



BlueCross BlueShield
of Alabama

Name of Policy:

Wireless Capsule Endoscopy (Given[®] Video Capsule)

Policy #: 017
Category: Radiology

Latest Review Date: August 2013
Policy Grade: B

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

- 1. The technology must have final approval from the appropriate government regulatory bodies;*
- 2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
- 3. The technology must improve the net health outcome;*
- 4. The technology must be as beneficial as any established alternatives;*
- 5. The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

- 1. In accordance with generally accepted standards of medical practice; and*
- 2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
- 3. Not primarily for the convenience of the patient, physician or other health care provider; and*
- 4. 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.*

Description of Procedure or Service:

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

Given[®] Diagnostic Imaging System consist of three basic elements: 1) a disposable video capsule, which is a single use device that is swallowed by the patient and excreted naturally out of the body, 2) the receiving unit, the Given[®] Data Recorder, which is worn around the patient's waist with an antenna array, 3) and the Given[®] workstation that uses the rapid (reporting and processing of image and data) application software that processes the data and produces a video of the small intestinal imaging, together with additional information from the digestive tract. The workstation will permit physicians to view, edit and archive the video and save individual images. This device is used to photograph the entire small bowel as it passes thru under normal peristalsis.

The PillCam[™] ESO is another wireless capsule from Given[®] Diagnostics that is intended for the visualization of the esophageal mucosa for conditions such as gastroesophageal reflux or GERD. The PillCam[™] ESO Capsule is a wireless, disposable capsule designed to pass through the esophagus. During its passage, the capsule transmits digital data that is captured by receiving antennas attached to the patient's body. The images are stored in the Data Recorder that is connected to the receiving antennas and is worn on a belt around the waist of the patient. When the test is completed, the images from the recorder are downloaded for processing and viewing by the physician.

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

The Given[®] AGILE Patency System is an accessory to the PillCam video capsule. According to the FDA, it is intended to verify adequate patency of the GI tract prior to administration of the PillCam in patients with known or suspected strictures. This capsule is of similar size to the endoscopy capsule, but is made of lactose and barium and dissolves within 30-100 hours of entering the GI tract. It carries a tracer material that can be detected by a scanning device. Excretion of the intact capsule without symptoms (abdominal pain or obstruction) is reported to predict the uncomplicated passage of the wireless capsule.

Policy:

Wireless Capsule Endoscopy/Given® Imaging System including the **disposable Pillcam SB capsule and interpretation of the data by the Given® data recorder** meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage for the following indications:

1. **Recurrent, obscure gastrointestinal bleeding**, suspected to be of small bowel origin and including the following:
 - Must be experiencing gastrointestinal blood loss and anemia secondary to bleeding.
 - Must have negative diagnostic work-up (e.g., upper GI, EGD, or colonoscopy). A negative diagnostic work up is defined as one which did not identify the source or condition which caused the blood loss. Positive findings which could not attribute to the blood loss would still constitute a negative diagnostic work up since the cause of blood loss was not identified.
2. In the **initial diagnosis** in patients with suspected Crohn's disease without evidence of disease on conventional diagnostic tests such as but not limited to:
 - a. upper GI,
 - b. EGD, **or**
 - c. Colonoscopy
3. In the evaluation for recurrence of Crohn's disease after previous surgery for Crohn's disease when there are symptoms suggestive of Crohn's disease. **(This statement was effective October 9, 2007.)**
4. For surveillance of the small bowel in patients with hereditary GI polyposis syndromes, including familial adenomatous polyposis and Peutz-Jeghers syndrome.

Non-covered Indications

Wireless Capsule Endoscopy/Given® Imaging System including the **disposable PillCam SB capsule and interpretation of the data by the Given® data recorder** does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational** for other than above indications, including but not limited to:

- Evaluation of the extent of involvement of known Crohn's disease or ulcerative colitis,
- Abdominal pain in the absence of gastrointestinal bleeding,
- Confirmation of lesion/pathology found by other diagnostic means,
- As initial procedure in the diagnosis of gastrointestinal bleeding where upper or lower endoscopies have not been performed,
- Evaluation of other gastrointestinal diseases not presenting with GI bleeding including, but not limited to celiac sprue, irritable bowel syndrome, Lynch syndrome, and small bowel neoplasm, ~~OR~~
- Evaluation of the colon including, but not limited to, detection of colonic polyps or colon cancer, **OR**

- Initial evaluation of patients with acute upper GI bleeding.

