Corporate Medical Policy

Capsule Endoscopy, Wireless

File Name: capsule_endoscopy_wireless
Origination: 5/2002
Last Review: 5/2023

Description of Procedure or Service

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 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.

CE has been proposed as a method for identifying Crohn's disease. There is no single criterion standard diagnostic test for Crohn's 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 in CE.

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.

Regulatory Status
In 2018, the PillCam Patency System (Given Imaging Ltd.) was cleared for marketing by the U.S. Food and Drug Administration, to verify adequate patency of the GI tract prior to administration of the PillCam video capsule in patients with known or suspected strictures.

In 2018, the MiroCam Capsule Endoscope System (IntroMedic Co. Ltd.) was cleared for marketed by the U.S. Food and Drug Administration, for use 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.

In 2019, the CapsoCam Plus (SV-3) (Capso Vision Inc.) was cleared for marketing by the U.S. Food and Drug Administration, 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.

In 2020, the NaviCam Stomach Capsule System (AnX Robotica, Inc.) was cleared for marketing by the U.S. Food and Drug Administration, for visualization of the stomach of adults (≥22 years) with a body mass index <38. This system can be used in clinics and hospitals, including emergency room settings.

In 2021, the Pillcam SB 3 Capsule Endoscopy System, Pillcam Software 9.0e (Given Imagin, Ltd.), was cleared for marketing by the U.S. Food and Drug Administration, 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 bleeding

not detected by upper and lower endoscopy; lesions that may be potential causes of iron deficiency anemia not detected by upper and lower endoscopy.

******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

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

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

This procedure may require prior review.

When wireless capsule endoscopy is covered

Wireless capsule endoscopy of the small bowel may be eligible for coverage for 1 or more of the following:

- Initial diagnosis in individuals with suspected Crohn's disease without evidence of disease on conventional diagnostic tests such as small-bowel follow-through (SBFT) OR upper and lower endoscopy who meet all of the following:
    - Persistent abdominal pain of greater than 4 weeks; AND
    - Persistent diarrhea: AND
    - Unintentional weight loss; AND
    - Negative stool cultures. OR

- In individuals 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; OR

- Suspected small bowel bleeding, as evidenced by prior inconclusive upper and lower gastrointestinal endoscopic studies performed during the current episode of illness and demonstrate 1 or MORE of the following:
    - An acute drop in hemoglobin/hematocrit: OR
    - Unexplained recurrent or persistent iron deficiency anemia; OR
    - Persistently positive fecal occult blood test; OR
    - Visible bleeding with no bleeding source found at original upper or lower endoscopy; OR
- For surveillance of the small bowel in individuals with hereditary GI polyposis syndromes, including familial adenomatous polyposis and Peutz-Jeghers syndrome.

When wireless capsule endoscopy is not covered

1.) Capsule endoscopy for any indication other than undiagnosed obscure GI bleeding, diagnosis of suspected Crohn's disease, or surveillance of the small bowel in individuals 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, Lynch syndrome (risk for hereditary nonpolyposis colorectal cancer), portal hypertensive enteropathy, small bowel neoplasm, and unexplained chronic abdominal pain.
    d) When used for the evaluation of the extent of involvement of known Crohn's disease or ulcerative colitis.
    e) When used for the evaluation of the colon including, but not limited to, the detection of colonic polyps or colon cancer.
    f) Initial evaluation of individuals with acute upper GI bleeding.

2.) The patency capsule is considered investigational, including use to evaluate patency of the gastrointestinal tract before wireless capsule endoscopy.

3.) Magnetic capsule endoscopy is considered investigational for the evaluation of individuals with unexplained upper abdominal complaints and all other indications.

Policy Guidelines

Summary

The evidence for individuals with suspected small bowel bleeding (previously referred to as obscure GI bleeding) who receive wireless capsule endoscopy, includes numerous case series that evaluate patients with a nondiagnostic standard workup and a randomized control trial. Relevant outcomes are test validity, other test performance measures, symptoms, and change in disease status. The evidence demonstrates that 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. Since there are few 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 that the technology results in a meaningful improvement in the net health outcome.

The evidence for individuals who have acute upper GI tract bleeding who receive wireless capsule endoscopy, includes RCTs and several cohort studies. Relevant outcomes are test validity, and other test performance measures, syptoms, hospitalizations, and resource utilization. The use of capsule endoscopy in the emergency department setting for suspected upper GI bleeding is based on efficiency (avoiding hospitalization, avoiding immediate endoscopy). Additional controlled studies are needed to further assess the impact of capsule endoscopy on health outcomes compared with standard management. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

The evidence for individuals who have ulcerative colitis, suspected celiac disease, esophageal conditions, hereditary GI polyposis syndromes, colon cancer screening, portal hypertensive

enteropathy, unexplained abdominal pain, or are scheduled to undergo capsule endoscopy with known or suspected small bowel stricture who receive wireless capsule endoscopy, the evidence includes case series and some diagnostic accuracy studies. Relevant outcomes are test validity, other test performance measures, symptoms, and change in disease status. 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's disease, the accuracy of the device needs to be established prior to determining whether outcomes are improved. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are scheduled to undergo capsule endoscopy with known or suspected small bowel stricture who receive a patency capsule, the evidence consists of case series. Relevant outcomes are test validity, symptoms, change in disease status, and treatement-related morbidity. 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 to other diagnostic strategies, 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.

For individuals who have unexplained upper abdominal complaints who receive magnetic capsule endoscopy, 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. The diagnostic characteristics of magnetic CE, however, 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.

Billing/Coding/Physician Documentation Information

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. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: *0651T, 91110, 91113*

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.

