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# Medicare

## **Comments and Responses Regarding Draft Local Coverage Determination: Endoscopy by Capsule**

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As an important part of Medicare Local Coverage Determination (LCD) development, National Government Services solicits comments from the provider community and from members of the public who may be affected by or interested in our LCDs. The purpose of the advice and comment process is to gain the expertise and experience of those commenting.

We would like to thank those who suggested changes to the draft Endoscopy by Capsule LCD. The official notice period for the final LCD begins on April 15, 2009, and the final determination will become effective on July 1, 2009.

**Comment:** (1) A commenter stated that capsule endoscopy has grown in use for Crohn's and inflammatory bowel disease, but added that an upper GI endoscopy was not needed prior to the capsule. Capsule can even be useful when there are strictures or stenosis by showing where the pathology is located. He was asked if it should be payable for any patient with irritable bowel. He indicated that if there were alarm symptoms present, it should. These are weight loss, malabsorption, obstructive physiology; situations where other studies have been done but symptoms still remain. The indications should be individual for each patient. He was asked if endoscopy needs to be done at all, or just not repeated. He asked if there any studies comparing capsule endoscopy to endoscopy as the first procedure. He did not know of any studies but has data comparing capsule to other procedures.

He feels that the decision for when lower and upper endoscopies are done prior to capsule should be left to the physician. For Crohn's disease, he does not always do a colonoscopy first but usually performs one after capsule.

(2) The commenter indicated the patient population that he cares for is quite diverse, as he is in clinical private practice, but also teaches within the Yale New Haven Hospital System, thereby allowing him to see a wide demographic of patient population and a wide diversity of disease pathology. He has been employing capsule endoscopy in his practice for several years and interprets the images for a large group of referring clinicians in the New Haven area. He has first hand knowledge of the benefit of this clinical tool in the diagnosis of small bowel disease, including inflammatory bowel disease, neoplasia,

and occult sources of gastrointestinal blood loss. Given the fact that he has found this tool to be an invaluable clinical device, he would strongly support allowing individual practicing clinicians to individualize care for their patients without requiring prerequisite endoscopic and colonoscopic evaluations in order for NGS to validate use of capsule endoscopy. Specifically, for the evaluation of patients with suspected small bowel Crohn's disease, he would strongly encourage the committee to validate the use of capsule endoscopy without requiring a conventional endoscopy prior to capsule endoscopy. In addition, he would encourage NGS to allow a prior colonoscopy within the prior 3 years to serve as an acceptable study for prerequisite testing, if performed for the same symptoms.

Again, however, he would above all else, strongly encourage that the discretion be left up to the practicing gastroenterologist to individualize care for each individual patient and thereby would preference no prerequisites for capsule endoscopy.

**Response:** Multiple commenters have noted that the upper GI tract is rarely affected by Crohn's disease, with which we agree. The requirement for prior upper and lower endoscopies has been based on the use of this test for diagnosis of occult bleeding or iron deficiency anemia of undetermined etiology. Certainly, in those instances in which there is a very high index of suspicion of Crohn's disease, the performance of an upper endoscopy should not be necessary. As discussed at the Open Meeting, however, the likelihood that a patient would require a colonoscopy even if Crohn's disease were discovered on capsule, and also if Crohn's disease were not diagnosed on capsule, justifies the retention of this prerequisite for the test. The suggestion that colonoscopies be considered as meeting the prerequisite, if performed within three years of the capsule, is problematic. If the patient was not symptomatic at that time or the colonoscopy was performed for unrelated symptoms then it might not be medically relevant. In such instances the colonoscopy should be repeated. We believe that the endoscopic procedures should be performed during and related to the same episode of care for which the capsule test is performed. We will revise the LCD to clarify the need for upper endoscopy and that colonoscopies must be related to the current episode of care.

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**Comment:** A commenter asked if ICD-9-CM code 579.0 (celiac disease) should be included.

**Response:** NGS will respectfully decline to add this diagnosis code.

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**Comment:** A question was asked if one suspected Crohn’s disease, what clinical signs and symptoms beyond abdominal pain would be expected. It was stated that with blood in the stool, one would do an endoscopy before using the capsule.

**Response:** We agree that upper and lower endoscopy should be performed prior to considering capsule in patients with documented bleeding, or iron deficiency anemia.

