wireless CE would be performed after an initial clinical examination.

Setting
The test would be performed in the outpatient specialty setting (gastroenterology).
Technical Reliability
For CE, in general, very little evidence exists for most indications regarding technical reliability, which in this case would evaluate concordance between different examinations in the same person and concordance between different examiners.

Clinical Validity and Clinical Utility

Suspected Small Bowel Bleeding
Suspected small bowel bleeding, previously referred to as obscure 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. Causes of obscure bleeding in the small intestine include angiodysplasia (70%-

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.

80%), tumor (5%-10%), and other causes (10%-25%), including those related to medication, infections (tuberculosis), CD, Meckel diverticulum, Zollinger-Ellison syndrome, vasculitis, radiation enteritis, jejunal diverticula, and chronic mesenteric ischemia. 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.

A 2007 position statement by the American Gastroenterological Association indicated that CE 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 American Gastroenterological Association 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 CE are based on several lines of evidence. CE appears to have a higher sensitivity of locating bleeding lesions than other diagnostic techniques when diagnostic yields are compared. The technical review summarized 10 studies comparing CE with push enteroscopy in the same patients. CE located a source of bleeding in 25% to 55% more patients than push enteroscopy. One study by Hartmann et al (2005) compared the findings of CE with what might be considered the criterion standard for localizing bleeding, intraoperative endoscopy. CE 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 (2004) in which long-term follow-up was used as the reference standard, CE 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 CE 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 CE 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 CE or mesenteric angiography in a 1:1 ratio after nondiagnostic endoscopy and colonoscopy. CE had a significantly higher diagnostic yield (53.3%) than angiography (20.0%; p=0.016). The cumulative risk of rebleeding in the angiography and CE 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 the use of CE in the evaluation of patients with suspected small bowel bleeding. These studies have consistently reported that a substantial proportion of

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.

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. CE appears to locate the source of bleeding at least as well as other diagnostic methods and direct treatment to the source of bleeding.

Suspected 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, CE 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 CE.

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

In 2017, Choi et al reported on a meta-analysis of studies on the effectiveness of CE compared with other diagnostic modalities in patients with small bowel CD. Reviewers selected 24 studies, which included patients with both suspected and established CD, and compared CE with a range of alternative diagnostic modalities, including small bowel follow-through, 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 CE (66%) was higher than that of small bowel follow-through (21.3%; weighted incremental yield [IYw], 0.44; 95% CI, 0.29 to 0.59, I^2=30%). The diagnostic yield of CE 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; I^2=68%) or that of MRE (85.7% for endoscopy vs 100% for MRE; IYw = -0.16; 95% CI, -0.63 to 0.32; I^2=44%). The reference standards varied for the included studies, so quantitative data were not synthesized for diagnostic accuracy. In the pooled analysis, in patients with suspected CD, the sensitivity and specificity of CE ranged from 89.6% to 92.0% and 100%, respectively.

Section Summary: Suspected CD

For patients with suspected Crohn of the small bowel who cannot be diagnosed by other modalities, CE can confirm the diagnosis in a substantial number of patients. The diagnostic yield in the available studies varied but is likely superior to alternative tests such as CT or magnetic resonance imaging scanning.

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.

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. CE has been evaluated as an alternative method of diagnosing celiac disease, assessing the extent of disease, and in the evaluation of celiac disease unresponsive to treatment.

A meta-analysis by El-Matary et al (2009) compared the diagnostic performance of CE with a reference standard of duodenal biopsy. The pooled analysis of 3 studies showed a sensitivity of 83% and a specificity of 98%. Another meta-analysis by Rokkas and Niv (2012) lso compared the diagnostic performance of CE with biopsy, summarizing 6 studies (total N=166 subjects). The overall pooled sensitivity was 89%, and the specificity was 95%. CE 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 CE for celiac disease, it does not appear to be an adequate alternative method of making an initial diagnosis.

The role of CE in nonresponsive celiac disease has been evaluated in only a few studies. One case series by Culliford et al (2005) evaluated 47 patients with complicated celiac disease and found unexpected additional findings in 60% of patients, most of which were ulcerations. However, the definition of “complicated” celiac disease included other factors such as evidence of blood loss, itself an indication for CE. 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 the confirmed celiac disease who were unresponsive to standard treatment were evaluated with CE. 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 CE 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, CE 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 CE to ascertain a final diagnosis.

Section Summary: Suspected Celiac Disease

In cases where the diagnosis of celiac disease is equivocal, CE can sometimes reveal morphologic changes in the small bowel consistent with celiac disease. However, it is unlikely that the appearance of small bowel on CE is itself sufficient to make a definitive diagnosis of celiac disease. Small bowel biopsy, celiac serologies, and human leukocyte antigen 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 CE have shown some yield of actionable diagnoses that have the potential to improve patient outcomes. Larger studies are needed to better determine the diagnostic yield of CE in these patients.

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.

Unexplained Chronic Abdominal Pain
CE has been proposed as a diagnostic tool for unexplained chronic abdominal pain. Xue et al (2015) reported on a systematic review of 21 studies (total N=1520 patients) evaluating CE 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 CE.

In a study not included in the systematic review, Yang et al (2014) reported on a case series evaluating 243 patients with CE for unexplained chronic abdominal pain. The diagnostic yield of CE 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 uncinariasis, 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 CE 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 CE needs to be defined to determine whether CE was necessary to diagnose the condition.