Scientific Background and Reference Sources

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
BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.33, 5/12/11
Specialty Matched Consultant Advisory Panel, 4/18/12.
BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.33, 8/9/12
Specialty Matched Consultant Advisory Panel, 4/2013
BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.33, 8/8/13
Specialty Matched Consultant Advisory Panel, 4/2014
BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.33, 9/11/14
Specialty Matched Consultant Advisory Panel, 5/2015
Medical Director review, 5/2015
BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.33, 9/10/15
Specialty Matched Consultant Advisory Panel, 5/2016
Medical Director review, 5/2016
BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.33, 11/2016
Medical Director review, 11/2016
Specialty Matched Consultant Advisory Panel, 5/2017
Medical Director review, 5/2017
BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.33, 11/2017
Specialty Matched Consultant Advisory Panel, 5/2018
Medical Director review, 5/2018
BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.33, 11/2018
BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.33, 12/2019
Specialty Matched Consultant Advisory Panel, 5/2019
Medical Director review, 5/2019
Specialty Matched Consultant Advisory Panel, 5/2020
Medical Director review, 5/2020
BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.33, 1/2021
Specialty Matched Consultant Advisory Panel 5/2021
Medical Director review 5/2021
Specialty Matched Consultant Advisory Panel 5/2022

Medical Director review 5/2022

Specialty Matched Consultant Advisory Panel 5/2023

Medical Director review 5/2023

Policy Implementation/Update Information

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 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)
6/22/10	Policy Number(s) removed (amw)
12/7/10	Added the statement to Benefits Application section: “This procedure may require prior review.” Medical Director review 9/8/10. (adn)
5/10/11	Specialty Matched Consultant Advisory Panel review 4/27/11. No change in medical criteria for coverage. Rationale in the Policy Guidelines section updated. (adn)
5/1/12	Patient Selection Criteria added to Policy Guidelines. Policy statement revised. No change to policy intent. Specialty Matched Consultant Advisory Panel review 4/18/12. (sk)
11/13/12	Reference added. Summary statement added. No change to policy intent. Medical director review. (sk)
4/30/13	Specialty Matched Consultant Advisory Panel review 4/17/13. (sk)
10/29/13	Reference added. Ulcerative colitis, acute GI bleeding and Lynch syndrome added to investigational policy statement. Medical Director review. Notification given 10/29/13 for policy effective date 12/31/13. (sk)
5/13/14	Specialty Matched Consultant Advisory Panel review 4/29/13. No change to Policy statement. (sk)
11/11/14	References updated. Description section updated. When Covered section updated. Billing section updated to include CPT code: 0355T effective as of July 2014. (td)
7/1/15	References updated**.** Specialty Matched Consultant Advisory Panel review 5/27/2015. Medical Director review 5/2015. Policy Statements remain unchanged. (td)
10/30/15	Description section extensively revised. Policy Guidelines section extensively revised. References updated. Policy Statement unchanged. (td)
7/1/16	Specialty Matched Consultant Advisory Panel review 5/25/16 . Portal hypertensive enteropathy and unexplained chronic abdominal pain added to Non-covered section. (jd)
12/30/16	Regulatory Status updated and revisions to Policy Guidelines. When Covered section updated with minor changes to wording, no change to intent of policy. References updated. Medical Director review. (jd)
6/30/17	Specialty Matched Consultant Advisory Panel, 5/2017. Medical Director review, 5/2017. (jd)
6/8/18	References updated. Specialty Matched Consultant Advisory Panel, 5/2018. Medical Director review, 5/2018. (jd)
12/14/18	Minor updates to Description section, When Not Covered section and Policy Guidelines. No change to policy intent. (jd)
5/28/19	Specialty Matched Consultant Advisory Panel, 5/2019. Medical Director review 5/2019. (jd)
7/30/19	Revised wording to 1st bullet under the When Covered section, replaced the term “and” with “OR” for clarity. No change in policy intent. Medical Director review 7/2019. (jd)
12/10/19	The following codes were removed from Billing/Coding section effective 10/1/19: 91110, 91111; references updated. (jd)

6/9/20	Specialty Matched Consultant Advisory Panel, 5/2020. Medical Director review, 5/2020. (jd)
7/1/21	References updated. The following code was added to the Billing/Coding section effective 7/1/21: 0651T. Specialty Matched Consultant Advisory Panel 5/2021. Medical Director review 5/2021. (jd)
12/30/21	Under the Billing/Coding section, added code 91113 and removed code 0355T as it is being deleted. Both will be effective 1/1/22. (jd)
2/8/22	Under the Billing/Coding section, added code 91110. (jd)
6/30/22	Policy title updated. Policy formatting updated to align with the new utilization management tool. No changes to policy statement. Updated Regulatory Status under the Description section. Added investigational statement regarding magnetic capsule endoscopy to the When Not Covered section as follows: "Magnetic capsule endoscopy is considered investigational for the evaluation of patients with unexplained upper abdominal complaints and all other indications." Policy guidelines updated. Specialty Matched Consultant Advisory Panel 5/2022. Medical Director review 5/2022. (jd)
7/26/22	When Covered section revised; moved Patient Selection criteria from the policy guidelines up under main bullet 1 and 3 for clarity, no change to policy intent. (jd)
8/23/22	Typo corrected under When Not Covered section. No change to policy statement. (tm)
5/30/23	When Covered, Not Covered and Policy Guidelines sections edited for clarity. References updated. No change to policy statement. Specialty Matched Consultant Advisory Panel 5/2023. Medical Director review 5/2023. (tm)