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**Comment:** A commenter presented information on the role of capsule endoscopy imaging of the small bowel mucosa and provided references supporting the use of this technique in patients with Crohn’s disease. They would like the draft LCD for Endoscopy by Capsule to be updated to include this indication which was understood to mean in the evaluation of patients with Crohn’s disease.

**Response:** NGS agrees that there is application of this technique, albeit limited, for the diagnosis of Crohn’s disease. As already indicated, the selection of individual patients for this testing needs to be appropriate, and the sequence of testing must also be appropriate.

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**Comment:** A commenter requested a clarification regarding the “Indications” paragraph addressing “Small Bowel Neoplasm.” It was not clear what tests were required prior to use of capsule endoscopy for detecting small bowel neoplasms.

**Response:** The patient must be symptomatic for a neoplasm (e.g., GI bleeding) or have a documented polyposis syndrome that is associated with small bowel neoplasia or there is other history suggesting the presence of small bowel neoplasia and other diagnostic testing to assess these symptoms (i.e., upper GI endoscopy and/or colonoscopy) must have been performed.

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**Comment:** A commenter questioned the requirement to have both upper and lower endoscopy prior to the capsule endoscopy for patients with Crohn’s disease. Most physicians agree that the lower GI is

customary, but question how the upper GI endoscopy would be helpful. They also asked about excluding upper GI endoscopy for abdominal complaints when there is no GI bleeding.

**Response:** In those instances in which there is a very high index of suspicion of Crohn's disease, the performance of an upper endoscopy should not be necessary. The likelihood that a patient would require a colonoscopy even if Crohn's were discovered on capsule and also if Crohn's were not diagnosed on capsule, justifies the retention of this prerequisite for the test. We will revise the LCD regarding the need for upper endoscopy.

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**Comment:** A commenter mentioned that a colon capsule has now been developed but it is not ready for "prime time" yet. Olympus Corporation is also now making the capsule, so references to "Given" should be removed from the LCD.

**Response:** We appreciate the comments. We will revise the LCD to remove any brand identification.

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**Comment:** A commenter wrote to urge NGS not to change its longstanding Medicare policy not to require a Barium Small Bowel Series prior to Video Capsule Endoscopy [VCE] of the small bowel.

In the early years of Capsule endoscopy Medicare did require a prior SBFT. The clinical experience and data showed that barium studies are essentially useless prior to a VCE especially in cases of occult bleeding. In fact, in his 20 years as a clinical gastroenterologist at a major academic Medical Center, he has never had a single small bowel series show any useful data in GI Bleeding cases. It's only use is to R/O obstruction. In such cases, we would not be considering a Video Capsule study.

Turning back the clock by imposing this requirement will only add costs, inconvenience and unnecessary expose patients to radiation with little or no benefits.

There are several published studies using the new Given Agile Patency Capsule in Crohn's disease patients even with known jejunal and ileal strictures. Those studies show that a standard Small bowel follow through [SBFT] is very poor if not useless in predicting Capsule retention even in Crohn's disease patients with known strictures. The Patency system is not yet in widespread use due to the costs of the scanner and the lack of universal coverage by insurance.

As you may know, overall Capsule retention is very rare in non-IBD patients, much lower in the real world than the 0.75% quoted number. He never had a retained capsule in a non-IBD patient. He had one single capsule get delayed in an unsuspected Crohn's disease patient. The capsule passed after 24 hours of steroids and the small bowel series and CT-scan did not define a stricture that we uncovered intra-operatively.

**Response:** The requirement for small bowel series, in the LCD, is limited only to those patients having Crohn's disease, and therefore in whom a stricture that could prevent passage of the capsule is possible. It is not required for all patients with bleeding. We are aware that the incidence of capsule-induced obstruction is very low. Rather than subject all at-risk patients to a small bowel x-ray to seek an obstruction that would only occur rarely, we will revise the LCD to exclude this and leave this issue to the judgment of clinicians.

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**Comment:** A commenter wrote that based upon the published literature and physician clinical use of capsule endoscopy, they request that the proposed draft changes related to the indication of 'suspected' Crohn's disease patients be stricken from the final NGS LCD and that the existing NGS LCD language remain unchanged. By keeping the language in its current version, it allows physicians the clinical discretion to appropriately choose the most appropriate sequence of diagnostic tests to use based upon the patients presenting symptoms and medical history.

As we are aware, capsule endoscopy is considered the "gold standard" to view and image the small intestine, and has been demonstrated to play an important role in the diagnostic evaluation of patients with gastrointestinal symptoms. Another advantage is that it is a minimally invasive tool, requiring no anesthesia or sedation, and does not require the use of an endoscopic suite. To that end, it could easily be the initial endoscopic test performed in the patient work-up.