Wireless Capsule Endoscopy/PillCam ESO for imaging of the esophagus **does not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational**.

The **Given[®] AGILE Patency System** including the patency capsule and the patency scanner, used to evaluate patency of the gastrointestinal tract before wireless capsule endoscopy, **does not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational**.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

Obscure GI Bleeding

Obscure gastro-intestinal (GI) bleeding is defined as bleeding from the GI tract that persists or recurs without an obvious etiology after imaging with upper and lower endoscopy and radiologic evaluation of the small bowel. Obscure GI bleeding is often detected by fecal occult blood testing performed for colon cancer screening, and the presence of anemia consistent with persistent blood loss. Without anemia, further testing beyond upper and lower endoscopy is not warranted. Most obscure GI bleeding is due to lesions in the esophagus, stomach, and colon; 5% are due to lesions in the small intestine. Causes of obscure bleeding in the small intestine include angiodysplasia (70–80%), tumor (5–10%), and other causes (10–25%) including those related to medication, infections (tuberculosis), Crohn's disease, Meckel's diverticulum, Zollinger-Ellison, vasculitis, radiation enteritis, jejunal diverticula, and chronic mesenteric ischemia. 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 (AGA) states that capsule endoscopy should be the third test after upper and lower endoscopy in the evaluation of obscure GI bleeding. Evidence cited in the accompanying technical review caused them to revise prior position statements in which other tests, such as bleeding scans, angiography, repeat endoscopy, enteroscopy, and enteroclysis were recommended, depending on the presence or absence of active bleeding. The arguments supporting the utility of capsule endoscopy are based on several lines of evidence. Capsule endoscopy appears to have higher sensitivity of locating bleeding lesions compared to other diagnostic techniques, when diagnostic yields are compared. Ten studies were summarized in the technical review in which capsule endoscopy was compared with push enteroscopy in the same patients. Capsule endoscopy located a source of bleeding in

between 25 to 55% more patients than push enteroscopy. One study by Hartmann et al compared the findings of capsule endoscopy to what might be considered the gold standard for localizing bleeding, intraoperative endoscopy. Capsule endoscopy was 95% sensitive in locating bleeding and was able to localize bleeding in a few cases in which intraoperative endoscopy was not able to. In a study by Pennazio et al in which long-term follow-up was used as the reference standard, capsule endoscopy was 89% sensitive and 95% specific in 56 patients in whom a confirmed diagnosis was obtained. A “true” reference standard for obscure GI bleeding is, in fact, difficult or impossible to achieve, as the bleeding source may resolve and invasive techniques such as surgery cannot be justifiably used.

A 2012 systematic review and meta-analysis by Koulaouzidis et al evaluated 24 studies on capsule endoscopy performed after negative findings on previous diagnostic evaluations including upper and lower endoscopy. Included in the studies were a total of 1,960 patients of which 1,194 (60.9%) had iron-deficiency anemia. The pooled per-patient diagnostic yield of all 24 studies, evaluated by a random-effects model, was 47% (95% confidence interval [CI]: 42 to 52%). Almost 50% of the diagnostic yield was for small bowel angioectasia. In a subset of four studies focused only on patients with iron-deficiency anemia (n=264, 13.47%), the pooled diagnostic yield with capsule endoscopy was 66.6% (95% CI: 61.0 to 72.3%) and included more vascular, inflammatory and mass/tumor lesions.

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

There are a large number of uncontrolled studies that evaluate the use of capsule endoscopy in the evaluation of patients with occult GI bleeding. These studies are consistent in reporting that a substantial proportion of patients receive a definitive diagnosis following this test when there are few if any other diagnostic options. A meta-analysis of 24 studies estimated that the diagnostic yield in this patient population was approximately half of the included patients, and was higher in patients with documented iron-deficiency anemia.

