Protocol

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

(60133)

Medical Benefit		**Effective Date**: 01/01/15	**Next Review Date**: 09/20
Preauthorization	Yes	**Review Dates**: 02/07, 03/08, 11/08, 09/09, 09/10, 09/11, 09/12, 09/13, 09/14, 09/15, 09/16, 09/17, 09/18, 09/19	

Preauthorization is required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: • With suspected small bowel bleeding	Interventions of interest are: • Wireless capsule endoscopy	Comparators of interest are: • Standard workup for gastrointestinal bleeding without capsule endoscopy	Relevant outcomes include: • Test validity • Other test performance measures • Symptoms • Change in disease status
Individuals: • With suspected Crohn disease	Interventions of interest are: • Wireless capsule endoscopy	Comparators of interest are: • Ileocolonoscopy • Barium small bowel follow-through • Computed tomography enterography • Magnetic resonance enterography	Relevant outcomes include: • Test validity • Other test performance measures • Symptoms • Change in disease status
Individuals: • With suspected celiac disease	Interventions of interest are: • Wireless capsule endoscopy	Comparators of interest are: • Endoscopy with biopsy	Relevant outcomes include: • Test validity • Other test performance measures • Symptoms • Change in disease status
Individuals: • With unexplained chronic abdominal pain	Interventions of interest are: • Wireless capsule endoscopy	Comparators of interest are: • Standard workup for abdominal pain without capsule endoscopy	Relevant outcomes include: • Test validity • Other test performance measures • Symptoms • Change in disease status

Populations	Interventions	Comparators	Outcomes
Individuals: • With an established diagnosis of Crohn disease	Interventions of interest are: • Wireless capsule endoscopy	Comparators of interest are: • Ileocolonoscopy • Small bowel follow-through • Computed tomography enterography • Magnetic resonance enterography	Relevant outcomes include: • Test validity • Other test performance measures • Symptoms • Change in disease status
Individuals: • With ulcerative colitis	Interventions of interest are: • Wireless capsule endoscopy	Comparators of interest are: • Optical colonoscopy	Relevant outcomes include: • Test validity • Other test performance measures • Symptoms • Change in disease status
Individuals: • With esophageal disorders	Interventions of interest are: • Wireless capsule endoscopy	Comparators of interest are: • Endoscopy	Relevant outcomes include: • Test validity • Other test performance measures • Symptoms • Change in disease status
Individuals: • With hereditary gastrointestinal polyposis syndromes	Interventions of interest are: • Wireless capsule endoscopy	Comparators of interest are: • Ileocolonoscopy • Barium small bowel follow-through • Computed tomography enterography • Magnetic resonance	Relevant outcomes include: • Test validity • Other test performance measures • Symptoms • Change in disease status
Individuals: • With portal hypertensive enteropathy	Interventions of interest are: • Wireless capsule endoscopy	Comparators of interest are: • Endoscopy	Relevant outcomes include: • Test accuracy • Test validity • Other test performance measures • Symptoms • Change in disease status
Individuals: • With acute upper gastrointestinal tract bleeding	Interventions of interest are: • Wireless capsule endoscopy	Comparators of interest are: • Standard workup for gastrointestinal bleeding without capsule endoscopy	Relevant outcomes include: • Test validity • Other test performance measures • Symptoms • Hospitalizations • Resource utilization
Individuals: • Who are screened for colon cancer	Interventions of interest are: • Wireless capsule endoscopy	Comparators of interest are: • Optical colonoscopy	Relevant outcomes include: • Overall survival • Disease specific survival • Test accuracy • Test validity • Other test performance measures

Populations	Interventions	Comparators	Outcomes
Individuals: • Who are scheduled to undergo capsule endoscopy for known or suspected small bowel stricture	Interventions of interest are: • Patency capsule	Comparators of interest are: • Capsule endoscopy without patency capsule • Alternative workup without capsule endoscopy	Relevant outcomes include: • Test validity • Symptoms • Change in disease status • Treatment-related morbidity