Thus, we request the language remain as is written in the existing guideline for the indication of suspected Crohn's disease as noted below:

*Capsule endoscopy may be reasonable without the patient having undergone upper GI endoscopy and colonoscopy.*

They also believe a required SBFT prior to capsule endoscopy may be unnecessary if the requirement is due to a concern with capsule retention. As documented in the ICCE consensus statement, the risk of capsule retention for the suspected Crohn's disease patient is very low (1.5%). Additionally, there is an added concern for the Crohn's disease patient related to the high levels of diagnostic radiation associated with SBFT.

Lastly, 30% of Crohn's disease is limited to the small bowel, and capsule endoscopy not only provides more information about disease extent provides images which can be of use in determining the most appropriate medical therapy.

If retention or strong suspicion of stricture is a concern, the Agile patency capsule offers a viable solution. It is a low cost, non-imaging, dissolvable capsule that is swallowable by the patient and at 30 hours begins to dissolve. The body of the capsule is lactose mixed with 10% barium to make it radio-opaque and it contains an RFID tag to determine capsule location. If Agile capsule is excreted within 30 hours, patency is confirmed and the physician can proceed with the ingested video imaging small bowel capsule.

A study by Herrerias demonstrated that the Agile patency system eliminated the risk of capsule retention in patients with known intestinal strictures. The non-imaging Agile capsule may determine whether patients who have a contraindication to video imaging small bowel capsule endoscopy. Once known, the patient may safely proceed to undergo the video imaging small bowel capsule endoscopy and the physician may obtain useful diagnostic information.

**Response:** Title XVIII of the Social Security Act requires that all services reimbursed under Medicare be reasonable and necessary of the treatment or diagnosis of the beneficiary. This extends to those services provided as diagnostic tests (see also 42 CFR 410.32). Furthermore, these tests must be utilized in the care of the patient and influence the patient outcomes. The sequence of testing is important in this regard, especially if duplicative information results from performing multiple tests.

In a condition in which only 30% of cases have disease confined to the small intestine, other sites accessible by other tests could be successful in making a diagnosis in approximately 70% of patients. A previous commenter has specifically stated that if the diagnosis of Crohn's disease were made by capsule virtually all of his patients would still undergo colonoscopy to evaluate the large intestine. The capsule would not obviate the need for colonoscopy. Furthermore, since these are patients with suspected Crohn's disease, those patients not having Crohn's disease on testing may indeed have disease outside of the small bowel thereby making other tests even more fruitful. For example, if Crohn's disease was not diagnosed on capsule, colonoscopy would still be performed in a patient with symptoms significant enough to warrant the use of the capsule.

The contractor therefore respectfully declines this request to unconditionally forego colonoscopy prior to capsule testing.

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**Comment:** A commenter indicated he would like to take this opportunity to express his support for capsule endoscopy medical technology which has been used for at least the last 8 years by

gastroenterologists and found to be a very effective and informative test in management of patients with unresolved gastrointestinal issues .Capsule endoscopy is the ONLY test available to examine the small intestine , and showed to be more reliable than other radiological tests especially in view of eliminating the risk of radiation exposure with capsule endoscopy mainly in young patients who mostly require this test.

Capsule Endoscopy of the small bowel has proven to be an invaluable asset to his practice affecting the management and treatment decisions related to patients with abnormalities of the small bowel.

He strongly recommends the following changes to the NGS draft LCD expressly for the guidelines for the patient suspected of Crohn's disease:

- a. Eliminate the mandate for pre requisite tests prior to CE, because patients present differently and decisions should be based upon the present symptoms and the history.
- b. Allow the physician the make the discretionary choice of which diagnostic procedure is most appropriate based upon the clinical presentation of the patient.
- c. 30% of patients have Crohn's disease exclusively in the small bowel, why not begin with a minimally invasive procedure? You may or may not need additional endoscopic procedures to reach a diagnosis and begin a plan a treatment plan.

ASGE Report (2006), CE is considered the 'first line' test for visualizing the mucosa of the small bowel intestine.

The indications are listed are:

- Obscure GI bleeding-including iron deficiency anemia,
- suspected Crohn's disease,
- suspected small intestinal tumors and surveillance in patients with polyposis syndromes,
- suspected or refractory malabsorptive syndromes (egg, celiac disease).

