APPENDIX to Wireless Capsule Endoscopy Policy

Prior Authorization Requirements

This service (or procedure) is considered **medically necessary** in certain instances and **investigational** in others (refer to policy for details).

For instances when the indication is **medically necessary**, clinical evidence is required to determine **medical necessity**.

For instances when the indication is **investigational**, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

Evidence Basis for the Policy

Rationale

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.

Obscure GI Bleeding

Obscure gastrointestinal (GI) bleeding is defined as bleeding from the GI tract that persists or recurs without an obvious etiology after imaging with upper and lower endoscopy and radiologic evaluation of the small bowel. Obscure GI bleeding is often detected by fecal occult blood testing performed for colon cancer screening and the presence of anemia consistent with persistent blood loss (Raju et al., 2007) .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% to 80%), tumor (5% to 10%), and other causes (10% to 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 (Zuckerman et al., 2000). 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 (Lewis, 2000).

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 (Raju et al., 2007). According to Raju and colleagues (2007) 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. The technical review summarizes 10 studies in which capsule endoscopy was compared with push enteroscopy in the same patients. Capsule endoscopy located a source of bleeding in between 25% to 55% more patients than push enteroscopy.

One study by Hartmann et al. (2005) 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.(2004) 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. The authors concluded that 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.

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 (OMED-ECCO) 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 (Bourreille et al., 2009).

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. The international consensus statement found 7 studies comparing capsule endoscopy to small-

bowel follow-through (SBFT), 1 study comparing capsule endoscopy to magnetic resonance imaging (MRI), and 4 studies comparing capsule endoscopy to computed tomography (CT) scan (Bourreille et al., 2009). The conclusion statements stated that capsule endoscopy may be superior to these alternative diagnostic tests.

The role of capsule endoscopy in established Crohn's disease is less certain. The 2009 international consensus statement recommends that radiographic imaging take precedence over capsule endoscopy because of the capability to detect obstructive strictures, extraluminal and transmural disease (Bourreille et al., 2009). 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.

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. (2009) compared the diagnostic performance of capsule endoscopy to 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) also compared the diagnostic performance of capsule endoscopy to biopsy, summarizing 6 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 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 (Culliford et al., 2005). 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.

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. Guturu et al. (2009) conducted a meta-analysis of 9 studies comparing capsule endoscopy to traditional endoscopy for detecting esophageal varices and calculated a sensitivity of 83% and specificity of 85%.

Bhardwaj and colleagues (2009) conducted a meta-analysis of 9 studies comparing capsule endoscopy to traditional endoscopy for detecting Barrett's esophagus showed a sensitivity and specificity of 77% and 86%, respectively. The authors concluded sensitivity of the test is not adequate 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 (Van Gossum et al., 2009). Other smaller studies show the sensitivity of capsule endoscopy for various types of lesions to be less than 80%. (Eliakim, 2006; Schoofs, 2006; Pilz et al., 2010) A meta-analysis by Spada et al. (2010) of 8 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 (2005) 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 4 additional patients with small bowel polyps, which were subsequently removed with endoscopic polypectomy. Another study by Brown et al. (2006) 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.

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. (2005) reported on findings in 22 patients with suspected intestinal stricture, 15 of who 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 3 patients, the delay in progression of the patency capsule led to cancellation of capsule endoscopy. In 3 patients, the patency capsule induced a symptomatic intestinal occlusion, which resolved spontaneously in 1 patient and required emergency surgery in 2 patients. The authors commented that the current technical development of the patency capsule limits its use in clinical practice, as it did not detect stenosis 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.(2007) 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, 4 of whom excreted a non-intact capsule, and hospitalization was required in 1 patient due to occlusive syndrome.

Several studies show that patients who had uncomplicated passage of the patency capsule subsequently underwent uncomplicated capsule endoscopy. (Herrerias et al., 2008; Postgate et al., 2008; Banerjee et al., 2007). 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, 3 of 106 patients had severe adverse events, including 1 patient who required surgery (Herrerias et al., 2008). The overall balance of harm and benefit of using the patency capsule cannot be determined from the existing studies.

Summary

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

In 2009 an international consensus panel (OMED-ECCO) 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 non-diagnostic
- 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

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract

language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

Type	Number	Description
CPT	91110	Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus through ileum, with physician interpretation and report
	91111	Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus with physician interpretation and report
	91299	Unlisted diagnostic gastroenterology procedure
HCPC	None	
ICD9 Procedure	None	
ICD9 Diagnosis	All Diagnoses	
Place of Service	All Places of Service	

Tables

N/A

Definitions

Small bowel (or small intestine) - The longest portion of the gastrointestinal (GI) tract; it is small because it is thin or narrow compared to the large bowel, but is much longer; it is a vital organ involved in nutrient absorption

Adenomatous - Multiple glandular tissue overgrowths

Barrett's esophagus - A premalignant condition associated with gastroesophageal reflux disease (GERD)

Obscure GI bleeding - Symptoms include recurrent or persistent iron-deficiency anemia, positive fecal occult blood test, or visible bleeding with no bleeding source found at original endoscopy

Celiac disease - A digestive disease that damages the small intestine and interferes with absorption of nutrients from food; people who have celiac disease cannot tolerate gluten, a protein in wheat, rye, and barley

Crohn's disease - Inflammation in the small intestine; normally occurs in the lower part of the small intestine, but can affect any part of the digestive tract with inflammation extending deep into the lining of the affected organ

Diverticulum - A sac or pouch in the walls of a canal or organ

Zenkers diverticulum - Diverticulum of the mucosa of the pharynx, just above the cricopharyngeal muscle (i.e., above the upper sphincter of the esophagus)

Polyposis - The presence of numerous polyps (tumor with a pedicle)

Peutz-Jeghers syndrome - An autosomal dominant inherited disorder characterized by intestinal hamartomatous polyps in association with mucocutaneous melanocytic macules

Colon - The large intestine from the end of the ileum to the rectum, about 59 inches long

Index / Cross Reference of Related BSC Medical Policies

The following Medical Policies share diagnoses and/or are equivalent BSC Medical Policies:

N/A

Key / Related Searchable Words

- Capsule camera
- Capsule endoscopy
- PillCam capsule camera

References

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Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	Reason
2/13/2002	BCBSA Medical Policy adoption	Medical Policy Committee

Effective Date	Action	Reason
10/16/2002	BCBSA Medical Policy adoption	Medical Policy Committee
11/1/2002	Administrative Review	Administrative Review
6/1/2004	BCBSA Medical Policy adoption	Medical Policy Committee
4/1/2005	BCBSA Medical Policy adoption Regarding the esophagus; modified, Title change	Medical Policy Committee
12/7/2006	BCBSA Medical Policy adoption Criteria revised.	Medical Policy Committee
3/1/2007	Policy Review Policy statement unchanged.	Medical Policy Committee
1/23/2008	Administrative Review Disclaimer stated added to Medical Policy.	Administrative Review
9/25/2009	Policy Revision	Medical Policy Committee
1/11/2013	Policy revision with position change	Medical Policy Committee

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.

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