Clinical Policy Title: Capsule endoscopy

Clinical Policy Number: 08.01.02

Effective Date: March 1, 2014
Initial Review Date: September 18, 2013
Most Recent Review Date: September 21, 2017
Next Review Date: September 2018

Related policies:

CP# 08.01.09  Colorectal cancer screening

ABOUT THIS POLICY: Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Keystone First when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First’s clinical policies are not guarantees of payment.

Coverage policy

Keystone First considers the use of capsule endoscopy (CE) to be clinically proven and, therefore, medically necessary when both criteria are met:

- The procedure is carried out by a gastroenterologist with training in CE.
- Any of the following indications are present (Gurudu, 2017; American College of Radiology [ACR], 2015; American Society for Gastrointestinal Endoscopy [ASGE], 2013):
  - For patients with objective evidence of gastrointestinal blood loss and/or iron-deficiency anemia, when other diagnostic methods performed during the same period of illness have failed to identify the source of bleeding and the small bowel is suspected as the source of bleeding.
  - For re-evaluation of patients with a confirmed diagnosis of Crohn's disease who either remain symptomatic after appropriate treatment or who have an onset of new symptoms suggestive of Crohn's disease at an undiagnosed small-bowel region, when imaging studies and/or upper or lower endoscopic examination fail to reveal the location or extent of the pathology and results of the test would affect treatment decisions.
- For initial diagnosis of patients in whom there is strong clinical suspicion of Crohn's disease (with abdominal pain, weight loss, diarrhea, anorexia, bleeding, and biochemical indicators of inflammation), when prior colonoscopy is negative and results of the test would affect treatment decisions.
- For assessment of patients with unexplained clinical symptoms suggestive of a malabsorption syndrome (e.g., celiac disease), when prior serology or gastrointestinal endoscopy are non-diagnostic.
- For detection of suspected small-bowel tumor, when imaging studies or gastrointestinal endoscopic findings have failed to confirm presence of a tumor.
- For surveillance of small bowel tumors in patients with Lynch syndrome or inherited polyposis syndromes such as familial adenomatous polyposis or Peutz-Jeghers syndrome, every 3 years beginning at age 8 years (McGarritty, 2001 updated 2013).

Limitations:

- All other uses of capsule endoscopy, including colorectal screening, are not medically necessary (U.S. Preventive Services Task Force [USPSTF], 2017; Lin, 2016; American Society for Gastrointestinal Endoscopy [ASGE], 2013).
- The use of any patency system for verification of gastrointestinal patency prior to CE is not medically necessary.
- Contraindications to CE include, but are not limited to (ASGE, 2013):
  - Known or suspected intestinal obstruction, fistulas, strictures, or swallowing abnormalities, since these abnormalities may hinder passage of the capsule.
  - Pregnancy.
  - Implantated cardiac pacemakers without prior clearance by a cardiologist.
  - Implantable cardiac defibrillators unless they are observed in a hospital setting with continuous cardiac monitoring.
  - History of abdominal irradiation.
  - Gastric emptying or motility disorders.
  - Magnetic resonance imaging after completion of the CE until the patient has passed the capsule.

For Medicare members only:

Keystone First considers the use of capsule endoscopy to be medically necessary for evaluation of esophageal varices in members with portal hypertension when performed in accordance with existing Local Coverage Determinations (LCDs) (L34081, L34270, L33774, L35089, and L36427) and supplemental instructions (A52384).

Alternative covered services:
Upper and lower endoscopies by network providers for appropriate indications are covered.

**Background**

CE, also known as wireless video endoscopy or video capsule endoscopy, is an ingestible video camera originally developed to visualize the small bowel, which is difficult to examine by colonoscopy and esophagogastroduodenoscopy from accessible orifices. More recently, double-ended capsules have been developed for the noninvasive examination of the esophagus and colon. The U.S. Food and Drug Administration (FDA) has approved three wireless capsule endoscopes for commercial use (FDA, 2017).

During CE, the patient swallows a small digestible pill the size of a multi-vitamin containing a video camera. The camera takes multiple pictures per second and sends wireless electronic signals to a data recorder. The data are downloaded into a computer program that captures the images for analysis. The body excretes the capsule naturally within eight to seventy two hours after ingestion. CE usually is performed in a physician’s office or outpatient clinic, does not require sedation, and is usually well tolerated. The major complication of CE is capsule retention.

