

### **Medical Coverage Policy**

Effective Date: 08/24/2023 Revision Date: 08/24/2023 Review Date: 08/24/2023 Policy Number: HUM-0376-022

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Change Summary: Updated Description, Coverage Determination, Coverage Limitations, References

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#### **Disclaimer**

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### Description

Capsule endoscopy (CE), also known as wireless capsule endoscopy or video capsule endoscopy, is a noninvasive diagnostic procedure that is designed to visualize the esophagus, stomach, small bowel or colon. To perform this procedure, a small digestible capsule (approximately the size of a large vitamin) containing a video camera and a light source is swallowed. The camera takes multiple pictures per second and sends electronic signals wirelessly to a data recorder worn around the individual's waist. The data is then downloaded into a computer program that captures the images to be analyzed by a physician. The body typically excretes the capsule naturally within 8 to 72 hours after ingestion.

Currently, CE is only utilized for diagnostic purposes; in an individual who requires a biopsy or therapeutic intervention must undergo a conventional endoscopic procedure.

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Examples of commercially available capsule endoscopy systems include, but may not be limited to:

- CapsoCam Plus (SV-3) capsule endoscope system is intended for visualization and detection of abnormalities of the small bowel mucosa in adults.
- Capsule delivery devices reportedly introduce the capsule, endoscopically, into
  the small bowel in an individual who cannot swallow the capsule, who has
  gastroparesis or some other impediment that may prevent passage of the
  capsule into the small bowel in a reasonable time. 58,59,67 Examples of these
  devices include, but may not be limited to, the AdvanCE endoscopy delivery
  system and the PillCam Express. (Refer to Coverage Limitations section)
- Magnetically maneuvered capsule endoscopy systems consist of an ingestible capsule and a magnetic controller. The capsule reportedly provides visualization of the stomach and duodenum and captures pictures images of the mucosa. The location and viewing direction are controlled outside the individual's body by a magnetic controller. An example of this type of device includes, but may not be limited to, is the NaviCam capsule endoscope system.<sup>71</sup> (Refer to Coverage Limitations section)
- MiroCam capsule endoscope 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 adults and children from 2 years of age or older.<sup>63</sup>
- Patency capsule systems (eg, Agile Patency Capsule, PillCam Patency Capsule) are intended to verify adequate patency of the gastrointestinal tract prior to administration of the PillCam video capsule in an individual with known or suspected strictures.<sup>60,68</sup> (Refer to Coverage Limitations section)
- PillCam COLON 2 is intended for visualization of the colon and detection of colon polyps ONLY in an individual who had an incomplete optical colonoscopy with adequate preparation and a complete evaluation of the colon was not technically possible. The device is also indicated for the detection of colon polyps in an individual with evidence of gastrointestinal (GI) bleeding of lower GI origin. This only applies to an individual with major risks for colonoscopy or moderate

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sedation but who could tolerate colonoscopy and moderate sedation in the event a clinically significant colon abnormality was identified on capsule endoscopy.<sup>65</sup> (Refer to Coverage Limitations section)

- PillCam Crohn's Capsule is intended to visualize both the small bowel and the colon in an individual with Crohn's disease via a capsule that has two camera heads. It is designed to provide a broader view of the intestinal mucosa. (Refer to Coverage Limitations section)
- PillCam ESO is intended for the visualization of the esophageal mucosa to detect abnormalities such as gastroesophageal reflux disease (GERD), Barrett's esophagus or varices. (Refer to Coverage Limitations section)
- PillCam UGI capsule endoscopy system is intended for visualization of the upper GI tract (esophagus, stomach, duodenum) in a hemodynamically stable individual who is 18 years of age or older.<sup>70</sup> (Refer to Coverage Limitations section)
- Pill Cam SB 3 and the Olympus small intestinal capsule endoscope system (eg, Endocapsule EC-10) are intended for the visualization of the small intestinal mucosa.

An ingestible gastrointestinal blood detection capsule is also being investigated. This capsule (eg, Pill Sense System) utilizes an optical sensor that purportedly measures the presence of blood by measuring the absorption of wavelengths of light. The data gathered is transmitted to an external receiver where an algorithm is used to process the presence of blood or no blood. No images are sent from the capsule. (Refer to Coverage Limitations section)

Artificial intelligence (AI) is under investigation to purportedly reduce the amount of time required to read and increase the accuracy of the interpretation of CE studies. AI reportedly utilizes a deep-learning convolutional neural network (CNN), which is a type of artificial neural network used in image recognition. CNN is designed to enable the identification of abnormal small bowel mucosa and bleeding, increase sensitivity and reduce reading times.<sup>21</sup> An example of a device that utilizes AI is the NaviCam SB – with ProScan, which is not yet available in the US. (Refer to Coverage Limitations section)

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## Coverage Determination

Humana members may be eligible under the Plan for **capsule endoscopy of the small bowel** for the following indications:

• Two years of age or older (with the exception of the CapsoCam Plus system, which is indicated for an adult, 18 years of age or older);