Capsule Endoscopy (CE) should be covered as a first-line diagnostic tool for abnormalities of the small bowel as stated in the ASGE Clinical Update of July 1, 2006:

CE has a higher diagnostic yield than other small bowel examinations including:

- Small-bowel radiographs,
- Push enteroscopy,
- CT scan.

These tools are inferior to CE in finding flat or subtle lesions such as angioectasias, superficial erosions or ulcers.

In 2003, the FDA removed the "adjunctive tool" qualifier recognizing CE as a first-line diagnostic tool.

Capsule endoscopy should not be listed as an adjunct to conventional endoscopy, CE is a diagnostic tool that allows him to evaluate a significant portion of the intestine that is difficult to visualize by other means.

Based upon the patient's history and the presenting symptoms, he believes he is the best judge of the appropriate procedure and the sequence to which they be performed.

- CE is an invaluable tool for finding small bowel disease quickly and possibly at a more curable stage.
- CE is a cost-effective procedure often mitigating the need for excessive and less-specific tests.
- CE is highly specific; therefore, patients with negative capsule studies in most instances do not have disease of the small intestine and this is VERY important to determine.
- Diarrhea and abdominal pain are frequent complaints commonly evaluated by gastroenterologists. It is often determined that patients with these symptoms have a final diagnosis of IBD or IBS. For anemic patients with similar symptoms, Celiac sprue or small bowel neoplasms may be the final outcome. The point is why not begin the initial work up with a minimally invasive procedure (CE) that views the entire small bowel vs. the alternative?
- Many times, these patients undergo lengthy, inconclusive work-ups. A 2006 ASGE technology evaluation report recommends wireless CE as a primary diagnostic tool for patients with symptoms consistent with regional enteritis. Therefore, at this time he feels that NGS should maintain current coverage language for the suspected Crohn's disease population.
- If there are no guidelines for upper GI endoscopy & lower colonoscopy, why would there be restrictive utilization guidelines for the sequencing of performing Capsule Endoscopy (CE)? CE is the endoscope (without the tail) that views a middle intestine (small intestine) that the other endoscopic procedures cannot reach

Retention in the suspected Crohn's population is very minor (1.5%) And if you have strong suspicion of stricture, then an Agile procedure should be done prior to CE. It is specifically designed to show patency within the intestine to allow for the passage of an imaging capsule. It is much more effective and much less costly and more patient friendly than SBFT.

**Response:** Title XVIII of the Social Security Act requires that all services reimbursed under Medicare be reasonable and necessary of the treatment or diagnosis of the beneficiary. This extends to those services provided as diagnostic tests (see also 42 CFR 410.32). Furthermore, these tests must be utilized in the care of the patient and influence the patient outcomes. The sequence of testing is important in this regard, especially if duplicative information results from performing multiple tests.

In a condition in which only 30% of cases have disease confined to the small intestine, other sites accessible by other tests could be successful in making a diagnosis in approximately 70% of patients. A previous commenter has specifically stated that if the diagnosis of Crohn's disease were made by

capsule virtually all of his patients would still undergo colonoscopy to evaluate the large intestine. The capsule would not obviate the need for colonoscopy. Furthermore, since these are patients with suspected Crohn's disease, those patients not having Crohn's disease on testing may indeed have disease outside of the small bowel thereby making other tests even more fruitful. For example, if Crohn's disease was not diagnosed on capsule, colonoscopy would still be performed in a patient with symptoms significant enough to warrant the use of the capsule.

The contractor therefore respectfully declines this request to unconditionally forego colonoscopy prior to capsule testing.

The diagnosis of celiac disease is still based upon endoscopic appearance coupled to biopsy, or serologic testing. Consequently, we respectfully decline to include this diagnosis as supporting medical necessity.

We appreciate the physician's rather lengthy comments, lauding the use of the capsule and recommending its use as the primary and initial test of choice. However, he has presented no studies to document the superiority of the capsule relative to endoscopy for the evaluation of patients with abdominal pain, diarrhea, and presumably bleeding. It is unclear that the small bowel is the most common location of pathology responsible for these signs and symptoms, and therefore it would not be efficient to utilize the capsule as the initial test. Furthermore, his assertion that a negative capsule test has a high sensitivity and negative predictive accuracy while laudable, is problematic since the purpose of the testing is to identify the source of the signs and symptom and not to pronounce the small bowel uninvolved.

