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, Ltd (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 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 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.

The device received marketing clearance from the U.S. Food and Drug Administration (FDA) on August 1, 2001, through the 510(k) process. The FDA clearance provides for the capsule's use "along with – not as a replacement for – other endoscopic and radiologic evaluations of the small bowel." The FDA clarified that the "capsule was not studied in the large intestine.” “On July 1, 2003, a supplemental 510(k) pre-market 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.”

Finally, 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 the FDA in June 2007, the PillCam ESO2 Capsule. In September 2007, the FDA cleared the Olympus Capsule Endoscope System, 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 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’s esophagus associated with gastroesophageal reflux disease (GERD). 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.

In 2006, the FDA also provided clearance for the Given AGILE patency system. This system is an accessory to the PillCam video capsule and, according to FDA material, is intended to verify adequate patency of the gastrointestinal (GI) tract prior to 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
30–100 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.

**When services are covered for commercial products (excluding Medicare HMO Blue and Medicare PPO Blue)**

We cover wireless capsule endoscopy 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,
- Obscure GI bleeding suspected of being of small bowel origin, as evidenced by prior inconclusive upper and lower gastrointestinal studies, and
- For surveillance of the small bowel in patients with hereditary GI polyposis syndromes, including familial adenomatosis polyposis, and Peutz-Jeghers syndrome.

**Note:** 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.

**When services are not covered for commercial products (excluding Medicare HMO Blue and Medicare PPO Blue)**

We do not cover wireless capsule endoscopy for other indications including but not limited to the following as it is considered investigational and does not meet our Medical Technology Assessment Guidelines, #350:

- Evaluation of the extent of involvement of known Crohn’s disease
- Evaluation of the esophagus, in patients with gastroesophageal reflux (GERD) or other esophageal pathologies
- Evaluation of other gastrointestinal diseases not presenting with gastrointestinal bleeding, including, but not limited to celiac sprue, irritable bowel syndrome, small bowel neoplasm
- Evaluation of the colon including, but not limited to, detection of colonic polyps or colon cancer.

We do not cover the patency capsule including its use to evaluate patency of the gastrointestinal tract before wireless capsule endoscopy as it is considered investigational and does not meet our Medical Technology Assessment Guidelines, #350.

**When services are covered for Medicare HMO Blue and Medicare PPO Blue**

We cover wireless capsule endoscopy for the following indications:

**Gastrointestinal Bleeding**

- The test is indicated for the diagnosis of occult gastrointestinal bleeding, the site of which has not been identified previously by any of the following: upper gastrointestinal endoscopy, colonoscopy, push enteroscopy, nuclear imaging, or radiological procedures. The test is especially helpful in the diagnosis of angiodysplasias of the gastrointestinal tract.
- Wireless capsule endoscopy is limited to those patients who have undergone upper GI endoscopy and colonoscopy, and when these tests have failed to reveal a source of bleeding. Documentation in the medical record must indicate that the beneficiary has GI blood loss and anemia secondary to the bleeding.

**Small Bowel Neoplasm**

- The test is indicated for the detection of neoplasms of the small bowel, when the diagnosis has not been previously confirmed by other studies (e.g. upper gastrointestinal endoscopy, colonoscopy, push enteroscopy, nuclear imaging, or radiological procedures). The patient must be symptomatic for a neoplasm (e.g., partial bowel obstruction, GI bleeding), and other diagnostic testing to assess these symptoms (i.e., upper GI endoscopy and colonoscopy) must have been performed.

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**Policy #185: Wireless Capsule Endoscopy as a Diagnostic Technique in Disorders of the Small Bowel, Esophagus, and Colon**

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Crohn's Disease
- The test is indicated for the diagnosis of Crohn's disease when the condition has not been previously confirmed. The wireless capsule endoscopy is limited to those patients who are symptomatic for Crohn's disease (e.g., diarrhea, GI bleeding, abdominal pain) and when they have undergone complete lower gastrointestinal studies (i.e., colonoscopy, barium enema, stool specimen) and when these studies have failed to reveal the source of the patient's symptoms. While there is evidence in the literature to support prior radiologic study to exclude strictures, this is not a requirement.