Acute Upper GI Bleeding

Three 2013 studies with small cohorts of patients (n=25-83) have reported on the use of capsule endoscopy before upper endoscopy for acute GI bleeding, in order to triage and/or risk-stratify patients in the emergency department or hospital. The studies report that capsule endoscopy provides useful information, such as identifying gross bleeding, inflammatory lesions, in a substantial proportion of patients and in stratifying patients into high- or low-risk categories. However, the yield of capsule endoscopy in localizing the bleeding source was lower than for esophagogastroduodenoscopy, which is the standard initial evaluation for acute upper GI bleeding. For this reason, it is unlikely that capsule endoscopy can take the place of upper endoscopy for initial evaluation of acute upper GI bleeding. Controlled studies are needed to

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

Suspected Crohn's Disease

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

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

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

For patients with suspected Crohn's disease of the small bowel who are unable to be diagnosed by other modalities, capsule endoscopy can confirm the diagnosis in a substantial number of patients. The diagnostic yield in the available studies is variable, but is likely superior to alternative tests such as CT or MRI scanning. The evidence on monitoring of Crohn's disease is less definitive, and it may not perform as well as other modalities for diagnosing complications of Crohn's disease.

Ulcerative Colitis

Ulcerative colitis is an inflammatory disease of the large intestine. It is usually diagnosed with colonoscopy and biopsy. Capsule endoscopy has been proposed as an alternative method for assessing the extent and severity of disease activity in known ulcerative colitis. Sung and colleagues evaluated 100 patients with suspected or known ulcerative colitis using capsule endoscopy and colonoscopy performed on the same day. The authors reported capsule endoscopy sensitivity and specificity to detect active colonic inflammation was 89% (95% CI: 80–95) and 75% (95% CI: 51 to 90), respectively. The positive and negative predictive values

were 93% (95% CI: 84 to 97) and 65% (95% CI: 43 to 83), respectively. It does not appear to be an adequate alternative method of assessing disease activity.

Suspected Celiac Disease

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

A meta-analysis by El-Matary et al compared the diagnostic performance of capsule endoscopy to a reference standard of duodenal biopsy. The pooled analysis of three studies showed a sensitivity of 83% and a specificity of 98%. Another meta-analysis by Rokkas and Niv also compared the diagnostic performance of capsule endoscopy to biopsy, summarizing six studies that evaluated a total of 166 subjects. The overall pooled sensitivity was 89% and the specificity was 95%. Capsule endoscopy was able to detect involvement of intestines beyond the duodenum; however, the clinical significance of detecting further extent of celiac disease is uncertain. Given the less than 90% sensitivity of capsule endoscopy for celiac disease, it does not appear to be an adequate alternative method of making an initial diagnosis.

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

In a 2013 study by Kurien and colleagues, 62 patients with an equivocal diagnosis of celiac disease and 69 patients with confirmed celiac disease who were unresponsive to standard treatment were evaluated with capsule endoscopy. Results were combined with HLA typing and response to gluten challenge, with the final diagnosis made by three expert physicians who were provided with the information from all three sources. The main outcome was the increase in diagnostic yield after capsule endoscopy combined with the other tests. The diagnostic yield was greatest in cases with anti-body negative villous atrophy where a diagnosis of celiac disease (or Crohn’s disease) was made in nine of 32 patients (28%). In eight of the 69 (12%) nonresponsive celiac disease patients, capsule endoscopy identified two cases of enteropathy-associated lymphoma, four Type 1 refractory disease cases, one fibroepithelial polyp, and one case of ulcerative jejunitis. This study is limited by the lack of control groups and small sample size, in addition to the use of other tests in conjunction with capsule endoscopy for the ascertainment of a final diagnosis.

