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.

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individuals: With occult GI bleeding</td>
<td>Interventions of interest are: Capsule endoscopy</td>
<td>Comparators of interest are: Standard workup for GI bleed without capsule endoscopy</td>
<td>Relevant outcomes include: Test accuracy, Test validity, Other test performance measures</td>
</tr>
<tr>
<td>Individuals: Who are being screened for colon cancer</td>
<td>Interventions of interest are: Capsule endoscopy</td>
<td>Comparators of interest are: Optical colonoscopy</td>
<td>Relevant outcomes include: Test accuracy, Test validity, Other test performance measures</td>
</tr>
<tr>
<td>Individuals: With GI symptoms possibly related to various GI conditions(^a)</td>
<td>Interventions of interest are: Capsule endoscopy</td>
<td>Comparators of interest are: Standard workup for GI bleed without capsule endoscopy</td>
<td>Relevant outcomes include: Test accuracy, Test validity, Other test performance measures</td>
</tr>
<tr>
<td>Individuals: Who are scheduled to undergo capsule endoscopy</td>
<td>Interventions of interest are: Capsule endoscopy without patency capsule</td>
<td>Comparators of interest are: Capsule endoscopy without patency capsule</td>
<td>Relevant outcomes include: Test validity, Other test performance measures</td>
</tr>
</tbody>
</table>

\(^a\) Inflammatory bowel disease, esophageal disorders, celiac disease, hereditary polyposis, or unexplained abdominal pain.

**Description**

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

**Summary of Evidence**

The evidence on wireless capsule endoscopy for patients with occult gastrointestinal (GI) bleeding includes numerous case series that evaluate patients with a nondiagnostic standard workup. Relevant outcomes are test accuracy, test validity, and other test performance measures. The evidence demonstrates that capsule endo-
Wireless 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. Because 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. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence on wireless capsule endoscopy for patients with suspected small bowel Crohn disease or patients with an established diagnosis of Crohn disease who remain symptomatic or develop new, unexpected symptoms includes case series. Relevant outcomes are test accuracy, test validity, and other test performance measures. Although the performance characteristics and diagnostic yield of the capsule for this indication is less certain, there are also no other good diagnostic options, and as a result it is likely to improve health outcomes by identifying some cases of these disorders and directing specific treatment. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence on wireless capsule endoscopy for other conditions, including acute upper GI bleeding, determining the extent of involvement in Crohn disease, ulcerative colitis, celiac disease, esophageal conditions, Lynch syndrome, colon cancer screening, portal hypertensive enteropathy, unexplained chronic abdominal pain, and for determination of patency of the GI tract includes case series and some diagnostic accuracy studies. Relevant outcomes are test accuracy, test validity, and other test performance measures. 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 disease, the accuracy of the device needs to be established before determining whether outcomes are improved. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence on the patency capsule when used as a preliminary test for wireless capsule endoscopy consists of case series. Relevant outcomes are test validity and other test performance measures. Available studies report that capsule endoscopy following a successful patency capsule test results in high rates of success with low rates of adverse events. Because of the lack of comparative data, it is not possible to determine whether use of the patency capsule improves the rate of successful capsule endoscopy or reduces the rate of adverse events. 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’s disease without evidence of disease on conventional diagnostic tests such as small-bowel follow-through (SBFT), and upper and lower endoscopy.
- In patients with an established diagnosis of Crohn’s 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.
- Obscure gastrointestinal (GI) bleeding suspected of being of small bowel origin, as evidenced by prior inconclusive upper and lower gastrointestinal 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 of wireless capsule endoscopy are considered investigational, including but not limited to:

- Evaluation of the extent of involvement of known Crohn’s disease or ulcerative colitis
- Evaluation of the esophagus, in patients with gastroesophageal reflux (GERD) or other esophageal pathologies
- Evaluation of other gastrointestinal diseases and conditions not presenting with GI bleeding including, but not limited to, celiac sprue, irritable bowel syndrome, Lynch syndrome, 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 gastrointestinal tract before wireless capsule endoscopy.

**Policy Guidelines**

Obscure GI bleeding is defined as “recurrent or persistent iron-deficiency anemia, positive fecal occult blood test, or visible bleeding with no bleeding source found at original endoscopy.” (Van Gossum 2001)

**Background**

Wireless capsule endoscopy is performed using the PillCam™ Given® Diagnostic Imaging System (previously called M2A®), which is a disposable imaging capsule manufactured by Given Imaging (Norcross, GA). 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 some 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.

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

**Regulatory Status**

On August 1, 2001, the PillCam™ Given® Diagnostic Imaging System (Given Imaging) was cleared for marketing by the U.S. Food and Drug Administration (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.” On July 1, 2003, a supplemental 510(k) premarket notification was cleared, and 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 November 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 was cleared by FDA in June 2007, the PillCam ESO2 Capsule. In September 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 these 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 also cleared by FDA through the 510(k) process. This system is an accessory to the PillCam video capsule and, according to FDA material, is intended to verify adequate patency of the GI tract before administration of the PillCam in patients with known or suspected strictures. This capsule is of similar size to the endoscopy capsule but is made of lactose and barium and dissolves within 30 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 granted a de novo 510(k) classification by FDA. 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.

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.

References

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