**Note:** For diagnoses that are considered covered for Medicare HMO Blue and Medicare PPO Blue, see footnotes 4 and 5.

<table>
<thead>
<tr>
<th>When services are not covered for Medicare HMO Blue and Medicare PPO Blue</th>
</tr>
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<tbody>
<tr>
<td>We do not cover wireless capsule endoscopy of the small intestine for the following:</td>
</tr>
<tr>
<td>- Colorectal cancer screening</td>
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<tr>
<td>- FDA non-approved devices</td>
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<tr>
<td>- Confirmation of lesions or pathology normally within the reach of upper or lower endoscopes (lesions proximal to the ligament of Treitz or distal to the ileum)</td>
</tr>
<tr>
<td>- Patients with hematemesis</td>
</tr>
<tr>
<td>- When performed by physicians not trained in endoscopy or for independent diagnostic testing facilities, which are not under the general supervision of a physician trained in endoscopy procedures.</td>
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</tbody>
</table>

**Individual consideration**

All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual’s unique clinical circumstances may be considered in light of current scientific literature. For consideration of an individual patient, physicians may send relevant clinical information to:

<table>
<thead>
<tr>
<th>For services already billed</th>
<th>Prior to performance of service</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blue Cross Blue Shield of Massachusetts</td>
<td>Blue Cross Blue Shield of Massachusetts</td>
</tr>
<tr>
<td>Provider Appeals</td>
<td>Case Creation/Medical Policy</td>
</tr>
<tr>
<td>PO Box 986065</td>
<td>One Enterprise Drive</td>
</tr>
<tr>
<td>Boston, MA 02298</td>
<td>Quincy, MA 02171</td>
</tr>
<tr>
<td>Tel: 1-800-327-6716</td>
<td>Fax: 1-888-641-5330</td>
</tr>
</tbody>
</table>

**Authorization Information**

**For Managed Care members:**
- No authorization is required for this service; *see Managed Care Guidelines for additional requirements*.

**For Indemnity and PPO members:**
- No authorization is required for this service; *see Indemnity and PPO Guidelines for additional requirements*.

**Managed Care Guidelines**

All authorization requirements are determined by the individual’s subscriber certificate, explanation of coverage, or summary plan description, however;

- **For Medicare HMO Blue members:** The service must meet the criteria for coverage noted in this policy, be medically necessary, prescribed by a plan physician and provided by a network provider.
- **For Medicare HMO Blue members:** Referrals are required for all visits to a specialist.

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**Policy #185: Wireless Capsule Endoscopy as a Diagnostic Technique in Disorders of the Small Bowel, Esophagus, and Colon**

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• For all other Managed Care plans, any specialist visit requires a referral, except for visits performed by OB/GYN specialists.
• Authorization is required for an inpatient admission.

**Indemnity and PPO Guidelines**

All authorization requirements are determined by the individual’s subscriber certificate, explanation of coverage, or summary plan description, however:

- Authorization is required for an inpatient admission.
- Authorizations are not required for most outpatient services as determined by the individual’s subscriber certificate.
- Referrals to a specialist are not required.

**Other information**

For our Medical Technology Assessment Guidelines, see document #350.

**Coding information**

*Coding information*

Procedure codes are from current CPT, HCPCS Level II, Revenue Code, and/or ICD-9-CM manuals, as recommended by the American Medical Association, Centers for Medicare and Medicaid Services and American Hospital Associations. Blue Cross Blue Shield Association national codes may be developed when appropriate.

The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

**CPT codes**

- **91110**: Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus through ileum, with physician interpretation and report.
- **0242T**: Gastrointestinal tract transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report

**Note**: See footnote 4 for covered diagnoses for CPT code 91110 for **Medicare HMO Blue and Medicare PPO Blue**.

The procedure noted below will reject as non-covered, leaving no patient balance, as this procedure does not meet our Medical Technology Assessment Guidelines. However, in accordance with CMS guidelines, the following procedures are covered for **our Medicare HMO Blue and Medicare PPO Blue only**

**CPT code**:

- **91111**: Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus with physician interpretation and report.

