CAPSULE ENDOSCOPY FOR EVALUATION OF OCCULT BLEEDING

ISSUE

Blue Shield has received requests for the use of capsule endoscopy for the evaluation of occult and obscure gastrointestinal bleeding. The Medical Policy Committee on Quality and Technology is asked to review the published data regarding the efficacy and safety of this new technology.

BACKGROUND

Gastrointestinal bleeding is classified as being derived from upper, lower or occult sources. Acute upper gastrointestinal bleeding is responsible for over 350,000 hospitalizations a year in the U.S. with a mortality rate of 10%. The most common presentation of upper gastrointestinal bleeding is hematemesis or melena while acute lower gastrointestinal bleeding generally presents with hematochezia. Melena develops with as little as 50-100 mL of blood in the upper gastrointestinal tract. Acute upper gastrointestinal bleeding may originate from a number of sources, though peptic ulcer disease accounts for over half of major upper gastrointestinal bleeding with an overall acute mortality rate of 6-10% (Current Medical Diagnosis and Treatment, 2001). Other sources of acute upper gastrointestinal bleeding include portal hypertension, mallory-weiss tears, vascular anomalies, gastric neoplasms and gastritis/esophagitis. Most episodes of acute upper gastrointestinal bleeding are self-limited (Steele et al, 1997).

Acute lower gastrointestinal bleeding is defined as that arising below the ligament of Treitz (i.e. the small intestine or colon). In general, patients with acute lower gastrointestinal bleeding are less likely to present with shock or orthostasis or to require blood transfusions than patients hospitalized with upper gastrointestinal bleeding. As with acute upper gastrointestinal bleeding, most episodes are self-limited. In younger patients, lower gastrointestinal bleeding is most commonly caused by infectious colitis, anorectal disease, and inflammatory bowel disease. Diverticulosis, vascular ectasias (angiodysplasias), malignancy, or ischemia are the most common causes of bleeding in older patients (Zuckerman et al, 1999)
Occult Gastrointestinal Bleeding

Approximately 5% of patients have an undiagnosed source of bleeding after standard evaluation with upper endoscopy and colonoscopy (Zuckerman et al 2000). These cases of unexplained or obscure bleeding have posed a significant diagnostic challenge and are often reported to be of small bowel origin. Occult gastrointestinal bleeding in an adult is typically detected by a positive fecal occult blood test (FOBT) or the presence of iron deficiency anemia (IDA). By definition, with occult bleeding there is no evidence of visible blood loss to the patient or physician. Studies that have reviewed occult bleeding have found that these two presentations probably represent a continuum of the same clinical spectrum; FOBT can detect bleeding at any point in a process that may culminate in IDA (Rockey et al, 1998). The major cause of iron deficiency in developed countries is blood loss. In men, the blood loss is most commonly from the GI tract; in women, menstrual blood must also be considered (Rockey, 1999).

The American Gastrointestinal Association suggests the following standardized nomenclature to describe chronic gastrointestinal blood loss (Zuckerman et al 2000):

- **Occult bleeding** -- initial presentation of an FOBT and/or IDA with no visible blood loss.
- **Obscure bleeding** -- bleeding of unknown origin that persists or recurs (may be visible or occult) after a negative initial upper or lower endoscopy.
- **Obscure-occult** -- recurrent IDA and/or recurrent FOBT
- **Obscure-overt** -- recurrent passage of visible blood

The United States Preventive Services Task Force (Pignone et al, 2002) and others recommend that clinicians screen for colon cancer in all patients over the age of 50 and younger patients with specific risk factors. Annual FOBT with flexible sigmoidoscopy every 5 years is one acceptable current method of screening. In spite of the fact that FOBT has a relatively low sensitivity and positive-predictive value, this approach has been associated with an up to a 33% reduction in mortality from colorectal cancer. As use of the FOBT as a screening tool gains wider acceptance, there are likely to be more patients identified with occult and obscure gastrointestinal bleeding in the future.
Evaluation of Occult and Obscure Gastrointestinal Bleeding