PATIENTS WITH ESTABLISHED GI CONDITIONS

Clinical Context and Test Purpose
The question addressed in this portion of the evidence review is whether there is sufficient evidence that wireless CE leads to improved diagnosis and better health outcomes in patients with established GI conditions compared with standard approaches to patient management.

The following PICOTS were used to select literature to inform this review.

Patients
The relevant population of interest is patients with established GI conditions.

Interventions
The intervention of interest is wireless CE.

Comparators
The comparator of interest is a standard workup without wireless CE and, with or without direct endoscopic procedures or specialized GI imaging.

Outcomes
The outcomes of interest for diagnostic accuracy include test accuracy and test validity (i.e., sensitivity, specificity). The primary outcomes of interest for the clinical utility are symptoms and disease status that would change due to patient management decisions following wireless CE.

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.

Timing
Wireless CE would be performed to further evaluate and/or monitor patients after a confirmed diagnosis.

Setting
The test would be performed in the outpatient specialty setting (gastroenterology).

Technical Reliability
For CE, in general, very little evidence exists for most indications regarding technical reliability, which in this case would evaluate concordance between different examinations in the same person and concordance between different examiners.

Clinical Validity and Clinical Utility

Established Diagnosis of CD
In 2017, Kopylov et al published a systematic review of studies on CE in the evaluation of CD. Reviewers included prospective studies comparing CE with MRE and/or small bowel contrast ultrasound in patients who had suspected and/or established CD. In pooled analyses of the 11 studies that included patients with established CD, the diagnostic yield of CE was similar to that of MRE (odds ratio [OR], 1.88; 95% CI, 0.53 to 1.48; I^2=48%) and to ultrasound (OR=0.57; 95% CI, 0.27 to 1.20; I^2=67%).

An international consensus statement indicated that radiographic imaging should take precedence over CE because of the capability to detect obstructive strictures as well as extraluminal and transmural disease. The consensus statement identified some studies in which CE 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 the therapeutic intervention. A 2013 European consensus statement indicated MRE or CT enterography is usually preferred to CE in patients with known CD patients. The 2013 consensus also indicated CE 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.

An international consensus statement indicated that radiographic imaging should take precedence over CE because of the capability to detect obstructive strictures as well as extraluminal and transmural disease. The consensus statement identified some studies in which CE 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 the therapeutic intervention. A 2013 European consensus statement indicated MRE or CT enterography is usually preferred to CE in patients with known CD patients. The 2013 consensus also indicated CE 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.

Section Summary: Established Diagnosis of CD
A 2017 systematic review of 11 studies in patients with established CD found a similar diagnostic yield with CE compared with radiography. International consensus statements state that radiographic imaging has

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.

advantages (e.g., ability to detect obstructive strictures) and that CE should be limited to certain situations (e.g., unexplained symptoms or other inconclusive investigations).

Ulcerative Colitis
Ulcerative colitis is an inflammatory disease of the large intestine. It is usually diagnosed by colonoscopy and biopsy. CE 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 (2012) evaluated 100 patients with suspected or known ulcerative colitis using CE and colonoscopy performed on the same day. They reported CE 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 and negative predictive values (PPVs and NPVs) 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 CE and colonoscopy to assess disease activity. Results were expressed with κ coefficients. There was a good correlation between colon CE and colonoscopy in disease severity (κ=0.79; 95% CI, 0.62 to 0.96) and extent of inflammation (κ=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 CE and colonoscopy to assess disease activity. The reference standard for disease activity was a Matts score greater than 6 as judged by colonoscopy. The sensitivity of CE was 96% (95% CI, 79% to 99%) and specificity was 100% (95% CI, 61% to 100%). The PPVs and NPVs of second-generation colon CE were 100% (95% CI, 85% to 100%) and 85% (95% CI, 49% to 97%), respectively. Although the 2 methods had a 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
Several diagnostic accuracy studies have compared CE and colonoscopy to assess disease activity in patients with ulcerative colitis. Two of 3 studies were small (i.e., <50 patients) and thus data on diagnostic accuracy are limited. Because there are insufficient data on diagnostic accuracy, a chain of evidence on clinical utility cannot be constructed.

Esophageal Disorders
CE can 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 CE. CE could triage patients for endoscopy if either the sensitivity or the specificity is high. Traditional endoscopy could then be performed on the appropriate group

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.

to determine false positives or false negatives, having spared the group with a high PPV an endoscopy procedure.

Most studies have shown that CE has inferior diagnostic characteristics compared with traditional upper endoscopy for a variety of esophageal conditions. A 2011 meta-analysis of 9 studies comparing CE with traditional endoscopy for detecting esophageal varices calculated a sensitivity of 83% and specificity of 85%. Another meta-analysis (2009) of 9 studies comparing CE 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.

Section Summary: Esophageal Disorders
Other available modalities are superior to CE. The diagnostic characteristics of CE are inadequate to substitute for other modalities or to triage patients to other modalities.

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 (2005) studied the role of CE 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, CE identified 4 additional patients with small bowel polyps, which were subsequently removed with endoscopic polypectomy. A study by Brown et al (2006) in 19 patients showed a greater number of polyps identified with CE than with barium follow-through examinations. Urquhart et al (2014) compared CE with MRE in 20 patients with Peutz-Jeghers syndrome. CE identified more polyps 10 mm or larger (47 polyps) than MRE (14 polyps; p=0.02). However, subsequent balloon enteroscopy in 12 patients showed a poor correlation of findings between techniques, with a 100% PPV of finding a polyp on balloon enteroscopy with MRE vs 60% for CE. Although these studies were small, they demonstrated that CE can identify additional lesions compared with 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 with 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 colon CE. 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 CE. 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 showed at least a low prevalence of small bowel neoplasms, these data are insufficient to determine whether evaluation with CE would improve patient outcomes. Further information on the prevalence and natural history of small bowel polyps in Lynch syndrome patients is necessary. At

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.