DESCRIPTION

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

SUMMARY OF EVIDENCE

PATIENTS WITH SUSPECTED GI DISORDERS

For individuals who have suspected small bowel bleeding (previously referred to as obscure GI bleeding) who receive wireless CE, the evidence includes numerous case series evaluating patients with a nondiagnostic standard workup. Relevant outcomes are test validity, other test performance measures, symptoms, and change in disease status. The evidence has demonstrated that CE can identify a bleeding source in a substantial number of patients who cannot be diagnosed by other methods, with a low incidence of adverse events. Because there are few other options for diagnosing obscure small bowel bleeding in patients with negative upper and lower endoscopy, this technique will likely improve health outcomes by directing specific treatment when a bleeding source is identified. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have suspected small bowel Crohn disease (CD) who receive wireless CE, the evidence includes case series. Relevant outcomes are test validity, other test performance measures, symptoms, and change in disease status. Although the test performance characteristics and diagnostic yields of the capsule for this indication are uncertain, the diagnostic yields are as good as or better than other diagnostic options, and these data are likely to improve health outcomes by identifying some cases of CD and directing specific treatment. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have suspected celiac disease who receive wireless CE, the evidence includes case series and diagnostic accuracy studies. Relevant outcomes are test validity, other test performance measures, symptoms, and change in disease status. The diagnostic characteristics of CE are inadequate to substitute for other modalities or to triage patients to other modalities. For other conditions (e.g., determining the extent of CD), direct evidence of improved outcomes or a strong indirect chain of evidence to improved outcomes is lacking. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have unexplained chronic abdominal pain who receive wireless CE, the evidence includes case series and diagnostic accuracy studies. Relevant outcomes are test validity, other test performance measures, symptoms, and change in disease status. The diagnostic characteristics of CE are inadequate to substitute for other modalities or to triage patients to other modalities. For other conditions (e.g., determining the extent of CD), direct evidence of improved outcomes or a strong chain of evidence to improved outcomes is lacking. The evidence is insufficient to determine the effects of the technology on health outcomes.

Patients With Confirmed GI Disorders

For individuals who have an established diagnosis of CD who receive wireless CE, the evidence includes diagnostic accuracy studies and a systematic review. Relevant outcomes are test validity, other test performance measures, symptoms, and change in disease status. A 2017 systematic review of 11 studies in patients with established CD found a similar diagnostic yield with CE and with radiography. Because there is evidence that the diagnostic yields are as good as or better than other diagnostic options, there is indirect evidence that CE is likely to improve health outcomes by identifying some cases of CD and directing specific treatment. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have ulcerative colitis who receive wireless CE, the evidence includes case series and diagnostic accuracy studies. Relevant outcomes are test validity, other test performance measures, symptoms, and change in disease status. Several diagnostic accuracy studies have compared CE with colonoscopy to assess disease activity in patients with ulcerative colitis. Two of three studies were small (i.e., <50 patients) and thus data on diagnostic accuracy are limited. Direct evidence of improved outcomes and a strong chain of evidence to improved outcomes are lacking. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have esophageal disorders who receive wireless CE, the evidence includes case series and diagnostic accuracy studies. Relevant outcomes are test validity, other test performance measures, symptoms, and change in disease status. Other available modalities are superior to CE. The diagnostic characteristics of CE are inadequate to substitute for other modalities or to triage patients to other modalities. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have hereditary GI polyposis syndromes who receive wireless CE, the evidence includes case series and diagnostic accuracy studies. Relevant outcomes are test validity, other test performance measures, symptoms, and change in disease status. The data are insufficient to determine whether evaluation with CE would improve patient outcomes. Further information on the prevalence and natural history of small bowel polyps in Lynch syndrome patients is necessary. At present, surveillance of the small bowel is not generally recommended as a routine intervention for patients with Lynch syndrome. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have portal hypertensive enteropathy who receive wireless CE, the evidence includes case series and diagnostic accuracy studies. Relevant outcomes are test validity, and other test performance measures, symptoms, and change in disease status. Systematic reviews of studies of CE's diagnostic performance for this indicated have reported limited sensitivity and specificity. Due to insufficient data on diagnostic accuracy, a chain of evidence on clinical utility cannot be constructed. The evidence is insufficient to determine the effects of the technology on health outcomes.