Many patients with occult bleeding will have the source of their bleeding localized with colonoscopy and/or upper endoscopy alone. Before examination of the small intestine, repeat upper endoscopy and colonoscopy is usually performed to identify lesions that were initially overlooked (Zaman et al, 1998, AGA 2000). In one study of 17 patients with obscure blood loss, 35 percent had a bleeding source identified on repeat endoscopy (upper endoscopy, 29 percent; colonoscopy, 6 percent) (Spiller et al, 1983). Lesions most commonly found with a "second look" or second opinion endoscopy include: erosions within large hiatal hernias (Cameron's erosions), peptic ulcer disease and vascular ectasia in the upper gastrointestinal tract, and angiodysplasia and neoplasia in the lower gastrointestinal tract (Zuckerman 1999) The American Gastrointestinal Association recommends that, in general repeat upper endoscopy and colonoscopy should be performed in the evaluation of occult or overt gastrointestinal bleeding prior to pursuing other procedures (Zuckerman 2000)

The small bowel is the most likely source of bleeding in patients with a negative upper and lower endoscopy in whom there is ongoing blood loss. The most common cause for GI bleeding of small bowel origin is angiodysplasia (70-80%), followed by tumors of the small intestine (primary benign or malignant tumors or metastatic lesions), small bowel ulcers (associated with non-steroidal anti inflammatory drugs), aortoenteric fistulas, diverticula, endometriosis, and hemobilia (Bashir 1996).

Capsule Endoscopy in the Evaluation of Obscure Bleeding

Wireless video endoscopy or Video Capsule Endoscopy (VCE) is a novel noninvasive technology designed primarily to provide diagnostic imaging of the small intestine. The Given M2A video capsule (Given Imaging, Ltd, Yoqneam, Israel) measures 11 mm x 26 mm, contains four light emitting diodes (LED), a lens, a color camera chip, two batteries, a radio frequency transmitter, and an antenna. Patients are asked to fast overnight after which an eight-lead sensor array is fastened to the abdomen. The array is connected to a solid state recorder and power pack worn on a belt around the patient’s waist. The video capsule is swallowed with water and is propelled by peristalsis through the gastrointestinal tract and is naturally excreted.
Capsule Endoscopy in the Evaluation of Obscure Bleeding, continued

There is no need for patients to retrieve the capsule after use. Clear fluids can be taken two hours after ingestion and food and medication can be taken four hours after ingestion. Patients may leave the medical facility during the 8-hour capsule endoscopy process though they are advised to refrain from strenuous activity during this time.

The capsule takes two images per second, which are transmitted as .jpg files to the recorder. The recorder acquires up to 50,000 images over approximately eight hours. The recorded images are then downloaded to a workstation and converted to a color video report for the physician to view and interpret. Review of the video, selection of representative images and generation of a report can take 45 to 90 minutes. Clinically important abnormalities may be represented on only one or two frames out of 50,000; thus, significant concentration is required during the review of images. The video may be reviewed as slowly as one frame at a time to 25 frames per second (standard video speed). The capsule is capable of viewing objects having a size of less than 0.1 mm; this is a higher magnification than obtained with conventional endoscopes. (Yu 2001; Iddan et al 2000; Seidman 2002)

Capsule endoscopy has several possible advantages compared to other means of visualizing the small bowel in the evaluation of patients with obscure bleeding. It is noninvasive and can be performed as an ambulatory procedure. There is no need for patient sedation or exposure to radiation. Capsule endoscopy permits examination of the majority of the small bowel mucosa, which is not possible with push enteroscopy. Radiologic techniques as well as intra-operative enteroscopy do examine the whole length of the small bowel but are either insensitive in the evaluation of obscure bleeding (enterocolysis and small bowel follow through) or invasive.

Capsule endoscopy is contraindicated for use in patients with known or suspected gastrointestinal obstruction, strictures, or fistulas based on the clinical picture or pre-procedure testing and profile. The capsule may be retained in patients with strictures, which may not have been apparent even with enteroclysis. The capsule does not appear to cause obstruction but tumbles around above the narrowed segment and may need to be removed surgically in such patients (Rabenstein et al 2002). Therefore capsule endoscopy should probably not be performed in patients who either refuse surgery or are not surgical candidates.
Capsule Endoscopy in the Evaluation of Obscure Bleeding, continued

The main disadvantages of capsule endoscopy are that it does not permit tissue sampling or therapeutic intervention and it is unable to pinpoint the exact location of the abnormal finding. Localization of a lesion is done by educated guess (i.e. by assuming uniform transit through the small bowel and localizing the lesion as being a fixed distance from a known landmark such as the pylorus or the ileocecal valve) thereby potentially requiring the patient to have another invasive procedure to confirm the findings.