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. CE has been considered as a diagnostic tool for portal hypertensive enteropathy. Several systematic reviews have been published.

A Cochrane systematic review on the use of CE for the diagnosis of esophageal varices was published in 2014. This analysis included 16 studies of adults with cirrhosis. All patients underwent CE followed by esophagogastroduodenoscopy. Most studies were judged at high risk for bias. On pooled analysis, the sensitivity of CE 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%).

In 2017, McCarty et al included 17 studies on wireless CE for identifying esophageal varices in patients with portal hypertension and had findings similar to the Cochrane review. Studies used either the first- or second-generation PillCam capsule. The investigators assessed the quality of individual studies and found that 8 studies were at high risk of bias. However, there was a low risk of bias in most studies in terms of whether an appropriate reference standard had been used. In a pooled analysis, the sensitivity and specificity of CE for diagnosing esophageal varices were 83% (95% CI, 76% to 89%) and 85% (95% CI, 75% to 91%), respectively.

Section Summary: Portal Hypertensive Enteropathy
CE has been used to diagnose portal hypertensive enteropathy. Systematic reviews of studies of its diagnostic performance for this purpose reported limited sensitivity and specificity. Because neither the sensitivity nor the specificity was high for identifying esophageal varices, CE 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.

ACUTE UPPER GI TRACT BLEEDING

Clinical Context and Test Purpose
The question addressed in this portion of the evidence review is whether there is sufficient evidence that wireless CE leads to improved diagnosis and better health outcomes in patients with acute upper GI tract bleeding compared with standard approaches.

The following PICOTS were used to select literature to inform this review.

Patients
The relevant population of interest is patients with acute GI tract bleeding.

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.

Interventions
The intervention of interest is wireless CE.

Comparators
The comparator of interest is a standard workup of acute bleeding without wireless CE and, with or without direct endoscopic procedures or specialized GI imaging.

Outcomes
The outcomes of interest for diagnostic accuracy include test accuracy and test validity (i.e., sensitivity, specificity). The primary outcomes of interest for clinical utility are symptoms and disease status that would change due to patient management decisions following wireless CE. Other outcomes of interest for clinical utility are avoidance of hospitalizations and resource utilization (e.g., need for additional testing or procedures).

Timing
Wireless CE would be performed as soon as possible after acute bleeding is identified.

Setting
The test would be performed in in an urgent care or emergency setting.

Technical Reliability
For CE, in general, very little evidence exists for most indications regarding technical reliability, which in this case would evaluate concordance between different examinations in the same person and concordance between different examiners.

Clinical Validity and Clinical Utility
In 2016, Sung et al reported on a prospective randomized controlled trial to evaluate the use of CE in the emergency department for patients with suspected upper GI bleeding. CE was used to determine whether patients would be admitted to the hospital or sent home, vs 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 the use of the capsule endoscope. Seventy-one patients were randomized to CE in the emergency department (n=37), followed by monitoring for upper GI bleeding, or standard care (n=34), which included mandatory hospital admission. Seven CE 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 CE 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 CE before upper endoscopy for acute GI bleeding, to triage and/or risk-stratify patients in the emergency department or hospital. These studies reported that CE provides useful information, such as identifying gross bleeding and inflammatory lesions in a substantial proportion of patients and in stratifying patients into

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.

high- or low-risk categories. However, the yield of CE 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 CE 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 assess further the impact of CE on health outcomes compared with standard management. Patients should be followed to their ultimate diagnosis to determine whether the use of CE vs other triage strategies or immediate endoscopy results in lower health care resource utilization.

COLON CANCER SCREENING

Clinical Context and Test Purpose
The question addressed in this portion of the evidence review is whether there is sufficient evidence that wireless CE leads to improved diagnosis and better health outcomes in patients who are being screened for colon cancer compared with other screening modalities.

The following PICOTS were used to select literature to inform this review.

Patients
The relevant population of interest is patients who are undergoing colon cancer screening.

Interventions
The intervention of interest is wireless CE.

Comparators
The comparator of interest is a standard workup without wireless CE.

Outcomes
The outcomes of interest for diagnostic accuracy include test accuracy and test validity (ie, sensitivity, specificity). The primary outcomes of interest for clinical utility are overall mortality and disease-specific mortality from colon cancer.

Timing
Wireless CE would be performed after an initial clinical examination.

Setting
The test would be performed in the outpatient specialty setting (gastroenterology).

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.

Technical Reliability
For CE, in general, very little evidence exists for most indications regarding technical reliability, which in this case would evaluate concordance between different examinations in the same person and concordance between different examiners.

Clinical Validity and Clinical Utility
Several studies have assessed the accuracy of CE for detection of colonic lesions. In 2016, Spada et al reported on a systematic review and meta-analysis of the diagnostic accuracy of CE 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 1. Colon Cancer Screening Systematic Review Characteristics

Study (Year)	Dates	Trials	N (Range)	Design	Outcome
Spada et al (2016)	2006-2015	14	2681 (40-884)	Diagnostic accuracy studies	Per-patient sensitivity of CCE for different categories of polyp size and for cancer

CCE: colon capsule endoscopy.

