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.

**RELATED PROTOCOL**

None

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Individuals:</strong> With suspected small bowel bleeding</td>
<td>Interventions of interest are: Wireless capsule endoscopy</td>
<td>Comparators of interest are: Standard workup for gastrointestinal bleeding without capsule endoscopy</td>
<td>Relevant outcomes include: Test validity, Other test performance measures, Symptoms, Change in disease status</td>
</tr>
<tr>
<td><strong>Individuals:</strong> With suspected Crohn disease</td>
<td>Interventions of interest are: Wireless capsule endoscopy</td>
<td>Comparators of interest are: Ileocolonoscopy, Barium small bowel follow-through, Computed tomography enterography, Magnetic resonance enterography</td>
<td>Relevant outcomes include: Test validity, Other test performance measures, Symptoms, Change in disease status</td>
</tr>
<tr>
<td><strong>Individuals:</strong> With suspected celiac disease</td>
<td>Interventions of interest are: Wireless capsule endoscopy</td>
<td>Comparators of interest are: Endoscopy with biopsy</td>
<td>Relevant outcomes include: Test validity, Other test performance measures, Symptoms, Change in disease status</td>
</tr>
<tr>
<td><strong>Individuals:</strong> With unexplained chronic abdominal pain</td>
<td>Interventions of interest are: Wireless capsule endoscopy</td>
<td>Comparators of interest are: Standard workup for abdominal pain without capsule endoscopy</td>
<td>Relevant outcomes include: Test validity, Other test performance measures, Symptoms, Change in disease status</td>
</tr>
<tr>
<td>Populations</td>
<td>Interventions</td>
<td>Comparators</td>
<td>Outcomes</td>
</tr>
<tr>
<td>-------------</td>
<td>---------------</td>
<td>-------------</td>
<td>----------</td>
</tr>
</tbody>
</table>
| 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 enterography | 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 |
DESCRIPTION

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

SUMMARY OF EVIDENCE

PATIENTS WITH SUSPECTED GASTROINTESTINAL 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 and a randomized control trial (RCT). 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 an 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 treat-
ment. The evidence is sufficient to determine that the technology results in an 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 that the technology results in an improvement in the net health outcome.

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 that the technology results in an improvement in the net health outcome.

PATIENTS WITH CONFIRMED GASTROINTESTINAL 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 an 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 the 3 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 that the technology results in an improvement in the net health outcome.

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 that the technology results in an improvement in the net health outcome.

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 that the technology results in an improvement in the net health outcome.

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, other test performance measures,
symptoms, and change in disease status. Systematic reviews of studies of CE’s diagnostic performance for this indication 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 that the technology results in an improvement in the net health outcome.

**ACUTE UPPER GASTROINTESTINAL BLEEDING**

For individuals who have acute upper GI tract bleeding who receive wireless CE, the evidence includes a RCT and several cohort studies. Relevant outcomes are test validity, 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 avoid 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 that the technology results in an improvement in the net health outcome.

**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, test accuracy, 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 that the technology results in an improvement in the net health outcome.

**LOWER GASTROINTESTINAL TRACT BLEEDING AND MAJOR RISKS FOR COLONOSCOPY OR MODERATE SEDATION**

For individuals who are screened for colon polyps with evidence of lower GI tract bleeding and major risks for colonoscopy or moderate sedation who receive wireless CE, the evidence includes diagnostic accuracy studies. Relevant outcomes are test accuracy, test validity, other test performance measures, symptoms, change in disease status, and resource utilization. Studies of CE in the intended use population are necessary to determine the diagnostic characteristics of the test in the triage setting. Studies of diagnostic characteristics alone are insufficient evidence to determine the clinical utility of CE in this population, and no studies adequately assess the impact of findings on specific health outcomes or patient adherence. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

**INCOMPLETE COLONOSCOPY**

For individuals who are screened for colon polyps following an incomplete colonoscopy with adequate preparation who receive wireless CE, the evidence includes case series. Relevant outcomes are test accuracy, test validity, other test performance measures, symptoms, change in disease status, and resource utilization. Studies of CE compared to standard management with repeat colonoscopy in the intended use population are necessary to determine the diagnostic characteristics of the test in the triage setting. Studies of diagnostic characteristics alone are insufficient evidence to determine the clinical utility of CE in this population, and no studies adequately assess the impact of findings on specific health outcomes or patient adherence. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

**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 that the technology results in an improvement in the net health outcome.

**MAGNETIC CAPSULE ENDOSCOPY FOR PATIENTS WITH SUSPECTED GASTROINTESTINAL DISORDERS**

For individuals who have unexplained upper abdominal complaints who receive magnetic CE, the evidence includes diagnostic accuracy studies. Relevant outcomes are test validity, symptoms, change in disease status, and treatment-related morbidity. Studies evaluating the diagnostic characteristics of magnetic CE as compared to conventional gastroscopy in the target population have generally demonstrated similar accuracy, sensitivity, and specificity, with increases in patient preference and an acceptable safety profile with the magnetic CE approach. However, the diagnostic characteristics of magnetic CE are inadequate to substitute for other modalities or to triage patients to other modalities based on the current literature. Direct evidence of improved outcomes or a strong chain of evidence to improved outcomes is lacking. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

**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.
- Evaluation of patients with evidence of lower GI bleeding and major risks for colonoscopy or moderate sedation.
- Evaluation of patients following incomplete colonoscopy.
The patency capsule is considered **investigational** including use to evaluate patency of the GI tract before wireless capsule endoscopy.