**TA Criterion 1: The technology must have final approval from the appropriate government regulatory bodies.**

On August 1, 2001 the FDA Center for Devices and Radiological Health cleared the Given Diagnostic Imaging System classified as a class II device under the generic name of Ingestible Telemetric Gastrointestinal Capsule Imaging System with special controls. The FDA used the DeNovo process which is neither PMA nor 510(K) and is used for the approval of low risk devices when neither of the other processes are deemed appropriate. The device is intended to be used for visualization of the small bowel mucosa as an adjunctive tool in the detection of abnormalities of the small bowel.

TA criterion 1 is met.

**TA Criterion 2: The scientific evidence must permit conclusions concerning the effectiveness of the technology regarding health outcomes.**

The usual outcomes assessed in the literature on GI bleeding include hospital mortality, length of hospital and intensive care unit stay, utility of diagnostic and therapeutic procedures, success of therapy in prevention of recurrence of bleeding, transfusion needs and repeat hospitalization.

Many of these outcomes are not relevant in the evaluation of procedures for the evaluation of obscure and occult GI bleeding. Instead, outcomes assessed in these studies include the relative sensitivity and specificity of the various procedures in localizing a bleeding source, the time from disease onset to diagnosis, recurrent bleeding, the therapeutic efficacy of the procedure and the relative costs of the evaluation.
TA Criterion 2, continued

Therefore, the few published studies on capsule endoscopy in the evaluation of patients with obscure intestinal bleeding are case reports or non-randomized comparative trials (Appleyard 2001; Gay et al 2002; Lewis and Swain 2002). The main outcome measure is the identification of a bleeding site. Other outcomes include the ability of the procedure to guide subsequent therapy and patient acceptance of the procedure. Much of the literature reporting on outcomes of capsule endoscopy are published as abstracts; these are not considered in this review. Currently, there is insufficient evidence to conclude if capsule endoscopy provides substantial benefits to important health outcomes and is safer or more beneficial than existing technologies.

TA criterion 2 is partially met.

Levels of Evidence: 3,5

TA Criterion 3: The technology must improve the net health outcomes.

Animal Studies

Appleyard (2000), compared the sensitivity, specificity, and safety of capsule endoscopy and push enteroscopy in detecting small-bowel lesions in a canine model. Nine to 13 radiopaque, colored beads (3-6 mm diameter) were sewn in random order inside 9 canine small bowels, half within the first meter, and confirmed on x-ray. After recovery, the number, order, and color of beads were assessed in 23 capsule endoscopies and 9 push enteroscopies in a random order. The surgeons, push enteroscopists, capsule video interpreters, and pathologist were blinded to the others’ findings. The capsules identified more beads than push enteroscopy (median, 6 [range, 2-9] vs. 3 [range, 2-6 beads]; P < 0.001). The sensitivity of the capsule was 64% compared with 37% for push enteroscopy. The specificity was 92% for capsule endoscopy and 97% for push enteroscopy. The capsules identified significantly more beads beyond the reach of the push enteroscope (median, 4 [range, 2-7] vs. 0; P < 0.0001). Hair, ingested plastic, ulceration, submucosal swelling, and worms were clearly identified by the capsule. The capsules passed safely through the animals with no significant histologic findings. They conclude that wireless capsule endoscopy detected more abnormalities in the small bowel than push enteroscopy.
TA Criterion 3, continued