Table 2. Summary of Colon Cancer Screening Results for Capsule Endoscopy (Spada et al)

Analysis	Trials	N	Outcomes	Effect Size	95% CI	I^2, %
Random-effects model for ≥ 10 mm polyps	10	NR	Diagnostic accuracy for ≥10 mm polyps	Sens=80.0% Spec=96.2% PLR=18.6 NLR=0.22 DOR=90.4 AUC=0.94	66% to 90.3% 94.0% to 97.6% 12.0 to 28.2 0.13 to 0.34 44 to 163 0.88 to 1.00	53.4 31.3
Random- effects model for ≥6 mm polyps	7	NR	Diagnostic accuracy for ≥6 mm polyps using 1st-generation CCE	Sens=58% Spec=85.7% PLR=3.7 NLR=0.51 DOR=7.4	44% to 70% 80.2% to 90.0%	65
Random-effects model for ≥6 mm polyps	6	NR	Diagnostic accuracy for ≥6 mm polyps using 2nd-generation CCE	Sens=86% Spec=88.1% PLR=7.9 NLR=0.16 DOR=50.5	82% to 89% 74.2% to 95.0% 3.7 to 16.1 0.12 to 0.21 20.3 to 107.0	0
Random- effects model for ≥ 10 mm polyps	3	NR	Diagnostic accuracy for ≥6 mm polyps using 1st-generation CCE	Sens=54% Spec=97.4% PLR=NR NLR=NR	29% to 77% 96.0% to 98.3%	76.2 0

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.

Analysis	Trials	N	Outcomes	Effect Size	95% CI	I^2, %
				DOR=NR		
Random- effects model for ≥10 mm polyps	6	NR	Diagnostic accuracy for ≥6 mm polyps using 2nd-generation CCE	Sens=8876% Spec=95.3% PLR=NR NLR=NR DOR=NR	81% to 91% 91.5% to 97.5%	0 67

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.

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

Other recent studies by Saito et al (2015), Morgan et al (2016), and Parodi (2017) have evaluated the diagnostic characteristics of CE, using subsequently performed colonoscopy as the reference standard.[36-38] 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 CE 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%). Parodi et al included 177 first-degree relatives of individuals with colorectal cancer and found, for lesions 6 mm or larger, a sensitivity of 91% (95% CI, 81% to 96%) and a specificity of 88% (95% CI, 81% to 93%).

Section Summary: Colon Cancer Screening
Studies of diagnostic characteristics alone are insufficient evidence to determine the efficacy of CE for colon cancer screening. Because diagnostic performance is worse than standard colonoscopy, CE would need to be performed more frequently than standard colonoscopy to have comparable efficacy potentially. Without direct evidence of efficacy in a clinical trial of colon cancer screening using CE, 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 CE in screening populations are necessary to determine the diagnostic characteristics of the test in this setting.

BOWEL STRICTURE
Contraindications to the use of CE 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 CE system. The capsule could be to select patients for CE 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 CE.

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.

Clinical Context and Test Purpose
The question addressed in this portion of the evidence review is whether there is sufficient evidence that a patency capsule before wireless CE leads to improved diagnosis and better health outcomes in patients with suspected GI conditions compared with no patency capsule.

The following PICOTS were used to select literature to inform this review.

Patients
The relevant population of interest is patients who are scheduled to undergo CE for known or suspected small bowel stricture

Interventions
The intervention of interest is a patency capsule before wireless CE.

Comparators
The comparators of interest are CE without patency capsule or a standard workup without CE.

Outcomes
The outcomes of interest for diagnostic accuracy include test accuracy and test validity (i.e., sensitivity, specificity). The primary outcomes of interest for clinical utility are symptoms and disease status that would change due to patient management decisions following patency capsule use. Another outcome of interest is treatment-related morbidity because there is risk associated with the use of the patency capsule.

Timing
Patency capsules would be performed before wireless CE; exact timing depends on the specific indication being evaluated.

Setting
The test would be performed in the outpatient specialty setting (gastroenterology).

Technical Reliability
For patency capsules, there is a lack of evidence regarding technical reliability, which in this case would evaluate concordance between different examinations in the same person and concordance between different examiners.

Clinical Validity and Clinical Utility
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 (2005) 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

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.

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 CE. In 3 patients, the patency capsule induced a symptomatic intestinal occlusion, which resolved spontaneously in one and required emergency surgery in two. 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 (2007) 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, four of whom excreted a nonintact capsule, and hospitalization was required in 1 patient due to the occlusive syndrome.

Several studies have shown that patients who had uncomplicated passage of the patency capsule subsequently underwent uncomplicated CE. These patients often had significant findings on CE. However, it is difficult to determine whether the findings of CE in these patients improved their outcomes beyond any alternative testing regimen that could have been done. In one of these studies, 3 of 106 patients had severe adverse events, including 1 patient who required surgery.

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

SUMMARY OF EVIDENCE
Patients With Suspected GI Disorders
For individuals who have suspected small bowel bleeding (previously referred to as obscure GI bleeding) who receive wireless CE, the evidence includes numerous case series evaluating patients with a nondiagnostic standard workup. Relevant outcomes are test accuracy and validity, other test performance measures, symptoms, and change in disease status. The evidence has demonstrated that CE 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 suspected small bowel CD who receive wireless CE, the evidence includes case series. Relevant outcomes are test accuracy and validity, other test performance measures, symptoms, and change in disease status. 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 CD and directing specific treatment. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.