**MEDICARE ADVANTAGE**

For Medicare Advantage, diagnostic and/or surveillance* (performed for signs/symptoms of disease) colon capsule colonoscopy (CCE) may be considered **medically necessary** for the detection of colon polyps when EITHER of the following criteria are met:

1. Secondary procedure after an incomplete diagnostic optical colonoscopy (OC) with adequate preparation, and a complete evaluation of the colon was not technically possible (1,2) when EITHER of the following criteria are met:
   a. Detection or surveillance of colon polyp(s) OR
   b. Diagnostic procedure when ANY of the following criteria are met (3):
      i. Fecal Occult Blood Test (FOBT) positive (guaiac or immunochemical) OR
      ii. Multitarget Stool DNA (sDNA) Test positive OR
      iii. Other evidence of lower GI bleed in hemodynamically stable patients

2. Primary procedure in patients with major risks for OC or moderate sedation as indicated from an evaluation of the patient by a board certified or board eligible gastroenterologist, a surgeon trained in endoscopy, or a physician with equivalent endoscopic training when EITHER of the following criteria are met:
   a. Surveillance of colon polyp(s) in previously diagnosed patients OR
   b. Diagnostic procedure when ANY of the following criteria are met (3):
      i. Fecal Occult Blood Test (FOBT) positive (guaiac or immunochemical) OR
      ii. Multitarget Stool DNA (sDNA) Test positive OR
      iii. Other evidence of lower GI bleed in hemodynamically stable patients

Diagnostic and/or surveillance CCE is considered **not medically necessary** for ANY of the following:

1. Known or suspected gastrointestinal obstruction, stricture, or fistula
2. Cardiac pacemaker or another implanted electro-medical device if the CCE device is contraindicated due to emission of a radiofrequency or other interfering signal
3. Swallowing disorder
4. Known contraindication or allergy to any medication or preparation agent used before or during the procedure
5. May not be done in conjunction with CT Colonography (CTC)
6. CCE is not a Medicare Benefit for colorectal cancer screening, regardless of family history or other risk factors for the development of colonic disease

**MEDICARE ADVANTAGE POLICY GUIDELINES**

*Cancer Diagnostic strategies refer to the measures taken to investigate persons with symptoms suspicious for
malignancy or as a result of positive screening tests. Cancer Surveillance refers to the interval utilization of diagnostic strategies in people with previously detected cancerous or pre-cancerous lesions. Cancer Screening strategies refer to those measures taken to diagnose cancerous and pre-cancerous lesions in asymptomatic people with no previous history of such.

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 8 hours. The indwelling camera takes images at a rate of 2 frames per second as peristalsis carries the capsule through the gastrointestinal 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.

Capsule endoscopy 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. 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.

MAGNETIC CAPSULE ENDOSCOPY

The U.S. Food and Drug Administration (FDA) approved a novel magnetically maneuvered CE system (NaviCam™; AnX Robotica, Inc.) in May 2020. This system consists of a single-use ingestible capsule and magnet linked to a physician-operated console. The capsule contains a camera that wirelessly captures images of the desired anatomy. The console allows the operator to control the motion and direction of the capsule, ensuring visualization of the entire stomach. The system is non-invasive, does not require sedation, and has a procedural time of approximately 15 to 20 minutes. The capsule leaves the body in 24 hours on average but may take as long as 2 weeks. The device is contraindicated for use in patients with gastrointestinal obstruction, stenosis, fistula, or those with dysphagia. Other contraindications include patients with cardiac pacemakers or other implantable electronic medical devices as well as pregnant women, those <22 years of age, and those with a body mass index ≥38.

REGULATORY STATUS

Table 1 summarizes various wireless CE devices with clearance by the FDA.