#### AND ANY of the following:

- Aid in the diagnosis of celiac disease in an individual with positive celiac-specific serology who is unable to undergo esophagogastroduodenoscopy (EGD) with biopsy (eg, medically unstable, presence of known or suspected perforated viscus); OR
- Evaluation of an individual with suspicion of obscure (hidden or indistinct) GI bleeding in the small bowel with the following:
  - EGD and colonoscopy within the previous 12 months that failed to identify bleeding source; AND
  - Laboratory proven iron deficiency anemia; OR
- Initial diagnosis of suspected Crohn's disease when there is no evidence of the disease found via standard diagnostic tests such as upper and lower endoscopy (EGD and colonoscopy), computed tomography (CT) enterography, magnetic resonance (MR) enterography or small bowel follow-through (SBFT); OR
- Re-evaluate known celiac or Crohn's disease in an individual remaining symptomatic despite adherence to prescribed therapy; OR
- Surveillance in an individual with Peutz-Jeghers syndrome for the following:
  - o A baseline test at 8 years of age or older (depending on age at diagnosis); AND
  - If polyps are present, repeat every 3 years; AND

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- If no polyps are present, repeat at 18 years of age and then every 3 years or earlier if symptoms are present (eg, abdominal pain, intestinal obstruction, nausea/vomiting, rectal bleeding); OR
- Suspected small bowel tumors with the following:
  - Persistent clinical symptoms (eg, abdominal pain, anemia, gastrointestinal bleeding, unexplained weight loss); AND
  - Standard diagnostic testing within the previous 12 months have failed to determine the etiology of symptoms (testing includes, but may not be limited to, upper and lower endoscopy [EGD and colonoscopy], upper gastrointestinal series, advanced imaging [eg, CT scan/MRI enteroscopy])

#### Coverage Limitations

Humana members may **NOT** be eligible under the Plan for **CE** for any indications other than those listed above including, but may not be limited to, the following indications and/or devices:

- Capsule delivery devices (eg, AdvanCE capsule delivery system, PillCam Express) for any indication; **OR**
- Evaluation of the colon for any indication including screening for colorectal cancer (eg, PillCam COLON 2, PillCam Crohn's Capsule); **OR**
- Evaluation of the esophagus for any indication including screening for Barrett's esophagus or esophageal varices (eg, PillCam ESO); OR
- Individual with a known or suspected GI obstruction, strictures or fistulas based on the clinical picture or pre-procedure testing and profile;
- Ingestible gastrointestinal blood detection capsules (eg, Pill Sense System); OR
- Magnetic guided capsule endoscopy systems (eg, NaviCam capsule endoscope system) for any indication; OR

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- Patency capsule (eg, Agile Patency Capsule, PillCam Patency System) for any indication; OR
- Small bowel monitoring or surveillance of any conditions not included in Coverage Determination section (eg, PillCam SB 3, Olympus small intestinal capsule endoscope system); OR
- Upper gastrointestinal tract CE (eg, PillCam UGI) for any indication

These are considered experimental/investigational as they are not identified as widely used and generally accepted for any other proposed uses as reported in nationally recognized peer-reviewed medical literature published in the English language.

Humana members may **NOT** be eligible under the Plan for **artificial intelligence (AI)**. This is considered experimental/investigational as is not identified as widely used and generally accepted for the proposed use as reported in nationally recognized peer-reviewed medical literature published in the English language.

#### Background

Additional information about **GI conditions** may be found from the following websites:

- American College of Gastroenterology
- American Gastroenterological Association
- National Library of Medicine

# Medical Alternatives

Alternatives to **CE for the colon** include, but may not be limited to, the following:

- Barium enema
- Colonoscopy
- Computed tomographic colonography (CTC)
- Fecal immunochemical test (FIT)
- Fecal occult blood test (FOBT)
- Flexible sigmoidoscopy

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> For information regarding colorectal cancer screening tests, please refer to Colorectal Cancer Screening and Surveillance Medical Coverage Policy.

Alternatives to **CE for the esophagus or small bowel** include, but may not be limited to:

- Angiography
- Enteroclysis
- Intraoperative enteroscopy
- Nuclear medicine scan
- Push enteroscopy
- Small bowel follow through (SBFT) x-ray series
- Sonde enteroscopy
- Upper GI endoscopy

Physician consultation is advised to make an informed decision based on an individual's health needs.

# **Codes**

**Provider Claims** Any CPT, HCPCS or ICD codes listed on this medical coverage policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
91110	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), esophagus through ileum, with interpretation and report	
91111	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), esophagus with interpretation and report	Not Covered
91113	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), colon, with interpretation and report	Not Covered

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91299	Unlisted diagnostic gastroenterology procedure	Not Covered if used to report any procedure outlined in Coverage Limitations section	
CPT®			
Category III	Description	Comments	
Code(s)			
0651T	Magnetically controlled capsule endoscopy, esophagus through stomach, including intraprocedural positioning of capsule, with interpretation and report	Not Covered	
HCPCS Code(s)	Description	Comments	
No code(s) identified			

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