For individuals who have suspected celiac disease who receive wireless CE, the evidence includes case series and diagnostic accuracy studies. Relevant outcomes are test accuracy and test validity, other test performance measures, symptoms, and change in disease status. The diagnostic characteristics of CE are inadequate enough to substitute for other modalities or to triage patients to other modalities. For other conditions (e.g., determining the extent of CD), 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 have unexplained chronic abdominal pain who receive wireless CE, the evidence includes case series and diagnostic accuracy studies. Relevant outcomes are test accuracy and validity, other test performance measures, symptoms, and change in disease status. The diagnostic characteristics of CE are inadequate to substitute for other modalities or to triage patients to other modalities. For other conditions (e.g., determining the extent of CD), direct evidence of improved outcomes or a strong chain of evidence to improved outcomes is lacking. The evidence is insufficient to determine the effects of the technology on health outcomes.

Patients With Confirmed GI Disorders
For individuals who have an established diagnosis of CD who receive wireless CE, the evidence includes diagnostic accuracy studies and a systematic review. Relevant outcomes are test accuracy and validity, other test performance measures, symptoms, and change in disease status. A 2017 systematic review of 11 studies in patients with established CD found a similar diagnostic yield with CE compared with radiography. Because there is evidence that the diagnostic yields are as good as or better than other diagnostic options, there is indirect evidence that CE is likely to improve health outcomes by identifying some cases of CD 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 who receive wireless CE, the evidence includes case series and diagnostic accuracy studies. Relevant outcomes are test accuracy and validity, other test performance measures, symptoms, and change in disease status. Several diagnostic accuracy studies have compared CE with colonoscopy to assess disease activity in patients with ulcerative colitis. Two of 3 studies were small (i.e., <50 patients) and thus data on diagnostic accuracy are limited. Direct evidence of improved outcomes or a strong 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 have esophageal disorders who receive wireless CE, the evidence includes case series and diagnostic accuracy studies. Relevant outcomes are test accuracy and validity, other test performance measures, symptoms, and change in disease status. Other available modalities are superior to CE. The diagnostic characteristics of CE are inadequate to substitute for other modalities or to triage patients to other modalities. The evidence is insufficient to determine the effects of the technology on health outcomes.
For individuals who have hereditary polyposis syndromes who receive wireless CE, the evidence includes case series and diagnostic accuracy studies. Relevant outcomes are test accuracy and validity, other test performance measures, symptoms, and change in disease status. The data are insufficient to determine

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.

whether evaluation with CE would improve patient outcomes. Further information on the prevalence and natural history of small bowel polyps in Lynch syndrome patients is necessary. At present, surveillance of the small bowel is not generally recommended as a routine intervention for patients with Lynch syndrome. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have portal hypertensive enteropathy who receive wireless CE, the evidence includes case series and diagnostic accuracy studies. Relevant outcomes are test accuracy and validity, and other test performance measures, symptoms, and change in disease status. Systematic reviews of studies of its diagnostic performance for this purpose reported limited sensitivity and specificity. Due to insufficient data on diagnostic accuracy, a chain of evidence on clinical utility cannot be constructed. The evidence is insufficient to determine the effects of the technology on health outcomes.

Acute Upper GI Bleeding
For individuals who have acute upper GI tract bleeding who receive wireless CE, the evidence includes a randomized controlled trial and several cohort studies. Relevant outcomes are test accuracy and validity, and other test performance measures, symptoms, change in disease status, and resource utilization. The use of CE 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 assess further the impact of CE on health outcomes compared with standard management. The evidence is insufficient to determine the effects of the technology on health outcomes.

Colon Cancer Screening
For individuals who are screened for colon cancer who receive wireless CE, the evidence includes diagnostic accuracy studies and systematic reviews. Relevant outcomes are overall survival, disease-specific survival, test accuracy and validity, and other test performance measures. Studies of CE in screening populations are necessary to determine the diagnostic characteristics of the test in this setting. Studies of diagnostic characteristics alone are insufficient evidence to determine the efficacy of CE for colon cancer screening. Because diagnostic performance is worse than standard colonoscopy, CE would need to be performed more frequently than standard colonoscopy to have comparable efficacy potentially. Without direct evidence of efficacy in a clinical trial of colon cancer screening using CE, modeling studies using established mathematical models of colon precursor incidence and progression to cancer could provide estimates of efficacy in preventing colon cancer mortality. The evidence is insufficient to determine the effects of the technology on health outcomes.

Patency Capsule for Patients with Bowel Stricture
For individuals who are scheduled to undergo CE for known or suspected small bowel stricture who receive a patency capsule, the evidence includes case series. Relevant outcomes are test accuracy and validity, symptoms, change in disease status, and treatment-related morbidity, The available studies have reported that CE 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 the use of the patency capsule

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.

improves the net health outcome. The evidence is insufficient to determine the effects of the technology on health outcomes.