Acute Upper GI Bleeding

For individuals who have acute upper GI tract bleeding who receive wireless CE, the evidence includes a randomized controlled trial and several cohort studies. Relevant outcomes are test validity, and other test performance measures, symptoms, hospitalizations, and resource utilization. The use of CE in the emergency department setting for suspected upper GI bleeding is intended to avoiding unnecessary hospitalization or immediate endoscopy. Controlled studies are needed to assess further the impact of CE on health outcomes compared with standard management. The evidence is insufficient to determine the effects of the technology on health outcomes.

Colon Cancer Screening

For individuals who are screened for colon cancer who receive wireless CE, the evidence includes diagnostic

accuracy studies and systematic reviews. Relevant outcomes are overall survival, disease-specific survival, test validity, and other test performance measures. Studies of CE in screening populations are necessary to determine the diagnostic characteristics of the test in this setting. Studies of diagnostic characteristics alone are insufficient evidence to determine the efficacy of CE for colon cancer screening. Because diagnostic performance is worse than standard colonoscopy, CE would need to be performed more frequently than standard colonoscopy to have comparable efficacy. Without direct evidence of efficacy in a clinical trial of colon cancer screening using CE, modeling studies using established mathematical models of colon precursor incidence and progression to cancer could provide estimates of efficacy in preventing colon cancer mortality. The evidence is insufficient to determine the effects of the technology on health outcomes.

Patency Capsule for Patients with Bowel Stricture

For individuals who are scheduled to undergo CE for known or suspected small bowel stricture who receive a patency capsule, the evidence includes case series. Relevant outcomes are test validity, symptoms, change in disease status, and treatment-related morbidity, The available studies have reported that CE following a successful patency capsule test results in high rates of success with low rates of adverse events. The capsule is also associated with adverse events. Because of the lack of comparative data to other diagnostic strategies, it is not possible to determine whether the use of the patency capsule improves the net health outcome. The evidence is insufficient to determine the effects of the technology on health outcomes.

POLICY

Wireless capsule endoscopy of the small bowel may be considered **medically necessary** for the following indications:

- Initial diagnosis in patients with suspected Crohn disease without evidence of disease on conventional diagnostic tests such as small-bowel follow-through and upper and lower endoscopy.
- In patients with an established diagnosis of Crohn disease when there are unexpected change(s) in the course of disease or response to treatment, suggesting the initial diagnosis may be incorrect and re-examination may be indicated.
- Suspected small bowel bleeding, as evidenced by prior inconclusive upper and lower gastrointestinal (GI) endoscopic studies performed during the current episode of illness.
- For surveillance of the small bowel in patients with hereditary GI polyposis syndromes including familial adenomatous polyposis and Peutz-Jeghers syndrome.

Other indications for wireless capsule endoscopy are considered **investigational**, including but not limited to:

- Evaluation of the extent of involvement of known Crohn disease or ulcerative colitis.
- Evaluation of the esophagus in patients with gastroesophageal reflux or other esophageal pathologies.
- Evaluation of other GI diseases and conditions not presenting with GI bleeding including but not limited to celiac sprue, irritable bowel syndrome, Lynch syndrome (risk for hereditary nonpolyposis colorectal cancer), portal hypertensive enteropathy, small bowel neoplasm and unexplained chronic abdominal pain.
- Evaluation of the colon including but not limited to detection of colonic polyps or colon cancer.
- Initial evaluation of patients with acute upper GI bleeding.

The patency capsule is considered **investigational** including use to evaluate patency of the GI tract before wireless capsule endoscopy.

BACKGROUND

WIRELESS CAPSULE ENDOSCOPY

Wireless capsule endoscopy (CE) is performed using the PillCam Given Diagnostic Imaging System (previously called M2A), which is a disposable imaging capsule manufactured by Given Imaging. The capsule measures 11 by 30 mm and contains video imaging, self-illumination, and image transmission modules, as well as a battery supply that lasts up to eight hours. The indwelling camera takes images at a rate of two frames per second as peristalsis carries the capsule through the gastrointestinal (GI) tract. The average transit time from ingestion to evacuation is 24 hours. The device uses wireless radio transmission to send the images to a receiving recorder device that the patient wears around the waist. This receiving device also contains localizing antennae sensors that can roughly gauge where the image was taken over the abdomen. Images are then downloaded onto a workstation for viewing and processing.