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

Esophageal Conditions

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

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

Colon Cancer Screening

Capsule endoscopy has been investigated as a method of colon cancer screening. The test may detect precancerous polyps or actual cancer. Several studies have assessed the accuracy of capsule endoscopy for detection of colonic lesions. In the largest study of 328 patients, the sensitivity of capsule endoscopy was 64% for polyps 6 mm or larger, 73% for advanced adenoma, and 74% for cancer. Other smaller studies show the sensitivity of capsule endoscopy for various types of lesions to be less than 80%. A meta-analysis by Spada et al. of eight studies enrolling 837 patients showed a sensitivity of 71% for polyps of any size and a specificity of 75%. Almost all the existing studies evaluating capsule endoscopy for detecting colonic lesions have been done on patients with a clinical indication for colonoscopy rather than a screening population. Based on the low sensitivity for colonic polyps, capsule endoscopy is unlikely to be an effective screening test for colon cancer unless it is repeated more frequently than colonoscopy. The specificity of the test is not optimal either, meaning that patients will undergo unnecessary follow-up colonoscopy.

Hereditary GI Polyposis Syndromes

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

There is a small amount of evidence on use of capsule endoscopy for small bowel screening in Lynch syndrome. These data are insufficient to determine the prevalence and/or natural history of small bowel polyps in patients with Lynch syndrome. In addition, surveillance of the small bowel is not generally recommended as a routine intervention for patients with Lynch syndrome.

For this reason, it is not possible to determine whether capsule endoscopy improves outcomes for patients with Lynch syndrome.

Patency Capsule

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

These improvements would need to be weighed against any complications due to the use of the patency capsule. The published studies are small and do not provide comparative data about the incremental value of this capsule over standard clinical evaluation. Also, in some series, administration of the patency capsule has produced symptoms requiring hospitalization and even surgery. In a series from Europe, Delvaux et al. reported on findings in 22 patients with suspected intestinal stricture, 15 of whom had Crohn's disease. In this study, at 30 hours after ingestion, the patency capsule was detected in 17 patients (72.3 %). In all patients in whom the capsule was blocked in the small intestine, the stenosis had been suspected on computed tomography (CT) scan or small-bowel follow-through. In three patients, the delay in progression of the patency capsule led to cancellation of capsule endoscopy. In three 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, as it did not detect stenoses undiagnosed by CT or small-bowel follow-through, and the start of dissolution at 40 hours after ingestion is too slow to prevent episodes of intestinal occlusion. They also comment that a careful interview eliciting the patient's history and symptoms remains the most useful indicator with regard to suspicion of an intestinal stenosis. In another study from Europe, Spada et al. reported on findings in 27 patients, 24 with Crohn's disease. In this study, 25 patients (92.6%) retrieved the patency capsule in the stools. Six patients complained of abdominal pain, four of whom excreted a nonintact capsule, and hospitalization was required in one patient due to occlusive syndrome.

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

Summary

Wireless capsule is a device that allows visualization of intestinal mucosa that is not accessible by traditional upper or lower endoscopy. It has been most extensively studied in patients with obscure gastrointestinal (GI) tract bleeding. For this population, the evidence demonstrates that capsule endoscopy can identify a bleeding source in a substantial number of patients who are unable to be diagnosed by other methods, with a low incidence of adverse events. Since there are no other options for diagnosing obscure small bowel bleeding in patients who have negative upper and lower endoscopy, this technique will likely improve health outcomes by directing specific treatment when a bleeding source is identified. Therefore wireless capsule endoscopy may be considered medically necessary for the evaluation of obscure GI bleeding.

Similarly, for patients with suspected small bowel Crohn's disease and for patients with familial polyposis syndromes who require surveillance of the small bowel, other methods are not available for visualizing the small bowel. Although the performance characteristics of the capsule for these indications are uncertain, it is likely to improve health outcomes by identifying some cases of these disorders and directing specific treatment. Therefore, wireless capsule endoscopy may be considered medically necessary for these indications.

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

Practice Guidelines and Position Statements

A 2007 position statement by the American Gastroenterological Association (AGA) states the following concerning obscure GI bleeding and capsule endoscopy:

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

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

- Small bowel capsule endoscopy is able to identify mucosal lesions compatible with Crohn's disease in some patients in whom conventional endoscopic and small-bowel radiographic imaging modalities have been nondiagnostic.
- A diagnosis of Crohn's disease should not be based on the appearances at capsule endoscopy alone.
- A normal capsule endoscopy has a high negative predictive value for active small-bowel Crohn's disease.
- For patients with established Crohn's disease, small bowel capsule endoscopy is better at identifying small-bowel mucosal lesions than barium and may be better than CT or MR enterography or enteroclysis, but the clinical significance of this potential difference remains to be defined.
- There are no validated diagnostic criteria for small bowel capsule endoscopy for the diagnosis of Crohn's disease.