Case Series

In a letter to the New England Journal of Medicine, Appleyard et al (2001) describe their experience using wireless capsule endoscopy (Given Imaging, Yokneam, Israel) with four patients to assess obscure or uncontrolled bleeding. Patient 1 was a 60-year-old woman with hereditary hemorrhagic telangiectasia who required transfusion of 12-15 units of blood per year. Treatment with estrogen and enteroscopy had reduced her transfusion requirement to 4 units per year. Capsule endoscopy revealed angiodysplasias in the stomach, duodenum and proximal jejunum and actively bleeding lesions in the jejunum and ileum. Bleeding stopped spontaneously in this patient and the capsule endoscopy results did not alter her evaluation or clinical course. Patient 2 was a 39-year-old man with hereditary hemorrhagic telangiectasia who required transfusion with 10 units of blood every 2 months. Capsule endoscopy revealed 8 angiodysplasias in the duodenum and proximal jejunum and 3 in the large bowel not seen during recent colonoscopy. No lesions were seen in the distal small bowel. As a result of the capsule study, intraoperative enteroscopy was not performed in this patient, but it should be noted that the sources of bleeding were within reach of conventional endoscopy and colonoscopy (as is true for 28-75% of patients with obscure bleeding) (Zaman A et al, 1998). Patient 3 was a 16-year-old boy with melena and a previous GI bleed at age 2. He presented with anemia and a evaluation with colonoscopy, push enteroscopy and Meckel scanning failed to reveal the source. Capsule endoscopy also failed to reveal the source of bleeding, though the planned intraoperative enteroscopy was averted. Patient 4 was a 78-year-old man with multiple gastrointestinal angiodysplasias requiring 72 units of blood per year. He had previously undergone treatment with bipolar electrocoagulation which reduced his transfusion requirement in half. Capsule endoscopy revealed multiple angiodysplasias affecting only the proximal small bowel and continued treatment of these, presumably with push enteroscopy, was recommended.
TA Criterion 3, continued

Case Report

In a case report accepted for publication, Gay et al (2002 in press) describes a patient with obscure gastrointestinal bleeding in whom the M2A Given Imaging capsule detected a bleeding lesion in the ascending colon of a patient that had been overlooked by previous endoscopic examinations. In brief, the patient, a 69 year-old woman on chronic anticoagulation, had multiple evaluations for obscure-overt bleeding from June 1996 to May 2001. During her last admission for work-up of hematochezia, the patient underwent 3 endoscopic evaluations (upper gastrointestinal endoscopy and colonoscopy), push enteroscopy, abdominal CT and a Meckel scan all of which failed to reveal the source of bleeding. Capsule endoscopy was performed which revealed a “spot of fresh red blood” in the right colon. After appropriate prep, colonoscopy was then repeated which identified a colonic Dieulafoys’s lesion about 20 cm distal to the ileocecal valve. The lesion was treated with endoscopically placed clips and the bleeding promptly ceased. While this is an interesting report, it does not lend support for the use of capsule endoscopy in the evaluation of obscure bleeding since as the author of this case report points out, “... the use of wireless capsule endoscopy to explore the colon is currently neither validated nor under investigation.”

Non Randomized, Comparative Trial

In this pilot study accepted for publication, Lewis and Swain (et al, 2000) compare the findings of capsule endoscopy and push enteroscopy in patients with obscure GI bleeding. Enrollment was limited to 20 patients between the ages of 21-80 who were referred for enteroscopy for obscure GI bleeding and who volunteered to undergo both capsule endoscopy and push enteroscopy. All patients had previously undergone colonoscopy, upper endoscopy, and small bowel series. Patients were excluded if they had a history of bowel obstruction (since the capsule could potentially cause bowel obstruction in patients with luminal narrowing), diabetes (potential delayed gastric emptying), pacemaker implantation or pregnancy. Capsule endoscopy was performed first using the Given M2A video capsule system; patients were observed for 8 hours after ingestion and asked to retrieve the capsule to confirm its integrity. All patients then underwent push enteroscopy without use of an overtube.
TA Criterion 3 (Non Randomized, Comparative Trial), continued