Code used: NEZ

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

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Date Cleared</th>
<th>510(k) No.</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pillcam SB 3 Capsule Endoscopy System, Pillcam Software 9.0e</td>
<td>Given Imaging Ltd.</td>
<td>8/27/2021</td>
<td>K211684</td>
<td>For visualization of the small bowel mucosa. It may be used in the visualization and monitoring of: lesions that may indicate Crohn’s disease not detected by upper and lower endoscopy; lesions that may be a source of obscure</td>
</tr>
<tr>
<td>Device</td>
<td>Manufacturer</td>
<td>Date Cleared</td>
<td>510(k) No.</td>
<td>Indication</td>
</tr>
<tr>
<td>----------------------------------------------------</td>
<td>-----------------------------</td>
<td>--------------</td>
<td>------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>NaviCam Stomach Capsule System</td>
<td>AnX Robotica, Inc.</td>
<td>5/22/2020</td>
<td>K203192</td>
<td>For visualization of the stomach of adults (≥22 years) with a body mass index &lt;38. The system can be used in clinics and hospitals, including emergency room settings.</td>
</tr>
<tr>
<td>CapsoCam Plus (SV-3)</td>
<td>CapsoVision Inc.</td>
<td>4/19/2019</td>
<td>K183192</td>
<td>For visualization of the small bowel mucosa in adults. It may be used as a tool in the detection of abnormalities of the small bowel.</td>
</tr>
<tr>
<td>Olympus Small Intestinal Capsule Endoscope System</td>
<td>Olympus Medical Systems Corp.</td>
<td>3/5/2019</td>
<td>K183053</td>
<td>For visualization of the small intestine mucosa.</td>
</tr>
<tr>
<td>MiroCam Capsule Endoscope System</td>
<td>IntroMedic Co. Ltd.</td>
<td>11/8/2018</td>
<td>K180732</td>
<td>May be used as a tool in the detection of abnormalities of the small bowel and this device is indicated for adults and children from 2 years of age.</td>
</tr>
<tr>
<td>Olympus Small Intestinal Capsule Endoscope System</td>
<td>Olympus Medical Systems Corp.</td>
<td>3/13/2018</td>
<td>K173459</td>
<td>May be used in the visualization and monitoring of lesions that may indicate Crohn’s disease not detected by upper and lower endoscopy. It may be used in the visualization and monitoring of lesions that may be a source of obscure bleeding (either overt or occult) not detected by upper and lower endoscopy. It may be used in the visualization and monitoring of lesions that may be potential causes of iron deficiency anemia (IDA) not detected by upper and lower endoscopy. The Red Color Detection Function is intended to mark frames of the video suspected of containing blood or red areas.</td>
</tr>
<tr>
<td>PillCam Patency System</td>
<td>Given Imaging Ltd.</td>
<td>3/8/2018</td>
<td>K180171</td>
<td>Intended to verify adequate patency of the gastrointestinal tract prior to administration of the PillCam video capsule in patients with known or suspected strictures.</td>
</tr>
<tr>
<td>MiroCam Capsule Endoscope System</td>
<td>IntroMedic Co. Ltd.</td>
<td>1/30/2018</td>
<td>K170438</td>
<td>For visualization of the small intestine mucosa.</td>
</tr>
<tr>
<td>PillCam SBC capsule endoscopy system PillCam Desktop Software 9.0</td>
<td>Given Imaging Ltd.</td>
<td>9/1/2017</td>
<td>K170210</td>
<td>For visualization of the small intestine mucosa.</td>
</tr>
<tr>
<td>RAPID Web</td>
<td>Given Imaging Ltd.</td>
<td>5/26/2017</td>
<td>K170839</td>
<td>Intended for visualization of the small bowel mucosa.</td>
</tr>
<tr>
<td>AdvanCE capsule endoscopy delivery device</td>
<td>United States Endoscopy Group Inc.</td>
<td>3/10/2017</td>
<td>K163495</td>
<td>Intended for visualization of the small bowel mucosa.</td>
</tr>
<tr>
<td>OLYMPUS SMALL INTESTINAL CAPSULE ENDOSCOPE</td>
<td>OLYMPUS MEDICAL SYSTEMS CORP.</td>
<td>1/19/2017</td>
<td>K163069</td>
<td>Intended for visualization of the small bowel mucosa.</td>
</tr>
<tr>
<td>Device</td>
<td>Manufacturer</td>
<td>Date Cleared</td>
<td>510(k) No.</td>
<td>Indication</td>
</tr>
<tr>
<td>--------------------------------------------</td>
<td>--------------------</td>
<td>--------------</td>
<td>------------</td>
<td>-----------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>SYSTEM</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CapsoCam (SV-1)</td>
<td>CapsoVision Inc.</td>
<td>2/9/2016</td>
<td>K151635</td>
<td>For use in diagnosing disorders of the small bowel, esophagus, and colon.</td>
</tr>
<tr>
<td>PillCam COLON2</td>
<td>Given® Imaging</td>
<td>1/14/2016</td>
<td>K153466</td>
<td>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, but who could tolerate colonoscopy or moderate sedation in the event a clinically significant colon abnormality was identified on capsule endoscopy.</td>
</tr>
<tr>
<td>ENDOCAPSULE SOFTWARE 10; ENDOCAPSULE SOFTWARE 10 LIGHT</td>
<td>OLYMPUS MEDICAL SYSTEMS CORP.</td>
<td>2/8/2015</td>
<td>K142680</td>
<td>Intended for visualization of the small bowel mucosa.</td>
</tr>
</tbody>
</table>

GI: gastrointestinal.

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


44. Hussey M, Holleran G, Stack R, et al. Same-day colon capsule endoscopy is a viable means to assess unexplored colonic segments after incomplete colonoscopy in selected patients. United European Gastroenterol J. Dec 2018;6(10):1556-1562. PMID 30574326