Key Words:

Wireless capsule endoscopy, Given[®] Imaging System, camera endoscopy, ingestible video capsule, PillCam ESO, PillCam SB, Given[®] AGILE Patency System, patency capsule

Approved by Governing Bodies:

On August 1, 2001, the Given Diagnostic Imaging System received 510(k) approval and stated the intended use is for visualization of the small bowel mucosa as an adjunctive tool in the detection of abnormalities of the small bowel in adults. The FDA warned that the capsule must be used in conjunction with other tests, not as a stand-alone exam.

On July 1, 2003, a supplemental 510(k) pre-market notification was cleared and revised the indications to state the system is indicated for visualization of the small bowel mucosa. It may be used as a tool in the detection of abnormalities of the small bowel.

In October 2003, the FDA expanded its approved indications for the system to include visualization of the small bowel and detection of abnormalities in symptomatic children age 10-18 years.

On October 25, 2004, the PillCam[™] ESO capsule from Given[®] Diagnostic System received a 510(k) premarket approval. It is intended for visualization of the esophageal mucosa.

On May 16, 2006, the Given[®] Agile Patency System received 510(k) approval as an accessory to the PillCam video capsule. It is intended to verify adequate patency of the gastrointestinal tract prior to administration of the PillCam video capsule in patients with known or suspected strictures.

Benefit Application:

Coverage is subject to member's specific benefits, group specific policy will supersede this policy when applicable.

ITS Home: No special benefit rules apply.

ITS Host: Not subject to Alabama bundling edits.

FEP contracts: FEP does not consider investigational if FDA approved. Will be reviewed for medical necessity. Special benefit consideration may apply. Refer to member's benefit plan.

Precertification/Pre-determination Requirements: Not applicable.

Current Coding:

91110	Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus through ileum, with interpretation and report (Effective 01/01/2004)
91111	Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus with interpretation and report (Effective 01/01/2007)
<u>0355T</u>	<u>Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), colon, with interpretation and report (Effective 7/1/2014)</u>

Previous Coding:

G0262	Small intestinal imaging; intraluminal, from ligament of Treitz to the ileo cecal valve, includes physician interpretation and report (<u>Deleted effective 01/01/2004</u>)
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Policy History:

Medical Policy Group, September 7, 2001
 Medical Policy Group, January 2003 **(1)**
 Medical Policy Administration Committee, January 2003
 Available for comment February 6-March 24, 2003
 Available for comment December 16, 2003-January 29, 2004
 Medical Policy Group, November 2005 **(3)**
 Medical Review Committee, December 2005
 Medical Policy Administration Committee, December 2005
 Available for comment December 27, 2005-February 9, 2006
 Medical Policy Group, December 2006 **(3)**
 Medical Policy Group, October 2007 **(3)**
 Medical Policy Administration Committee, October 2007
 Available for comment October 20-December 3, 2007
 Medical Policy Group, October 2008 **(3)**
 Medical Policy Group, June 2009 **(3)**
 Medical Policy Administration Committee, July 2009
 Available for comment July 1-August 14, 2009
 Medical Policy Group, June 2011 **(3)**: Updated Policy Section
 Medical Policy Administration Committee, June 2011

Available for comment June 23 – August 8, 2011

Medical Policy Group, October 2012 (3): 2012 Update to Key Points and References

Medical Policy Group, December 2012 (3): 2013 Coding Update – Verbiage change to Codes **91110 & 91111**

Medical Policy Group, May 2013(3): Updated References; no change in policy statement

Medical Policy Panel, August 2013

Medical Policy Group, August 2013 (3): 2013 Updates to Description, Policy Statement, Key Points and References; added additional investigational/non-covered indications; no changes in covered indications

Medical Policy Administration Committee, September 2013

Available for comment August 30 through October 13, 2013

Medical Policy Group, June 2014 (5): Added new code 0355T for 2014 quarterly coding update effective 7/1/2014.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.