CE has been proposed as a method for identifying Crohn disease. There is no single criterion standard diagnostic test for Crohn disease; rather, diagnosis is based on a constellation of findings.[1] Thus it is difficult to determine the diagnostic characteristics of various tests used to diagnose the condition and difficult to determine a single comparator diagnostic test to CE.

REGULATORY STATUS

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

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

Device	Manufacturer	Year	Indication
PillCam™	Given® Imaging	2001	Detection of abnormalities in the small bowel and visualization of the small bowel mucosa
Given AGILE™ patency system	Given® Imaging	2006	Verification of adequate patency of the GI tract before administration of the PillCam into patients with known or suspected strictures
PillCam™ ESO2 Capsule	Given® Imaging	2007	Visualization of the esophageal mucosa
Olympus Capsule Endoscope System	Olympus Medical Systems	2007	Visualization of the small intestine mucosa
PillCam™ COLON	Given® Imaging	2014	Visualization of the colon in patients who have had an incomplete colonoscopy due to a technical impossibility and not incomplete evacuation
PillCam™ COLON 2	Given® Imaging	2016	Detection of colon polyps in patients after an incomplete colonoscopy and a complete evaluation of the colon was not technically possible, and for detection of colon polyps in patients with evidence of GI bleeding of lower GI origin with major risks for colonoscopy or moderate sedation

In 2001, the PillCam™ Given® Diagnostic Imaging System (Given Imaging) was cleared for marketing by FDA through the 510(k) process. FDA clearance provides for the capsule's use "along with - not as a replacement for - other endoscopic and radiologic evaluations of the small bowel." FDA clarified that the "capsule was not studied in the large intestine." In 2003, after a supplemental 510(k) premarket notification, the labeled indications were modified by removing the "adjunctive" use qualification: "the Given® Diagnostic System is intended for visualization of the small bowel mucosa. It may be used as a tool in the detection of abnormalities of the small bowel."

In 2004, the device received FDA clearance for the following labeled indication: "the Given® Diagnostic System with the PillCam™ ESO Capsule is intended for the visualization of esophageal mucosa." A new model (PillCam™ ESO2 Capsule) was cleared by FDA in June 2007.

In 2007, the Olympus Capsule Endoscope System was cleared for marketing by FDA through the 510(k) process for "visualization of the small intestine mucosa." More recent versions of both systems also incorporate a blood indicator feature to assist with rapid screening of intestinal lesions with bleeding potential.

In 2006, the Given AGILE™ patency system was cleared by FDA through the 510(k) process. This system is an accessory to the PillCam™ video capsule and, according to FDA, is intended to verify adequate patency of the GI tract before administration of the PillCam™ into patients with known or suspected strictures. This capsule is of similar size to the endoscopy capsule but made of lactose and barium and dissolves within 30 to 100 hours of entering the GI tract. It carries a tracer material that can be detected by a scanning device. Excretion of the intact capsule without symptoms (abdominal pain or obstruction) is reported to predict the uncomplicated passage of the wireless capsule.

In 2014, PillCam™ COLON was cleared for marketing by FDA through a de novo 510(k) classification. The new classification applies to devices with low-to-moderate risk that have no predicate on the market. PillCam™ COLON is intended to visualize the colon in patients who have had an incomplete colonoscopy due to a technical impossibility and not incomplete evacuation.

In 2016, the PillCam™ COLON 2 Capsule Endoscopy System was cleared by FDA through the 510(k) process for the detection of colon polyps in patients after an incomplete colonoscopy with adequate preparation, and a complete evaluation of the colon was not technically possible, and for detection of colon polyps in patients with evidence of GI bleeding of lower GI origin in patients with major risks for colonoscopy or moderate sedation, but who could tolerate a colonoscopy and moderate sedation in the event that a clinically significant colon abnormality was identified on capsule endoscopy.

FDA product code: NEZ.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

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We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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