

## Corporate Medical Policy

### Capsule Endoscopy, Wireless

**File Name:** capsule\_endoscopy\_wireless  
**Policy Number:** RAD5023  
**Origination:** 5/2002  
**Last CAP Review:** 1/2009  
**Next CAP Review:** 1/2011  
**Last Review:** 11/2009

#### Description of Procedure or Service

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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 ES02 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 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

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of the intact capsule without symptoms (abdominal pain or obstruction) is reported to predict the uncomplicated passage of the wireless capsule.

**\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

### Policy

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BCBSNC will provide coverage for Wireless Capsule Endoscopy when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

### Benefits Application

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Please refer to Certificate for availability of benefit. This policy relates only to the services or supplies described herein. Benefits may vary according to benefit design, therefore certificate language should be reviewed before applying the terms of the policy.

### When Capsule Endoscopy, Wireless is covered

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Capsule endoscopy may be eligible for coverage when criteria are met for clinical scenarios under either A., or B., or C. below:

- A. For undiagnosed **obscure** gastrointestinal bleeding. All of the following criteria must be met:
1. GI bleeding is significant as demonstrated by one of the following:
    - a. an acute drop in hemoglobin/hematocrit; **or**
    - b. unexplained recurrent or persistent iron deficiency anemia demonstrated by low serum iron studies or low serum ferritin level; **or**
    - c. persistently positive fecal occult blood test; **or**
    - d. visible bleeding with no bleeding source found at original endoscopy; **and**
  2. Failure of previous diagnostic studies to diagnose the source of GI bleeding, including upper and lower GI endoscopy; **and**
  3. Source of GI bleeding is thought to be in the upper gastrointestinal tract.
- OR**
- B. For suspected Crohn's Disease when diagnosis has not been established by upper and lower endoscopy studies, all of the following must be met:
1. Persistent abdominal pain of greater than 4 weeks; **and**
  2. Persistent diarrhea; **and**
  3. Unintentional weight loss; **and**
  4. Negative stool cultures; **and**
  5. Negative upper/lower endoscopy studies.

**OR**

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- C. For surveillance of the small bowel in patients with hereditary GI polyposis syndromes, including familial adenomatous polyposis and Peutz-Jeghers syndrome.

### When Capsule Endoscopy, Wireless is not covered

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1. Capsule endoscopy for undiagnosed obscure GI bleeding or for diagnosis of suspected Crohn's disease is considered to be not medically necessary when all the criteria under A. (GI bleeding) or B. (Crohn's disease) above are not met.
2. Capsule endoscopy for any indication other than undiagnosed obscure GI bleeding, diagnosis of suspected Crohn's disease, or surveillance of the small bowel in patients with hereditary GI polyposis syndromes is considered investigational including but not limited to the following indications:
  - a. When the test is performed for screening.
  - b. When the wireless capsule endoscopy is used to view the esophagus.
  - c. When used as a technique to evaluate other gastrointestinal diseases not presenting with gastrointestinal bleeding, including, but not limited to celiac sprue, irritable bowel syndrome, small bowel neoplasm, or non-familial intestinal polyposis syndrome.
  - d. When used for the evaluation of the extent of involvement of known Crohn's disease.
  - e. When used for the evaluation of the colon including, but not limited to, the detection of colonic polyps or colon cancer.
3. The patency capsule is considered investigational, including use to evaluate patency of the gastrointestinal tract before wireless capsule endoscopy.

### Policy Guidelines

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To date there has been minimal published literature regarding the diagnostic performance of this device for the esophagus which is inadequate to permit scientific conclusions regarding the clinical role of esophageal capsule endoscopy. One article published in 2005 explored the use of capsule endoscopy to determine the extent of Crohn's disease in patients already diagnosed. The clinical trial did show that capsule endoscopy was able to identify additional areas of Crohn's disease that had not been previously identified by enteroclysis. It is still unclear how knowledge regarding the extent of the disease would impact patient medical management.

Capsule endoscopy has been evaluated in comparison to traditional optical colonoscopy for detection of polyps and cancer. In the largest study of 328 patients, the sensitivity of capsule endoscopy was 64% for polyps 6 mm or larger, 73% for advanced adenoma, and 74% for cancer. Other smaller studies show the sensitivity of capsule endoscopy for various types of lesions to be less than 80%. Based on these data, the use of capsule endoscopy for evaluation of the colon is investigational.

Esophageal endoscopy is the standard of care at this time in that it allows for a biopsy at the time of the procedure if needed. Capsule endoscopy offers a potential alternative to endoscopy; those patients with a negative study could potentially forego conventional endoscopy. An assessment of the capsule endoscopy of the esophagus requires a comparison of its diagnostic performance against the conventional esophageal endoscopy.