References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Wireless Capsule Endoscopy to Diagnose Disorders of the Small Bowel, Esophagus, and Colon", 6.01.33, 11:2017.
2. Raju GS, Gerson L, Das A, et al. American Gastroenterological Association (AGA) Institute medical position statement on obscure gastrointestinal bleeding. *Gastroenterology.* Nov 2007;133(5):1694-1696. PMID 17983811
3. Zuckerman GR, Prakash C, Askin MP, et al. AGA technical review on the evaluation and management of occult and obscure gastrointestinal bleeding. *Gastroenterology.* Jan 2000;118(1):201-221. PMID 10611170
4. Lewis BS. Small intestinal bleeding. *Gastroenterol Clin North Am.* Mar 2000;29(1):67-95, vi. PMID 10752018
5. Raju GS, Gerson L, Das A, et al. American Gastroenterological Association (AGA) Institute technical review on obscure gastrointestinal bleeding. *Gastroenterology.* Nov 2007;133(5):1697-1717. PMID 17983812
6. Hartmann D, Schmidt H, Bolz G, et al. A prospective two-center study comparing wireless capsule endoscopy with intraoperative enteroscopy in patients with obscure GI bleeding. *Gastrointest Endosc.* Jun 2005;61(7):826-832. PMID 15933683
7. Pennazio M, Santucci R, Rondonotti E, et al. Outcome of patients with obscure gastrointestinal bleeding after capsule endoscopy: report of 100 consecutive cases. *Gastroenterology.* Mar 2004;126(3):643-653. PMID 14988816
8. Koulaouzidis A, Rondonotti E, Giannakou A, et al. Diagnostic yield of small-bowel capsule endoscopy in patients with iron-deficiency anemia: a systematic review. *Gastrointest Endosc.* Nov 2012;76(5):983-992. PMID 23078923
9. Leung WK, Ho SS, Suen BY, et al. Capsule endoscopy or angiography in patients with acute overt obscure gastrointestinal bleeding: a prospective randomized study with long-term follow-up. *Am J Gastroenterol.* Sep 2012;107(9):1370-1376. PMID 22825363
10. Bourreille A, Ignjatovic A, Aabakken L, et al. Role of small-bowel endoscopy in the management of patients with inflammatory bowel disease: an international OMED-ECCO consensus. *Endoscopy.* Jul 2009;41(7):618-637. PMID 19588292
11. Choi M, Lim S, Choi MG, et al. Effectiveness of capsule endoscopy compared with other diagnostic modalities in patients with small bowel Crohn's disease: a meta-analysis. *Gut Liver.* Jan 15 2017;11(1):62-72. PMID 27728963
12. El-Matary W, Huynh H, Vandermeer B. Diagnostic characteristics of given video capsule endoscopy in diagnosis of celiac disease: a meta-analysis. *J Laparoendosc Adv Surg Tech A.* Dec 2009;19(6):815-820. PMID 19405806
13. Rokkas T, Niv Y. The role of video capsule endoscopy in the diagnosis of celiac disease: a meta-analysis. *Eur J Gastroenterol Hepatol.* Mar 2012;24(3):303-308. PMID 22266837
14. Culliford A, Daly J, Diamond B, et al. The value of wireless capsule endoscopy in patients with complicated celiac disease. *Gastrointest Endosc.* Jul 2005;62(1):55-61. PMID 15990820
15. Kurien M, Evans KE, Aziz I, et al. Capsule endoscopy in adult celiac disease: a potential role in equivocal cases of celiac disease? *Gastrointest Endosc.* Feb 2013;77(2):227-232. PMID 23200728
16. Xue M, Chen X, Shi L, et al. Small-bowel capsule endoscopy in patients with unexplained chronic abdominal pain: a systematic review. *Gastrointest Endosc.* Jan 2015;81(1):186-193. PMID 25012561
17. Yang L, Chen Y, Zhang B, et al. Increased diagnostic yield of capsule endoscopy in patients with chronic abdominal pain. *PLoS One.* Jan 31 2014;9(1):e87396. PMID 24498097
18. Kopylov U, Yung DE, Engel T, et al. Diagnostic yield of capsule endoscopy versus magnetic resonance enterography and small bowel contrast ultrasound in the evaluation of small bowel Crohn's disease: Systematic review and meta-analysis. *Dig Liver Dis.* Aug 2017;49(8):854-863. PMID 28512034
19. Annese V, Daperno M, Rutter MD, et al. European evidence based consensus for endoscopy in inflammatory bowel disease. *J Crohns Colitis.* Dec 15 2013;7(12):982-1018. PMID 24184171
20. Sung J, Ho KY, Chiu HM, et al. The use of Pillcam Colon in assessing mucosal inflammation in ulcerative colitis: a multicenter study. *Endoscopy.* Aug 2012;44(8):754-758. PMID 22696193
21. San Juan-Acosta M, Caunedo-Alvarez A, Arguelles-Arias F, et al. Colon capsule endoscopy is a safe and useful tool to assess disease parameters in patients with ulcerative colitis. *Eur J Gastroenterol Hepatol.* Aug 2014;26(8):894-901. PMID 24987825
22. Oliva S, Di Nardo G, Hassan C, et al. Second-generation colon capsule endoscopy vs. colonoscopy in pediatric ulcerative colitis: a pilot study. *Endoscopy.* Jun 2014;46(6):485-492. PMID 24777427
23. Guturu P, Sagi SV, Ahn D, et al. Capsule endoscopy with PILLCAM ESO for detecting esophageal varices: a meta-analysis. *Minerva Gastroenterol Dietol.* Mar 2011;57(1):1-11. PMID 21372764

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.