Consequently, the contractor declines to revise the LCD other than as already noted to delete the requirement for prerequisite upper endoscopy and small bowel follow through when suspecting Crohn's disease.

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**Comment:** A commenter indicated he is part of an 8 person gastroenterology practice that has existed in Fairfield, CT for over 30 years. They were actually the first practice to perform a capsule endoscopy in the state of Connecticut. Their practice has now performed approximately 600 capsule studies. It has come to his attention that new regulations regarding the use of capsule endoscopy are being considered. If understood correctly, it would require that a small bowel series be obtained prior to approval of a capsule study in cases of Crohn's disease. He thinks it is important to point out that capsule endoscopy has greatly advanced our ability to evaluate the small bowel precisely due to the limitations and inaccuracies that small bowel series and even CT scanning have had. While both small bowel follow through and CT have a role in evaluating these patients it is wasteful and potentially harmful to assume that all patients with suspected Crohn's disease require this type of evaluation prior to a capsule. Exposure to radiation is an issue that must be considered given many of these patients are

young and are facing many years of periodic testing. The mandate to have all of these patients undergo this testing seems foolish after years of accumulated data has shown the capsule to be the single most accurate tool for investigating the small bowel mucosa. It is minimally invasive, very well tolerated and has facilitated the diagnosis of many forms of small bowel abnormalities. In an era when cost is always a consideration the small bowel series would almost certainly simply place another step in the work up of these patients rather than serve as a substitute for the capsule. Studies have demonstrated how inaccurate small bowel series are for not only subtle mucosal disease but also problems as serious as strictures and even tumors. It can be a helpful tool for the evaluation of Crohn's disease as well as other GI disorders but making it a mandatory step will not be beneficial to patient care. An additional consideration will be the trickle down effect to managed care. Unfortunately experience has clearly shown that private insurers will take advantage of any opportunity to limit the use of a tool like capsule. The precedent Medicare sets is often used as a guideline for managed care and that would be unfortunate in this case.

**Response:** We appreciate the physician's comments and advice. Based upon this and other comments regarding the small bowel studies, we agree that the incidence of strictures in this population may not justify its mandatory performance in the presence of physicians exercising good clinical judgment. We will revise the LCD to exclude this requirement.

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**Comment:** A commenter indicated it has come to his attention that NGS is considering a change to its LCD regarding capsule endoscopy. Capsule endoscopy of the small bowel has proven to be an invaluable tool and asset to his practice affecting the management and treatment decisions related to patients with abnormalities of the small bowel. He strongly recommends the following changes to your draft LCD for the guidelines of patients with suspected Crohn's disease:

- Eliminate the mandate for prerequisite tests prior to capsule endoscopy because patients present differently and decisions should be based upon the present symptoms and the patient's history.
- Allow the physician to make the discretionary choice of which diagnostic procedure is most appropriate and cost effective based upon the clinical presentation of the patient.
- 30% of patients who have Crohn's disease have the disease exclusively in the small bowel. Why not begin the patient's evaluation with a minimally invasive procedure? You may or may not need additional diagnostic procedures to diagnose the patient's disease which would be a tremendous cost savings.

The ASGE Clinical Update of July 1, 2006, stated, and he agrees, capsule endoscopy should be covered as a first-line diagnostic tool for abnormalities of the small bowel. Capsule endoscopy has a higher diagnostic yield than other small bowel examinations including: small bowel radiographs, push

enteroscopy, and CT scan. These tools are inferior to capsule endoscopy in finding flat or subtle lesions such as angioectasias, superficial erosions or ulcers.

As we probably know, the FDA removed the “adjunctive tool” qualifier recognizing capsule endoscopy as a first-line diagnostic tool. Again, capsule endoscopy is a diagnostic tool that allows me to evaluate a significant portion of the intestines that is difficult to visualize by any other means.

Based upon the patient’s history and presenting symptom complex, he believes he is the best judge of the appropriate diagnostic procedure or procedures and sequence to which they should be performed. Many times these patients undergo lengthy, expensive, inconclusive work-ups prior to being allowed the capsule endoscopy. At this time, he feels that NGS should maintain the current coverage language for the suspected Crohn’s disease population.

**Response:** We thank the physician for his comments.

Title XVIII of the Social Security Act requires that all services reimbursed under Medicare be reasonable and necessary of the treatment or diagnosis of the beneficiary. This extends to those services provided as diagnostic tests (see also 42 CFR 410.32). Furthermore, these tests must be utilized in the care of the patient and influence the patient outcomes. The sequence of testing is important in this regard, especially if duplicative information results from performing multiple tests.