### Billing/Coding/Physician Documentation Information

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Poli-

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cies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable codes: 91110, 91111*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

### Medical Term Definitions

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#### **Endoscopy**

visual inspection of any cavity of the body by means of an endoscope.

#### **Obscure**

hidden, indistinct, as the cause of a condition; to make less distinct or to hide.

### Scientific Background and Reference Sources

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- BCBSA Medical Policy Reference Manual, 2/15/2002; 6.01.33
- ECRI, Target Report #819, *Capsule Endoscopy*. March 29, 2002
- BCBSA TEC Assessment, Volume 16, No. 18, April 2002
- BCBSA TEC Assessment, MAP meeting, Page 34-37; October 10, 2002
- Specialty Matched Consultant Advisory Panel, 6/2002
- BCBSA Medical Policy Reference Manual, 12/18/2002; 6.01.33
- Specialty Matched Consultant Advisory Panel, 3/2003
- BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.33, 11/9/2004
- Specialty Matched Consultant Advisory Panel, 2/2005.
- BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.33, 4/1/2005
- BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.33, 4/25/2006
- Specialty Matched Consultant Advisory Panel, 1/2007.
- BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.33, 7/10/2008
- Specialty Matched Consultant Advisory Panel, 1/2009.
- BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.33, 8/13/09

### Policy Implementation/Update Information

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- 5/2002 Original policy issued.
- 6/2002 Specialty Matched Consultant Advisory Panel.

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- 3/2003 Specialty Matched Consultant Advisory Panel review 3/2003. Policy revised. No longer considered investigational for specific criteria. Deleted code 58999 and added codes 91299 and G0262 to Billing/Coding section. Added terms to the Medical Term Definitions. Added colonoscopy to the Policy Key Words section. System coding changes.
- 1/04 Benefits Application and Billing/Coding sections updated for consistency.
- 5/04 Added code 91110 to the Billing/Coding section.
- 03/17/05 Specialty Matched Consultant Advisory Panel review 2/24/2005. Added device name "PillCam™ Given® Diagnostic Imaging System" to Description of Procedure or Service. Deleted "G0262" from Coding/Billing section. Added "RAD5023" to Key Words section. References added.
- 8/18/05 Revised "Description of Procedure or Service" section to include additional information related to FDA approval and the wireless capsule endoscopy's use in the esophagus. Added additional signs of significant GI bleeding under "When covered" section. Added second bullet under "When not covered" section to indicate this test would not be covered; "When the Wireless capsule endoscopy is used to view the esophagus. It is considered investigational" and the third bullet, "When used as a technique to evaluate other gastrointestinal diseases not presenting with gastrointestinal bleeding, including, but not limited to celiac sprue, irritable bowel syndrome, small bowel neoplasm, or intestinal polyposis syndrome." Rationale added to "Policy Guidelines" section. "ESO and Esophageal" added to "Policy Key Words" section. Notification given 8/18/2005. Policy effective 10/20/2005.
- 1/3/07 Added the following 2007 new CPT code to the "Billing/Coding" section, 91111.
- 2/26/07 Added new indication to the "When Covered" section, "C. For surveillance of the small bowel in patients with hereditary GI polyposis syndromes, including familial adenomatous polyposis and Peutz-Jeghers syndrome." Under the section "When Not Covered" first bullet "All other indications are considered investigational including but not limited to the following examples." and the last bullet, "When used for the evaluation of the extent of involvement of known Crohn's disease". Rationale updated in "Policy Guidelines" section. Removed CPT code 91299 from "Billing/Coding" section now that specific codes exist. References added.
- 3/2/09 Specialty Matched Consultant Advisory Panel review 1/28/2009. Policy reformatted. Added information regarding other similar devices to the "Description" section. In the "When Covered" section removed the statement; "hematocrit less than 34" and changed wording in A.1.b. "unexplained recurrent or persistent iron deficiency anemia demonstrated by low serum iron studies or low serum ferritin level". B. "For suspected Crohn's Disease when diagnosis has not been established by upper and lower endoscopy studies..." B.3. added "unintentional weight loss". Reformatted information under the "When Not Covered" section for clarification. References added. (btw)
- 12/7/09 Updated "Description" section. Added "2.e. When used for the evaluation of the colon including, but not limited to, the detection of colonic polyps or colon cancer." to the "When Not Covered" section for clarification, no change to policy intent. Updated "Policy Guidelines" section. Senior Medical Director review 11/9/09. References added. (btw)

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.