The two study physicians reviewed the capsule images separately; the second reviewer was blinded to the patient’s medical history and findings on push enteroscopy as well as to the results of the first physician’s review. Patients completed a questionnaire about their impression of the two procedures. Twelve women and 9 men volunteered for the study with an average age of 61. Patients had been bleeding for an average of 36.5 months, transfused an average of 28 units of blood, and undergone numerous procedures. All patients completed the study and there were no complications. Twenty of 21 capsules were recovered and found to be intact. Data from one capsule was lost and this patient was eliminated from the study. A bleeding site was discovered through the capsule exam in 11 of 20 patients: angioectasia (5); fresh blood (4); ileal ulcer (1) and tumor (1). Push enteroscopy found a cause of bleeding in 6 of 20 patients (angioectasia ) and two additional patients were found to have large hiatal hernias with Cameron lesions which were suspected to be the cause of hemorrhage. (These patients were not included in the analysis since the capsule was not used to evaluate patient’s stomachs.) Overall, the yield of push enteroscopy was 30% (excluding the 2 patients with Cameron lesions) which is consistent with other research. The yield of capsule endoscopy was 55%, and the results from capsule endoscopy were used to guide subsequent therapy. Capsule endoscopy found a source of bleeding in 5 of 14 patients with normal push enteroscopic exams. However, the difference between the two did not reach statistical significance. All patients preferred capsule endoscopy to enteroscopy.

TA criterion 3 is not met.

TA Criterion 4: The technology must be as beneficial as any established alternatives.

The established alternatives to capsule endoscopy for the evaluation of obscure bleeding include radiologic techniques such as small bowel follow through and enterocolysis; other radiographic modalities such as radioisotope bleeding scans, Meckels scans and angiography; and endoscopic techniques such as push and sonde enteroscopy.
TA Criterion 4, continued

**Small bowel x-ray series and enteroclysis** are sometimes recommended for the initial evaluation of patients with suspected small bowel pathology. Ingestion of a barium suspension is used for the small bowel follow-through (SBFT) x-ray series, whereas enteroclysis is a double contrast study performed by passing a tube into the proximal small bowel (either directly or facilitated by endoscopy) and injecting barium, methylcellulose, and air. Diluted methylcellulose solution enhances the double-contrast effect, thereby improving the quality of the study. Although radiation exposure and patient discomfort are higher with enteroclysis, studies have documented significantly higher overall diagnostic yield, higher sensitivity, and shorter procedure times than with SBFT (Dixon et al, 1993). However, both techniques have performed poorly in studies when used to evaluate patients for occult and obscure bleeding. Yield of enteroclysis in the evaluation of patients with obscure bleeding range have been reported to be in the range of 10%, (Rex et al, 1989), 11% (Antes et al, 1996) and 25% (Moch et al, 1994). In addition to relatively low diagnostic yields, other disadvantages of these radiological techniques include the inability to visualize flat/mucosal lesions and patient exposure to radiation.

**Push enteroscopy** has evolved into the standard approach for further evaluation of obscure bleeding, facilitated by the availability of long videoscopes and relative ease of use. The depth of insertion past the ligament of Treitz can range from 40-60 cm, and longer with the use of an overtube (Lewis et al, 1999; Davies et al, 1995). Studies addressing the yield of push enteroscopy in the investigation of obscure GI bleeding report a diagnostic yield of 38 to 75 percent, with angiodysplasia being the most common lesion identified (Waye 2001; Chong et al 1994). In one study, many of the lesions detected (and treated) during push enteroscopy were within reach of a standard endoscope (Zaman et al, 1998). Push enteroscopy appears to be a relatively safe procedure, with a low incidence of complications, some of which are related to the overtube. Complications reported include post-procedure abdominal pain, acute pancreatitis, Mallory-Weiss tear with bleeding requiring cauterization, and a pharyngoesophageal tear (Chong, J, et al, 1994). Other disadvantages of push enteroscopy include patient discomfort, need for patient sedation and its inability to examine the entire small bowel (up to one-third of the 22-foot small intestine). Advantages include the fact that there is a potential for treating and/or performing a biopsy on identified lesions, its ease of use and relatively brief examination time.
TA Criterion 4, continued