In a condition in which only 30% of cases have disease confined to the small intestine, other sites accessible by other tests could be successful in making a diagnosis in approximately 70% of patients. A previous commenter has specifically stated that if the diagnosis of Crohn’s disease were made by capsule virtually all of his patients would still undergo colonoscopy to evaluate the large intestine. The capsule would not obviate the need for colonoscopy. Furthermore, since these are patients with suspected Crohn’s disease, those patients not having Crohn’s disease on testing may indeed have disease outside of the small bowel thereby making other tests even more fruitful. For example, if Crohn’s disease was not diagnosed on capsule, colonoscopy would still be performed in a patient with symptoms significant enough to warrant the use of the capsule.

The contractor therefore respectfully declines this request to unconditionally forego colonoscopy prior to capsule testing.

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**Comment:** A commenter strongly recommends the following changes to our draft policy expressly for the guidelines for the patients suspected of having Crohn’s disease:

- a. Allow the physician the make the discretionary choice of which diagnostic procedure is most appropriate based upon the clinical presentation of the patient.

- b. Eliminate the requirement for upper esophagogastroduodenoscopy (EGD) prior to CE, as there are no studies showing clinical or cost effectiveness of such an approach. As patients present differently, decisions should be based upon the presenting symptoms, the history, and other diagnostic findings.

In 2006, the American Society for Gastrointestinal Endoscopy (ASGE) issued a Technology Status Evaluation Report on Wireless Capsule Endoscopy (Volume 63, No. 4: 2006 GASTROINTESTINAL ENDOSCOPY 539-545). The report notes the benefits of CE for visualizing the mucosa of the small bowel intestine in the evaluation of:

- Obscure GI bleeding-including iron deficiency anemia;
- Suspected Crohn's disease;
- Suspected small intestinal tumors and surveillance in patients with polyposis syndromes.

The report notes "Radiographic methods are relatively insensitive for flat or subtle lesions such as vascular malformations and superficial erosions or ulcers. In contrast, the global diagnostic yield of capsule endoscopy of the small bowel is about 65%. Hence, in 2003 the FDA modified the previous labeling of the Pillcam SB by removing its designation as an adjunctive tool and approving its use as a first-line test."

Based upon the patient's history and the presenting symptoms, the treating physician should be the best judge of the appropriate procedure and the sequence to which they be performed.

Further,

- CE is an invaluable diagnostic tool for the evaluation of the small bowel that may allow the physician to find small bowel disease quickly and possibly at a more curable stage.
- Requiring upper endoscopies prior to a small bowel capsule endoscopy to try to establish the diagnosis of Crohn's disease in a patient with indeterminate colitis will not reduce the number of capsule endoscopies, but will increase the costs for noncontributory upper endoscopies.
- CE is a cost-effective procedure often mitigating the need for excessive and less-specific tests.
- CE is highly specific; patients with negative capsule studies do not have disease of the small intestine.
- Diarrhea and abdominal pain are frequent complaints commonly evaluated by gastroenterologists. It is often determined that patients with these symptoms have a final diagnosis of inflammatory bowel disease (IBD) or irritable bowel syndrome (IBS). For Medicare beneficiaries that are anemic with diarrhea and abdominal discomfort, small bowel neoplasms may be the final outcome. Why not allow the physician to begin the initial work up with a minimally invasive procedure (CE) that views the entire foregut and small bowel?
- As retention in the suspected Crohn's population is very minor (1.5%), this should not be the sole reason for requiring a SBFT study which is less sensitive compared to CT enterography for the evaluation of patients with suspected CD. SBFT has poor sensitivity for mid gut Crohn's, ulcers, and strictures, and is unreliable for excluding stenosis of the small intestine.

**Response:** As noted in previous responses, NGS will remove the requirements for prior upper endoscopy and small bowel x-rays for capsule endoscopy when the diagnosis is for Crohn's disease. However, we believe that the need for colonoscopy persists even if Crohn's disease is made on capsule. Therefore, we will continue to require this procedure during the same episode of care. The commenter failed to present any data supporting the use of the capsule as the initial test for anemia or other gastrointestinal symptoms to support its use as the initial test. We would be interested in reviewing the supporting data from the scientific medical literature and encourage the commenter to forward such literature to us.