**Searches**

Keystone First searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on August 3, 2017. Search terms were: “capsule endoscopy(MeSH).”

We included:
- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews**.
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

Results of upper and lower GI endoscopic procedures are presented typically in terms of detection rate or diagnostic yield, which is the likelihood that a test or procedure will provide the information needed to establish a diagnosis. For CE, diagnostic yield is expressed as the ratio of the number of positive detections divided by the total number of CE procedures. Diagnostic yield is determined as much by appropriateness criteria used to improve patient selection as by the sensitivity of the test. Moreover,
higher diagnostic yield does not necessarily equate to higher diagnostic accuracy or improved therapeutic impact. A high diagnostic yield may actually be the result of inclusion of false-positive results, whereas low diagnostic yield does not necessarily indicate lower accuracy and could result from an accurate reflection of a low incidence of the pathology in question (Xie, 2012).

A majority of studies represent patients in whom CE was performed only after other established endoscopic or imaging procedures had been carried out and their findings were negative or indeterminate. In this highly selected group, a higher probability of the suspected disease is likely, with a corresponding and potentially misleading higher diagnostic yield for CE relative to prior methods.

According to the ASGE, contraindications to CE include (ASGE, 2013):

- Known or suspected gastrointestinal (GI) obstruction, strictures or fistulas based on the clinical picture or pre-procedure testing.
- Swallowing disorders.
- Pregnancy.

ASGE (2013) recommends using CE cautiously in patients with cardiac pacemakers. During CE there is a theoretical potential for interference from the digital radiofrequency communication between the capsule and the data recorder, but published reports on small series of patients have shown no significant interference with pacemaker or implantable cardiac defibrillator function, or with the CE images. CE was found to be safe in patients who were monitored and studied in a hospital setting. Because large studies are not available, patients with implanted cardiac devices should be evaluated by a cardiologist before CE, and patients should be observed in a hospital setting with continuous cardiac monitoring (Qureshi, 2006). ASGE (2013) also recommends patients not undergo MRI after having completed CE until they have passed the capsule; the capsule can be easily identified on plain radiographs, and this should be performed if there is any question.

**Policy updates:**

We added an update of a previous systematic review (Hayes, 2013, updated 2016), one new systematic review/meta-analysis (Health Quality Ontario, 2015) and three evidence-based guidelines to the policy. Evidence-based guidelines recommend CE as one of several diagnostic options in the workup of obscure gastrointestinal bleeding (OGB) when upper and lower endoscopic evaluations are negative (OHTAC, 2015; ACR, 2015). The National Institute for Health and Clinical Excellence (2015) acknowledged a potential, albeit limited, role for CE in assessment of celiac disease after intestinal obstruction has been ruled out. The new evidence confirms previous findings that CE has a role in the evaluation of suspected small bowel disease when previous findings are non-diagnostic and intestinal obstruction has been ruled out. No changes to the policy are warranted at this time.

In 2017, we added updates of two systematic reviews (Hayes, 2017a and 2017b) and three evidence-based guidelines (Gurudu, 2017 for the ASGE; USPSTF, 2017; ASGE, 2013). The new information is
consistent with the current policy. No policy changes are warranted at this time.