**Sonde enteroscopy** was developed in the late 1970s and provides the potential for direct examination of the entire small bowel mucosa. After transnasal or oral passage into the stomach, the tip is dragged into the proximal small bowel with the aid of an endoscope. Intrinsic gut peristalsis can propel the balloon at the tip of the endoscope to the terminal ileum (Gostout et al, 1996). The endoscopic examination is performed during withdrawal of the instrument. In one study, Sonde enteroscopy detected the site of small bowel blood loss in 33% of 60 patients with obscure GI bleeding. (Lewis et al, 1988) Sonde-type enteroscopy is less popular than push-type enteroscopy and in fact is rarely used today. In contrast to the push enteroscope, Sonde enteroscopy does not allow for biopsy or therapy of visualized lesions. In addition, patient discomfort is aggravated by the length of the procedure (average insertion time, four hours; average withdrawal/examination time, 45 minutes) and mucosal visualization is more limited. The advantage of Sonde enteroscopy is the potential for total small bowel examination; serious complications such as bowel perforation are uncommon.

**Retrograde enteroscopy** or ileoscopy involves examination of the distal ileum at colonoscopy using a standard colonoscope, a small bowel enteroscope, or a smaller endoscope passed through the instrument channel of a specially designed therapeutic colonoscope (Waye 1992).

The ileocecal valve is intubated 72 to 79 percent of the time at routine colonoscopy. In a study in which push enteroscopy from above was combined with retrograde ileoscopy (using a small bowel enteroscope) in the investigation of obscure GI bleeding and IDA, ileoscopy provided a diagnosis in only 1.3 percent of cases (Waye 1992).

**Intraoperative enteroscopy** (IOE) is usually applied in cases of transfusion-dependent bleeding that is not localized in spite of extensive diagnostic evaluation, with or without preceding nonoperative enteroscopy. In these instances, the severity of the blood loss warrants further work-up, and the risks of continued bleeding outweigh the risks of laparotomy. Laparotomy has been coupled with the passage of an endoscope orally, transnasally (using a Sonde endoscope), per rectum, or through enterotomies performed on the small bowel. The endoscope is advanced through the small bowel with the assistance of the surgeon, who pleats the small bowel over the endoscope.
TA Criterion 4, continued

The lights in the operating room are lowered, and while the endoscopist examines the luminal aspect, the surgeon examines the transilluminated serosal aspect of the small bowel (Ress et al 1992). When performed for obscure GI bleeding, the ability of IOE to identify potential bleeding lesions has been impressive, ranging from 70 to 100 percent. However, finding a lesion does not always equate to cessation of bleeding.

Radioisotope bleeding scans may be helpful in localizing the site of obscure-overt bleeding, although there are few studies specifically addressing this approach. The in vitro technetium 99m-labeled red blood cell (TRBC) scan is the most used method of radioisotope scanning, its advantage being the long half-life of the label, which allows for repeat scanning if necessary over a 24-hour period. The TRBC scan requires a bleeding rate of 0.1 to 0.4 mL/min (5 mL of intraluminal blood over the 1-2 hour acquisition time) for a positive result and is readily available and safe (Rantis et al, 1995)

Specific data on the utility of TRBC scans in obscure GI bleeding are limited. In a preliminary report, 24 percent of all positive TRBC scans performed for presumed acute lower GI bleeding were localized to the small bowel (Zuckerman, Prakash 1998).

It is unknown if these data can be applied to obscure bleeding cases. Because of the significant false localization and miss rates, verification with an alternate test such as angiography or endoscopy is usually necessary before an invasive therapeutic intervention is made.

Meckel's scanning using 99mTc-pertechnate is also used for the evaluation of small bowel bleeding. The sensitivity is reported to be 75 to 100 percent (Brown et al, 1988). However, a positive scan result only indicates the presence of gastric mucosa in the small bowel, which may or may not represent the bleeding source.

Angiography can detect bleeding at a rate of 0.5 mL/minute. This technique can localize a site of bleeding in 50% to 72% of patients with massive hemorrhage, but this rate decreases significantly when the bleeding has slowed or stopped (Browder 1986). Angiography can identify lesions that are not actively bleeding by demonstrating typical vascular patterns seen in angiodysplasia and neoplasia. The role of angiography in obscure bleeding is difficult to assess, however, because a limited number of angiographic protocols specifically address obscure bleeding.
**TA Criterion 4, continued**

**Small bowel biopsy** — Celiac disease may be an under-appreciated cause of occult GI bleeding and IDA. Small bowel biopsy performed during upper endoscopy or enteroscopy may be used to detect celiac sprue as a cause of IDA. Although as many as one half of anemic patients with untreated celiac disease have iron deficiency, the prevalence in patients with IDA is much lower, 0 to 11 percent (Corazza et al, 1995).

