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

Policy # 00137
Original Effective Date: 01/27/2003
Current Effective Date: 12/11/2019

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.

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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
- 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.*

Background/Overview

Wireless Capsule Endoscopy

Wireless capsule endoscopy (CE) 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 gastrointestinal (GI) tract. The average transit time from ingestion to evacuation is 24 hours. The
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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 gauge where the image was taken over the abdomen. Images are then downloaded onto a workstation for viewing and processing.

CE has been proposed as a method for identifying Crohn disease. There is no single criterion standard diagnostic test for Crohn disease; 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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
Table 1 summarizes various wireless CE devices with clearance by the U.S. Food and Drug Administration (FDA).

Table 1. Wireless Capsule Endoscopy Devices Cleared by the Food and Drug Administration

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Year</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>PillCam™</td>
<td>Given® Imaging</td>
<td>2001</td>
<td>Detection of abnormalities in the small bowel and visualization of the small bowel mucosa</td>
</tr>
<tr>
<td>Given AGILE™ patency system</td>
<td>Given® Imaging</td>
<td>2006</td>
<td>Verification of adequate patency of the GI tract before administration of the PillCam into patients with known or suspected strictures</td>
</tr>
<tr>
<td>PillCam™ ESO2 Capsule</td>
<td>Given® Imaging</td>
<td>2007</td>
<td>Visualization of the esophageal mucosa</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>System</th>
<th>Manufacturer</th>
<th>Year</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Olympus Capsule Endoscope</td>
<td>Olympus Medical</td>
<td>2007</td>
<td>Visualization of the small intestine mucosa</td>
</tr>
<tr>
<td>System</td>
<td>Systems</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PillCam™ COLON</td>
<td>Given® Imaging</td>
<td>2014</td>
<td>Visualization of the colon in patients who have had an incomplete colonoscopy due to a technical impossibility and not incomplete evacuation</td>
</tr>
<tr>
<td>PillCam™ COLON 2</td>
<td>Given® Imaging</td>
<td>2016</td>
<td>Detection of colon polyps in patients after an incomplete colonoscopy 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 with major risks for colonoscopy or moderate sedation</td>
</tr>
</tbody>
</table>

GI: gastrointestinal.

In 2001, the PillCam Given Diagnostic Imaging System (Given Imaging) was cleared for marketing by 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 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.”
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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 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 capsule endoscopy.

FDA product code: NEZ.
Rationale/Source

The wireless capsule endoscopy (CE) uses a noninvasive device to visualize segments of the gastrointestinal tract. Patients swallow a capsule that records images of the intestinal mucosa as it passes through the gastrointestinal (GI) tract. The capsule is collected after being excreted and images interpreted.

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 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 have suspected Crohn disease (CD) who receive wireless CE, the evidence includes case series. Relevant outcomes are test validity, other test performance measures, symptoms, and change in disease status. Although the test performance characteristics and diagnostic yields of the capsule for this indication 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.

For individuals who have suspected celiac disease who receive wireless CE, the evidence includes case series and diagnostic accuracy studies. Relevant outcomes are test 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 (eg, 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.
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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 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 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 and 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 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 and a strong chain of evidence to improved outcomes are 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 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 GI polyposis syndromes who receive wireless CE, the evidence includes case series and diagnostic accuracy studies. Relevant outcomes are test validity, other test
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performance measures, symptoms, and change in disease status. The 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 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 validity, and other test performance measures, symptoms, and change in disease status. Systematic reviews of studies of CE’s diagnostic performance for this indicated have 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 validity, and other test performance measures, symptoms, hospitalizations, and resource utilization. The use of CE in the emergency department setting for suspected upper GI bleeding is intended to avoiding unnecessary hospitalization or immediate endoscopy. 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 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. 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 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 improves the net health outcome. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Supplemental Information**

**Practice Guidelines and Position Statements**

**Canadian Association of Gastroenterology**

In 2017, the Canadian Association of Gastroenterology published guidelines on the use of video capsule endoscopy (CE), which included the following consensus recommendations (see Table 2).

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>QOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crohn disease</td>
<td></td>
</tr>
<tr>
<td>Patients presenting with clinical features consistent with CD and negative ileocolonoscopy and imaging studies</td>
<td>Very low or low</td>
</tr>
</tbody>
</table>
Patients with CD and clinical features not explained by negative ileocolonoscopy and imaging studies | Very low or low  
---|---  
Patients with CD, when assessment of small-bowel mucosal healing is needed, and the area is beyond the reach of ileocolonoscopy | Very low or low  
Patients with suspected small bowel recurrence of CD after colectomy, undiagnosed by ileocolonoscopy and imaging studies | Very low or low  
Celiac disease  
Recommend against CE in patients with suspected celiac disease | Very low or low  
Recommend for CE in patients with celiac disease and unexplained symptoms despite treatment and appropriate investigations | Very low or low  
Gastrointestinal bleeding  
Recommend for CE in patients with documented overt gastrointestinal bleeding (excluding hematemesis) and negative colonoscopy and high-quality esophagagogastroduodenoscopy | Very low or low  
Recommend for CE in patients with an overt, obscure bleeding episode | Very low or low
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<table>
<thead>
<tr>
<th>Recommend for endoscopy, colonoscopy and/or CE in patients with prior negative CE who have repeated obscure bleeding</th>
<th>Very low or low</th>
</tr>
</thead>
</table>

CD: Crohn disease; CE: capsule endoscopy; QOE: quality of evidence (all consensus-based).