**Note**: See footnote 5 for covered diagnoses for CPT code 91111 for **Medicare HMO Blue and Medicare PPO Blue**.

**Policy update history**

Issued 4/1/2002. Updated 4/2002 to exclude coverage for wireless capsule endoscopy as a technique to identify the source of gastrointestinal bleeding or other gastrointestinal pathology. Updated 4/2003 to include coverage for wireless capsule endoscopy, effective 8/2003; and to include individual consideration guidelines for wireless capsule endoscopy for Medicare HMO Blue members. Updated 12/2003 to include coverage for wireless capsule endoscopy for the 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; effective April 2004. Reviewed 11/2004 MPG Gastroenterology, Nutrition and Organ Transplantation, no changes in coverage were made. Updated 4/2005 to remove the IC guideline language for wireless endoscopy for Medicare HMO Blue and Medicare PPO Blue as the procedure is covered for all plans for the covered indications previously listed under Individual Consideration. Reviewed 11/2005 MPG Gastroenterology, Nutrition and Organ Transplantation, no changes in coverage were made. Updated 1/2006 to include non-coverage language for wireless capsule endoscopy under ‘when services are not covered’ in contrast to existing covered indications. Reviewed 11/2006 MPG-Gastroenterology, Nutrition and Organ Transplantation, no changes in coverage were made. Updated 4/2007, 4/07 BCBSA national policy comparison review, policy statement unchanged. Language of #007 edited to be in-line with November 2006 Provider Focus publication: added coverage for surveillance of the small bowel in patients with hereditary polyposis syndromes, including familial adenomatosis polyposis, and Peutz-Jeghers syndrome, effective 1/2007; and clarification of non-covered indication: wireless capsule endoscopy to determine the extent of Crohn’s disease. Updated 7/2007 comparison review of the BCBSA national policy Wireless Capsule Endoscopy as a Diagnostic Technique in Disorders of the Small Bowel and Esophagus; no changes in policy statement. Reviewed 11/2007 MPG-Gastroenterology, Nutrition and Organ Transplants, no changes in coverage were made; coverage indications for Wireless Capsule Endoscopy were clarified based on Medicare LCD for Medicare HMO Blue and Medicare PPO Blue only. Updated 9/2008 comparison review of the BCBSA national medical policy, BCBSA covered indications unchanged; investigational indications clarified to include the accessory capsule-patency system. Reviewed 11/2008 MPG - Gastroenterology, Nutrition and Organ Transplantation, no changes in coverage were made. Updated 11/2009 after review of BCBSA national policy issued 8/2009 without change in coverage and non-coverage statements. Clarified investigational statement. Updated 5/2010 to clarify coverage and non-coverage statements for Medicare HMO Blue and Medicare PPO Blue members, and to issue new policy document #185, Wireless Capsule Endoscopy as a Diagnostic Technique in Disorders of the Small Bowel, Esophagus, and Colon. (Wireless capsule endoscopy was previously addressed under policy #007 Ultrasound.). Reviewed 11/2010 MPG Gastroenterology, Nutrition and Organ Transplantation, no changes in coverage were made. Updated 12/10 to add new CPT code 0242T effective 1/1/2011. Reviewed 10/2011 MPG GI, Nutrition and Organ Transplantation, no changes in coverage were made. Updated 1/1/2012 with additional references based on BCBSA national policy reviewed 5/12/2011.

References

References for footnote 1:


Footnotes

1 Based on BCBSA national policy 6.01.33 Wireless Capsule Endoscopy as a Diagnostic Technique in Disorders of the Small Bowel, Esophagus, and Colon, reviewed 5/12/2011.


ICD-9-CM diagnosis codes that are covered for Medicare HMO Blue and Medicare PPO Blue when billed with CPT code 91110:
152.0 - 152.9 malignant neoplasm of duodenum - malignant neoplasm of small intestine unspecified site
197.4 secondary malignant neoplasm of small intestine including duodenum
211.2 benign neoplasm of duodenum jejunum and ileum
230.7 carcinoma in situ of other and unspecified parts of intestine
280.0 iron deficiency anemia secondary to blood loss (chronic)
555.0 regional enteritis of small intestine
560.9 unspecified intestinal obstruction
562.02 diverticulosis of small intestine with hemorrhage
562.03 diverticulitis of small intestine with hemorrhage
569.85 angiodysplasia of intestine with hemorrhage
569.86 dieulafoy lesion (hemorrhagic) of intestine
578.1 blood in stool
578.9 hemorrhage of gastrointestinal tract unspecified
787.91 diarrhea
789.00 - 789.09 abdominal pain unspecified site - abdominal pain other specified site
792.1 nonspecific abnormal findings in stool contents

ICD-9-CM diagnosis codes that are covered for Medicare HMO Blue and Medicare PPO Blue when billed with CPT code 91111:
456.1 esophageal varices without bleeding
456.21 esophageal varices in diseases classified elsewhere without bleeding
571.2 alcoholic cirrhosis of liver
571.5 cirrhosis of liver without alcohol
571.6 biliary cirrhosis
572.3 portal hypertension