Only one study (Lewis and Swain, 2002) compares the performance of capsule endoscopy with an existing technique (push enteroscopy) in the evaluation of obscure bleeding. In this non-randomized pilot study, they found that capsule endoscopy appeared to perform as well or better than push enteroscopy in locating previously undiagnosed bleeding sites, particularly in the distal small bowel out of reach of the push enteroscope. This finding needs to be confirmed by larger, randomized studies. In addition, it will be important to demonstrate that the additional information provided by capsule endoscopy leads to a significant improvement in clinical outcomes such as fewer bleeding episodes, less need for transfusions, fewer hospitalizations, fewer overall procedures, timely diagnosis of small bowel tumors and others.

TA criterion 4 is met.

**TA Criterion 5: The improvement must be attainable outside the investigational settings.**

Although capsule endoscopy is currently being used at a number of medical centers in the United States and abroad, the indications for its use and its exact role are not clear at the current time. When criteria 3 and 4 are satisfied, capsule endoscopy should be able to be used under the usual conditions of medical practice.

TA criteria 5 is met.

**RECOMMENDATIONS OF OTHERS**

**Blue Cross Blue Shield Association**

Reviewed by BCBSA/TEC April 2002 with the following determination:

Wireless capsule endoscopy is considered investigational as a technique to identify the source of gastrointestinal bleeding or other gastrointestinal pathology.
**American College of Radiology**

The College does not have a formal position regarding this technology and is unable to provide representation at the meeting.

**California Radiological Society**

A position/concensus statement and representation at the meeting have been requested.

**American Society of Gastrointestinal Endoscopy**

The ASGE has provided a status evaluation report regarding wireless capsule endoscopy. The summary notes as follows:

“Wireless capsule endoscopy is a new technology that allows visualization of the small bowel. Further research and experience are required to assess the role of wireless capsule endoscopy in the evaluation and management of digestive tract disorders.”

Representation at the meeting has been requested.

**American Gastroenterology Association**

A position/concensus statement and representation at the meeting have been requested.

**Medicare (CMS)**

CMS does not have a formal national policy regarding Capsule Endoscopy.

Nineteen states, including California currently have coverage policy regarding the use of capsule imaging endoscopy.
CONCLUSION

Standard evaluation with upper endoscopy and colonoscopy fails to reveal the source of bleeding in approximately 5% of patients (Richter 1994). These cases have posed a significant diagnostic challenge. Unexplained, or obscure, bleeding is frequently reported to be of small bowel origin, up to 75% of patients in one review (Chong et al, 1994). The small bowel is difficult to access in its entirety, however, and even when this is accomplished angiodysplastic and other small, flat lesions responsible for the bleeding may be overlooked. A number of diagnostic strategies have been developed to examine and treat small bowel pathology, specifically bleeding thought to be of small bowel origin, but all have significant problems. Patient discomfort, the need for sedation and its inability to reach half of the small bowel limit the utility of push enteroscopy. Radiologic studies such as enterocolysis have poor sensitivity in the evaluation of obscure bleeding, and intraoperative enteroscopy will always be reserved for the most challenging cases.

There is clearly a need for new and better techniques for the evaluation of patients with obscure bleeding of small bowel origin. More comparative research is needed to determine if capsule endoscopy can help fill this important gap in the gastroenterologic diagnostic armamentarium.

RECOMMENDATION

It is recommended that the Given M2A video capsule system does not meet Blue Shield TA criteria.

Committee approval as follows:

It is recommended that use of wireless capsule endoscopy in obscure digestive tract bleeding suspected to be of small bowel origin meets Blue Shield TA criteria.

Use of wireless capsule endoscopy in all other settings does not meet Blue Shield TA criteria.

October 16, 2002

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