24. Bhardwaj A, Hollenbeak CS, Pooran N, et al. A meta-analysis of the diagnostic accuracy of esophageal capsule endoscopy for Barrett's esophagus in patients with gastroesophageal reflux disease. *Am J Gastroenterol.* Jun 2009;104(6):1533-1539. PMID 19491867
25. Mata A, Llach J, Castells A, et al. A prospective trial comparing wireless capsule endoscopy and barium contrast series for small-bowel surveillance in hereditary GI polyposis syndromes. *Gastrointest Endosc.* May 2005;61(6):721-725. PMID 15855978
26. Brown G, Fraser C, Schofield G, et al. Video capsule endoscopy in peutz-jeghers syndrome: a blinded comparison with barium follow-through for detection of small-bowel polyps. *Endoscopy.* Apr 2006;38(4):385-390. PMID 16680639
27. Urquhart P, Grimpen F, Lim GJ, et al. Capsule endoscopy versus magnetic resonance enterography for the detection of small bowel polyps in Peutz-Jeghers syndrome. *Fam Cancer.* Jun 2014;13(2):249-255. PMID 24509884
28. Saurin JC, Pilleul F, Soussan EB, et al. Small-bowel capsule endoscopy diagnoses early and advanced neoplasms in asymptomatic patients with Lynch syndrome. *Endoscopy.* Dec 2010;42(12):1057-1062. PMID 20821360
29. Haanstra JF, Al-Toma A, Dekker E, et al. Prevalence of small-bowel neoplasia in Lynch syndrome assessed by video capsule endoscopy. *Gut.* Oct 2015;64(10):1578-1583. PMID 25209657
30. Colli A, Gana JC, Turner D, et al. Capsule endoscopy for the diagnosis of oesophageal varices in people with chronic liver disease or portal vein thrombosis. *Cochrane Database Syst Rev.* Oct 01 2014;10(10):CD008760. PMID 25271409
31. McCarty TR, Afinogenova Y, Njei B. Use of Wireless Capsule Endoscopy for the Diagnosis and Grading of Esophageal Varices in Patients With Portal Hypertension: A Systematic Review and Meta-Analysis. *J Clin Gastroenterol.* Feb 2017;51(2):174-182. PMID 27548729
32. Sung JJ, Tang RS, Ching JY, et al. Use of capsule endoscopy in the emergency department as a triage of patients with GI bleeding. *Gastrointest Endosc.* Dec 2016;84(6):907-913. PMID 27156655
33. Gutkin E, Shalomov A, Hussain SA, et al. Pillcam ESO((R)) is more accurate than clinical scoring systems in risk stratifying emergency room patients with acute upper gastrointestinal bleeding. *Therap Adv Gastroenterol.* May 2013;6(3):193-198. PMID 23634183
34. Chandran S, Testro A, Urquhart P, et al. Risk stratification of upper GI bleeding with an esophageal capsule. *Gastrointest Endosc.* Jun 2013;77(6):891-898. PMID 23453185
35. Gralnek IM, Ching JY, Maza I, et al. Capsule endoscopy in acute upper gastrointestinal hemorrhage: a prospective cohort study. *Endoscopy.* Dec 2013;45(1):12-19. PMID 23254402
36. Spada C, Pasha SF, Gross SA, et al. Accuracy of first- and second-generation colon capsules in endoscopic detection of colorectal polyps: a systematic review and meta-analysis. *Clin Gastroenterol Hepatol.* Nov 2016;14(11):1533-1543 e1538. PMID 27165469
37. Saito Y, Saito S, Oka S, et al. Evaluation of the clinical efficacy of colon capsule endoscopy in the detection of lesions of the colon: prospective, multicenter, open study. *Gastrointest Endosc.* Nov 2015;82(5):861-869. PMID 25936450
38. Morgan DR, Malik PR, Romeo DP, et al. Initial US evaluation of second-generation capsule colonoscopy for detecting colon polyps. *BMJ Open Gastroenterol.* May 3 2016;3(1):e000089. PMID 27195129
39. Parodi A, Vanbiervliet G, Hassan C, et al. Colon capsule endoscopy to screen for colorectal neoplasia in those with family histories of colorectal cancer. *Gastrointest Endosc.* May 26 2017. PMID 28554656
40. Delvaux M, Ben Soussan E, Laurent V, et al. Clinical evaluation of the use of the M2A patency capsule system before a capsule endoscopy procedure, in patients with known or suspected intestinal stenosis. *Endoscopy.* Sep 2005;37(9):801-807. PMID 16116529
41. Spada C, Shah SK, Riccioni ME, et al. Video capsule endoscopy in patients with known or suspected small bowel stricture previously tested with the dissolving patency capsule. *J Clin Gastroenterol.* Jul 2007;41(6):576-582. PMID 17577114
42. Herrerias JM, Leighton JA, Costamagna G, et al. Agile patency system eliminates risk of capsule retention in patients with known intestinal strictures who undergo capsule endoscopy. *Gastrointest Endosc.* May 2008;67(6):902-909. PMID 18355824
43. Postgate AJ, Burling D, Gupta A, et al. Safety, reliability and limitations of the given patency capsule in patients at risk of capsule retention: a 3-year technical review. *Dig Dis Sci.* Oct 2008;53(10):2732-2738. PMID 18320313
44. Banerjee R, Bhargav P, Reddy P, et al. Safety and efficacy of the M2A patency capsule for diagnosis of critical intestinal patency: results of a prospective clinical trial. *J Gastroenterol Hepatol.* Dec 2007;22(12):2060-2063. PMID 17614957
45. Enns RA, Hookey L, Armstrong D, et al. Clinical practice guidelines for the use of video capsule endoscopy. *Gastroenterology.* Feb 2017;152(3):497-514. PMID 28063287
46. Rubio-Tapia A, Hill ID, Kelly CP, et al. ACG clinical guidelines: diagnosis and management of celiac disease. *Am J Gastroenterol.* May 2013;108(5):656-676; quiz 677. PMID 23609613

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.

