



## Corporate Medical Policy

### Capsule Endoscopy, Wireless

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

#### Description of Procedure or Service

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Wireless capsule [endoscopy](#) is a disposable imaging capsule called PillCam™ Given® Diagnostic Imaging System (previously called M2A®) manufactured by Given Imaging, Ltd. 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 for up to 8 hours. The indwelling camera takes images at a rate of 2 frames per second as peristalsis (contractions) 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 approval from the U.S. Food and Drug Administration (FDA) on August 1, 2001, through a 510 (k) approval 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." In July of 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."

In November 2004 the FDA approved the Given® Diagnostic System with the PillCam™ ESO Capsule for visualization of the esophageal mucosa. Other devices cleared by the FDA 510K process since that time are the PillCam ESO2 Capsule, the Olympus Capsule Endoscopic System, and the Given AGILE patency system. The AGILE patency system is intended to verify adequate patency of the GI tract prior to administration of the PillCam in patients with known or suspected strictures. The capsule is made of lactose and barium and excretion of an intact capsule without any symptoms predicts an open passage through the GI tract.

The capsule camera has been used most often in the small bowel as a technique to identify the source of [obscure](#) intestinal bleeding. Recently there has been interest in exploring its use in patients with inflammatory bowel disease. Standard diagnostic tools for this condition include barium studies or small intestinal endoscopy. The ESO capsule has been proposed as a screening technique for Barrett's esophagus associated with gastroesophageal reflux disease (GERD). The current standard diagnostic technique is the upper endoscopy.

#### 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.**

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### 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**
- 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.

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- 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.
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.

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 Policies 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.

### Policy Key Words

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Key Words: Capsule Endoscopy, Wireless, Obscure Digestive Tract Bleeding, Gastrointestinal, GI, Camera, Recorder, Video Imaging, Colonoscopy, ESO, Esophageal, RAD5023

## 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.

## Policy Implementation/Update Information

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

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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.

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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.