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 CE 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).

CE 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 CE 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 radiographic examinations. However, because there is a risk of capsule retention in up to 13% of patients with CD, which could require surgical intervention, CE is considered to be a contraindication in patients with known small bowel strictures. It was recommended that radiographic studies such as computed tomography enterography, small bowel follow-through, or magnetic resonance imaging be done to assess for the presence of unsuspected bowel strictures before CE. 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 CE (see Table 3).
Table 3. Recommendations on Diagnosis and Management of Small Bowel Bleeding

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>SOR</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>“… VCE should be considered as a first-line procedure for SB evaluation after upper and lower GI sources have been excluded, including second-look endoscopy when indicated”</td>
<td>Strong</td>
<td>Moderate</td>
</tr>
<tr>
<td>“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”</td>
<td>Strong</td>
<td>High</td>
</tr>
</tbody>
</table>

LOE: level of evidence; SB: small bowel; SOR: strength of recommendation; VCE: video capsule endoscopy.

**American Society of Gastrointestinal Endoscopy**

In 2016, the American Society of Gastrointestinal Endoscopy released guidelines for the use of endoscopy in the management of suspected small bowel bleeding. These guidelines made the following recommendations on capsule endoscopy (see Table 4).

Table 4. Recommendations on Use of Endoscopy to Manage Suspected Small Bowel Bleeding

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>QOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>We suggest VCE as the initial test for patients with overt or occult small-bowel bleeding. Positive VCE results should be followed with push enteroscopy if within reach or DAE.”</td>
<td>Moderate</td>
</tr>
</tbody>
</table>
“We suggest DAE or push enteroscopy if VCE is unavailable or nondiagnostic in patients with overt small bowel bleeding.”

**Moderate**

DAE: device-assisted enteroscopy; QOE: quality of evidence; VCE: video capsule endoscopy.

**American Gastroenterological Association Institute**
A 2007 position statement by American Gastroenterological Association Institute indicated the following on obscure GI bleeding and CE:

“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.”

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

**Medicare National Coverage**
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.

**Ongoing and Unpublished Clinical Trials**
Some currently unpublished trials that might influence this review are listed in Table 5.
### Table 5. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01371591a</td>
<td>Pilot Study to Investigate the Use of Wireless Capsule Endoscopy for Emergency Department Patients With Suspected Acute Upper Gastrointestinal Bleeding</td>
<td>100</td>
<td>Aug 2018 (ongoing)</td>
</tr>
<tr>
<td>NCT03291743</td>
<td>The Biologic Onset of Crohn’s Disease: A Screening Study in First Degree Relatives</td>
<td>144</td>
<td>Feb 2020</td>
</tr>
<tr>
<td>NCT03241368a</td>
<td>Multicenter, Prospective, Randomized Study Comparing PillCam® Crohn’s Capsule Endoscopy to Ileocolonoscopy (IC) Plus MRE for Detection of Active CD in the Small Bowel and Colon in Subjects With Known CD and Mucosal Disease</td>
<td>352</td>
<td>Aug 2020</td>
</tr>
<tr>
<td>Unpublished</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCT02754661a</td>
<td>Multicenter, Prospective, Randomized Study Comparing the Diagnostic Yield of Colon Capsule Endoscopy Versus Computed Tomographic Colonography in a Screening Population</td>
<td>320</td>
<td>Aug 2018 (completed)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.
a Denotes industry-sponsored or cosponsored trial.

References
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**Policy History**
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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
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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 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
09/01/2011 Medical Policy Committee review
09/06/2012 Medical Policy Committee review

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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
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.
12/06/2018 Medical Policy Committee review
12/19/2018 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/05/2019 Medical Policy Committee review
Wireless Capsule Endoscopy to Diagnose Disorders of the Small Bowel, Esophagus, and Colon

Policy #  00137
Original Effective Date:  01/27/2003
Current Effective Date:  12/11/2019

Next Scheduled Review Date:  12/2020

**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 2018 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.

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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:

<table>
<thead>
<tr>
<th>Code Type</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>0355T, 91110, 91111, 91112, 91299</td>
</tr>
<tr>
<td>HCPCS</td>
<td>No codes</td>
</tr>
<tr>
<td>ICD-10 Diagnosis</td>
<td>C49.A0-C49.A9, D13.2-D13.39, K50.00-K50.019, K50.10-K50.119</td>
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K50.80-K50.819, K50.90-K50.919, K92.0-K92.2, 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
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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.
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