47. Lichtenstein GR, Hanauer SB, Sandborn WJ, et al. Management of Crohn's disease in adults. *Am J Gastroenterol.* Feb 2009;104(2):465-483; quiz 464, 484. PMID 19174807
48. Gerson LB, Fidler JL, Cave DR, et al. ACG Clinical Guideline: diagnosis and management of small bowel bleeding. *Am J Gastroenterol.* Sep 2015;110(9):1265-1287; quiz 1288. PMID 26303132
49. ASGE Standards of Practice Committee, Gurudu SR, Bruining DH, et al. The role of endoscopy in the management of suspected small-bowel bleeding. *Gastrointest Endosc.* Jan 2017;85(1):22-31. PMID 27374798
50. Spada C, Hassan C, Galmiche JP, et al. Colon capsule endoscopy: European Society of Gastrointestinal Endoscopy (ESGE) Guideline. *Endoscopy.* May 2012;44(5):527-536. PMID 22389230
51. Lansdorp-Vogelaar I, von Karsa L, International Agency for Research on Cancer. European guidelines for quality assurance in colorectal cancer screening and diagnosis. First Edition--Introduction. *Endoscopy.* Sep 2012;44 Suppl 3:SE15-30. PMID 23012118
52. Force USPST, Bibbins-Domingo K, Grossman DC, et al. Screening for Colorectal Cancer: US Preventive Services Task Force Recommendation Statement. *JAMA.* Jun 21 2016;315(23):2564-2575. PMID 27304597

Policy History

Original Effective Date: 01/27/2003
Current Effective Date: 12/20/2017

03/21/2002	Medical Policy Committee review
03/25/2002	Managed Care Advisory Council approval
06/24/2002	Format revision. No substance change to policy.
11/21/2002	Medical Policy Committee review. Format revision. No substance change to policy.
01/27/2003	Managed Care Advisory Council approval
02/01/2005	Medical Director review
02/15/2005	Medical Policy Committee review. Format revision
03/07/2005	Managed Care Advisory Council approval
07/13/2005	Medical Director review
07/19/2005	Medical Policy Committee review
08/24/2005	Managed Care Advisory Council approval
03/09/2006	Medical Director review
03/15/2006	Medical Policy Committee approval. Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
06/13/2007	Medical Director review
06/20/2007	Medical Policy Committee approval. Wireless capsule endoscopy for surveillance of the small bowel in patients with hereditary GI polyposis syndromes, including familial adenomatous polyposis and Peutz-Jeghers syndrome are now eligible for coverage. Rationale updated.
09/09/2008	Medical Director review
09/17/2008	Medical Policy Committee approval. Added bullets to investigational statement as follows: • Evaluation of the extent of involvement of known Crohn's disease; or • Evaluation of the esophagus, in patients with gastroesophageal reflux (GERD) or other esophageal pathologies. Added that the patency capsule, including use to evaluate patency of the gastrointestinal tract before wireless capsule endoscopy is considered to be investigational.
09/03/2009	Medical Policy Committee approval.
09/16/2009	Medical Policy Implementation Committee approval. Added "and Colon" to the end of the current title to read, "Wireless Capsule Endoscopy as a Diagnostic Technique in Disorders of the Small Bowel, Esophagus and Colon". Removed both sets of patient selection criteria from the When Services May be Eligible for Coverage section and added a new set of patient selection criteria to

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.

	this section. Added a fourth criteria bullet to the When Services Are Considered Investigational. Updated the entire policy.
09/09/2010	Medical Policy Committee review
09/15/2010	Medical Policy Implementation Committee. Coverage eligibility unchanged.
09/01/2011	Medical Policy Committee review
09/14/2011	Medical Policy Implementation Committee. Coverage eligibility unchanged.
09/06/2012	Medical Policy Committee review
09/19/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/05/2013	Medical Policy Committee review
09/18/2013	Medical Policy Implementation Committee approval. Added ulcerative colitis, Lynch syndrome, and acute GI bleeding to investigational statements.
10/02/2014	Medical Policy Committee review
10/15/2014	Medical Policy Implementation Committee approval. Added portal hypertensive enteropathy and unexplained chronic abdominal pain to the investigational policy statement; Added a statement indicating wireless capsule endoscopy may be eligible for coverage, in patients with an established diagnosis of Crohn disease, for 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.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
12/03/2015	Medical Policy Committee review
12/16/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/01/2016	Coding update
12/01/2016	Medical Policy Committee review
12/21/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
12/07/2017	Medical Policy Committee review
12/20/2017	Medical Policy Implementation Committee approval. Title changed from “Wireless Capsule Endoscopy as a Diagnostic Technique in Disorders of the Small Bowel, Esophagus, and Colon“ to “Wireless Capsule Endoscopy to Diagnose Disorders of the Small Bowel, Esophagus, and Colon”. Coverage criteria changed from “Obscure gastrointestinal bleeding” to “Suspected small bowel bleeding”. Policy statements otherwise unchanged.

Next Scheduled Review Date: 12/2018

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2016 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.

Wireless Capsule Endoscopy to Diagnose Disorders of the Small Bowel, Esophagus, and Colon

Policy # 00137
Original Effective Date: 01/27/2003
Current Effective Date: 12/20/2017

Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code			
CPT	0355T, 91110, 91111, 91112, 91299			
HCPCS	No codes			
ICD-10 Diagnosis	C49.A0-C49.A9 K50.80-K50.819	D13.2-D13.39 K50.90-K50.919	K50.00-K50.019 K92.0-K92.2	K50.10-K50.119 Q85.8-Q58.9

*****Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.