**Summary of clinical evidence:**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enns (2017)</td>
<td>Key points:</td>
</tr>
<tr>
<td>Guideline: video CE</td>
<td>• Colon CE should not be substituted routinely for colonoscopy.</td>
</tr>
<tr>
<td>USPSTF (2017)</td>
<td>Key points:</td>
</tr>
<tr>
<td>Colorectal cancer screening</td>
<td>• CE not used for screening.</td>
</tr>
<tr>
<td>Hayes (2013, updated 2017a)</td>
<td>Key points:</td>
</tr>
</tbody>
</table>
| OGIB                             | • Systematic review of 17 prospective comparative studies of CE with other small bowel investigations, two randomized comparative studies of two different capsule endoscopes (50 to 218 patients), six case series and chart reviews of CE for OGIB/Iron Deficiency Anemia (427 to 911 patients).  
• Update included one randomized controlled trial, one comparison study, three retrospective comparison studies, one retrospective study, three retrospective reviews, one meta-analysis and pooled analysis, one case series, and one economic analysis.  
• Quality of evidence: moderate, limited by small sample sizes (for prospective studies); lack of well-defined reference standards, blinding, and standardized follow-up.  
• CE is safe, has adequate diagnostic yield, and is sensitive for detecting bleeding source in patients referred for small bowel investigation following a negative or non-diagnostic upper gastrointestinal (GI) endoscopy and colonoscopy.  
• Inconclusive for CE’s ability to detect tumors compared to push enteroscopy, small bowel follow through (SBFT), and angiography.  
• Impact on patient management and overall positive impact on health outcomes comparable to push enteroscopy, SBFT, and angiography.  
• Inconclusive comparative effectiveness and safety data of different CE systems. |
| Hayes (2011a, updated 2017b)    | Key points:                       |
| Diagnosis of small bowel Crohn’s disease (CD) in adults | • Systematic review of nine prospective or retrospective cohort studies and eight prospective or retrospective cross-sectional studies. Sample size range 41 to 674 patients.  
• Overall quality: moderate with moderate risk of bias.  
• Consistent evidence shows CE is safe. Most common adverse event was capsule retention in 0% to 10% of patients.  
• Consistent evidence shows CE is equivalent to ileocolonoscopy and magnetic resonance enterography, and superior to SBFT and enteroclysis, for identifying disease activity or recurrence in the small bowel of patients with known or suspected CD.  
• There is insufficient evidence to assess CE relative to push endoscopy, CT enterography, and double-balloon enteroscopy.  
• Consistent, low-quality evidence that CE improves patient management and health outcomes. |
<p>| Health Quality Ontario (2015)    | Key points:                       |</p>
<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
</table>
| Detection of colorectal polyps in adults | • Systematic review and meta-analysis of five observational studies; all evaluated PillCam COLON 2.  
• Overall quality: very low to low.  
• In adults with signs, symptoms, or increased risk of colorectal cancer, acceptable sensitivity and specificity for detecting colorectal polyps  
• Compared with computed tomographic (CT) colonography, no statistically significant difference in accuracy.  
• Acceptable safety profile with few adverse events: 3.9% due to bowel preparation; 0.8% due to capsule retention. |
| ASGE (2013) | **Key points:**  
• WCE is inferior to upper endoscopy for diagnosis and/or screening for the noninvasive diagnosis of complicated GERD, Barrett’s esophagus, and esophageal varices. |
| Xie (2012) | **Key points:**  
• Systematic review of 14 systematic reviews and three health technology assessments (HTA) and evidence from four meta-analyses.  
• Overall quality of evidence: low with consistent results.  
• OGIB — diagnostic yield of CE is significantly higher than push enteroscopy and small bowel barium radiography, but similar to double balloon enteroscopy; outcomes of CE not superior to alternatives at one-year follow up.  
• CD — diagnostic yield of CE is significantly higher than small bowel barium radiography, CT enterography (CTE)/enteroclysis, colonoscopy with ileoscopy and push enteroscopy, but not different than magnetic resonance enterography.  
• Tumors — no significant differences between CE and push enteroscopy.  
• More research needed to determine associations between higher diagnostic yield, better identification of clinically significant conditions and better clinical outcomes.  
• Optimal sequence of diagnostic tests must be determined for each case; CE should not be a first-line test. |
| Hayes (2011b) | **Key points:**  
• Systematic review of 14 clinical studies (six prospective, eight retrospective) and one meta-analysis.  
• Overall quality: low with high risk of bias and small sample sizes.  
• All but two studies evaluated CE older than age 10 years. Most subjects had negative or inconclusive upper and lower endoscopy with persistent symptoms.  
• Most common diagnoses: CD (35%); polyposis (15%); OGIB (13%), and malabsorption/celiac disease (2%).  
• Results suggest CE using the PillCam® system is feasible in pediatric patients with acceptable technical success rates, has good diagnostic yield for small-bowel disorders and a positive impact on patient management in children ≥ age 5 years.  
• The risks of endoscopic capsule placement are unclear.  
• CE with PillCam® SB or PillCam® SB2 recommended for children ≥ age 5 years, who are able and willing to swallow the capsule, for the evaluation of known or suspected small bowel disease such as IBD, OGIB, and suspected polyposis, after negative or inconclusive results from conventional upper and lower GI endoscopy. |
References

Professional society guidelines/other:


ASGE Standards of Practice Committee:


Peer-reviewed references:


**CMS National Coverage Determinations (NCDs):**


**Local Coverage Determinations (LCDs):**


**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICD-10 Code</td>
<td>Description</td>
<td>Comment</td>
</tr>
<tr>
<td>------------</td>
<td>-------------</td>
<td>---------</td>
</tr>
<tr>
<td>D50.0</td>
<td>Iron deficiency anemia secondary to blood loss (chronic)</td>
<td></td>
</tr>
<tr>
<td>D50.9</td>
<td>Iron deficiency anemia, unspecified</td>
<td></td>
</tr>
<tr>
<td>K50.00</td>
<td>Crohn's disease of small intestine without complications</td>
<td></td>
</tr>
<tr>
<td>K50.011</td>
<td>Crohn's disease of small intestine with rectal bleeding</td>
<td></td>
</tr>
<tr>
<td>K50.012</td>
<td>Crohn's disease of small intestine with intestinal obstruction</td>
<td></td>
</tr>
<tr>
<td>K50.013</td>
<td>Crohn's disease of small intestine with fistula</td>
<td></td>
</tr>
<tr>
<td>K50.014</td>
<td>Crohn's disease of small intestine with abscess</td>
<td></td>
</tr>
<tr>
<td>K50.018</td>
<td>Crohn's disease of small intestine with other complication</td>
<td></td>
</tr>
<tr>
<td>K50.019</td>
<td>Crohn's disease of small intestine with unspecified complications</td>
<td></td>
</tr>
<tr>
<td>K50.08</td>
<td>Crohn's disease of both small and large intestine without complications</td>
<td></td>
</tr>
<tr>
<td>K50.011</td>
<td>Crohn's disease of both small and large intestine with rectal bleeding</td>
<td></td>
</tr>
<tr>
<td>K50.012</td>
<td>Crohn's disease of both small and large intestine with intestinal obstruction</td>
<td></td>
</tr>
<tr>
<td>K50.013</td>
<td>Crohn's disease of both small and large intestine with fistula</td>
<td></td>
</tr>
<tr>
<td>K50.014</td>
<td>Crohn's disease of both small and large intestine with abscess</td>
<td></td>
</tr>
<tr>
<td>K50.018</td>
<td>Crohn's disease of both small and large intestine with other complication</td>
<td></td>
</tr>
<tr>
<td>K50.019</td>
<td>Crohn's disease of both small and large intestine with unspecified complications</td>
<td></td>
</tr>
<tr>
<td>K50.90</td>
<td>Crohn's disease, unspecified, without complications</td>
<td></td>
</tr>
<tr>
<td>K50.911</td>
<td>Crohn's disease, unspecified, with rectal bleeding</td>
<td></td>
</tr>
<tr>
<td>K50.912</td>
<td>Crohn's disease, unspecified, with intestinal obstruction</td>
<td></td>
</tr>
<tr>
<td>K50.913</td>
<td>Crohn's disease, unspecified, with fistula</td>
<td></td>
</tr>
<tr>
<td>K50.914</td>
<td>Crohn's disease, unspecified, with abscess</td>
<td></td>
</tr>
<tr>
<td>K50.918</td>
<td>Crohn's disease, unspecified, with other complication</td>
<td></td>
</tr>
<tr>
<td>K50.919</td>
<td>Crohn's disease, unspecified, with unspecified complications</td>
<td></td>
</tr>
<tr>
<td>K90.0</td>
<td>Celiac Disease</td>
<td></td>
</tr>
<tr>
<td>K90.4</td>
<td>Malabsorption due to intolerance, not classified elsewhere</td>
<td></td>
</tr>
<tr>
<td>K90.89</td>
<td>Other intestinal malabsorption</td>
<td></td>
</tr>
<tr>
<td>K90.9</td>
<td>Intestinal malabsorption, unspecified</td>
<td></td>
</tr>
<tr>
<td>K92.1</td>
<td>Melena</td>
<td></td>
</tr>
<tr>
<td>K92.2</td>
<td>Gastrointestinal hemorrhage, unspecified</td>
<td></td>
</tr>
<tr>
<td>Q85.8</td>
<td>Other phakomatoses, not elsewhere classified</td>
<td></td>
</tr>
<tr>
<td>Z86.010</td>
<td>Personal history of colonic polyps</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HCPCS Level II</th>
<th>Description</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>NA</td>
<td>NA</td>
<td></td>
</tr>
</tbody>
</table>