Wireless Capsule Endoscopy

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INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PLAN PRODUCT AND BENEFIT APPLICATION

☒ **Commercial** ☐ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

Notice to Medicaid Policy Readers: For comprehensive rules and guidelines pertaining to this policy, readers are advised to consult the Oregon Health Authority. It is essential to ensure full understanding and compliance with the state's regulations and directives. Please refer to OHA's prioritized list for the following coverage guidelines:

Wireless Capsule Endoscopy: Guideline Note D9

Other Types of Wireless Capsule Endoscopy: Guideline Note 173

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

COVERAGE CRITERIA

Note: Wireless capsule endoscopy for diagnostic purposes may only be performed once during an illness period.

Gastrointestinal Bleeding

I. Small-bowel wireless capsule endoscopy may be considered **medically necessary** for the diagnosis of gastrointestinal bleeding, suspected to be of small bowel origin, when upper and lower endoscopic examinations are negative or nondiagnostic.

Crohn's Disease

II. Small-bowel wireless capsule endoscopy may be considered **medically necessary** for the initial diagnosis of Crohn's disease (CD) when **all** of the following (A.-C.) criteria are met:

A. Negative or nondiagnostic ileocolonoscopy during the period of illness; **and**
B. No obstructive symptoms; **and**

C. There is documented suspicion of CD indicated by abdominal pain and **one or more** of the following (1.-6.):
    1. Elevated c-reactive protein (CRP); **or**
    2. Elevated erythrocyte sedimentation rate (ESR); **or**
    3. Elevated white blood cell (WBC) count; **or**
    4. Positive stool lactoferrin WBC test; **or**
    5. Suspicious small bowel imaging; **or**
    6. Elevated fecal calprotectin test.

III. Small-bowel wireless capsule endoscopy may be considered **medically necessary** in patients with a history of small bowel Crohn's disease (CD) when either of the following are met:

A. Patients are symptomatic and a recurrence of CD is suspected;
B. To ensure medication response and adequate mucosal healing after medical intervention.

Celiac Disease

IV. Small-bowel wireless capsule endoscopy may be considered **medically necessary** for patients with positive-celiac specific serology who are contraindicated for upper endoscopy with biopsy (e.g., medically unstable, presence of known or suspected perforation).

Surveillance of Specific Conditions

V. Small-bowel wireless capsule endoscopy may be considered **medically necessary** for surveillance of the following conditions:

A. Polyposis syndrome (i.e., Peutz-Jeghers syndrome); **or**
B. Suspected small-bowel tumor(s); **or**

VI. Esophageal wireless capsule endoscopy may be considered **medically necessary** for esophageal varices in cirrhotic members with significantly compromised liver function (i.e., Child-Pugh score of Class B or greater) or other situations where a standard upper endoscopy with sedation or anesthesia is contraindicated.

Not Medically Necessary

VII. Small-bowel or esophageal wireless capsule endoscopy is considered **not medically necessary** when any one of the criteria I.-VI. above are not met, including, but not limited to the following:

A. Lynch syndrome (hereditary nonpolyposis colorectal cancer) surveillance
B. Colorectal cancer screening
C. To diagnose or evaluate esophageal disease other than esophageal varices in which standard upper endoscopy is contraindicated
D. In patients with any known contraindication to wireless capsule endoscopy, including:
    1. Hematemesis
    2. Dysphagia
    3. Known or suspected gastrointestinal obstruction

4. Strictures or fistulas
5. In patients with cardiac pacemakers or other implanted electro-medical devices

E. To confirm lesions or other pathology normally within the reach of upper or lower endoscopies (lesions proximal to the ligament of Treitz or distal to the ileum)

VIII. Colon capsule endoscopy (i.e., PillCam™ COLON 2) (CPT code 91113) is considered **not medically necessary** for all indications.

IX. Magnetically controlled capsule endoscopy (e.g. NaviCam™ (CPT code 0651T)) is considered **not medically necessary** for all indications.

X. The use of a patency capsule (i.e., AGILE™ Patency System) to evaluate gastrointestinal patency is considered **not medically necessary** for all indications.

XI. The use of a sensor capsule with interpretation and report for upper gastrointestinal blood detection (e.g., PillSense™ system) is considered **not medically necessary** for all indications

Link to Evidence Summary

POLICY CROSS REFERENCES

- Wireless Capsule for Gastrointestinal Motility Monitoring, MP80

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

BACKGROUND

Wireless Capsule Endoscopy

Wireless capsule endoscopy, also called capsule endoscopy or video capsule endoscopy, is a "noninvasive procedure in which the patient swallows a multivitamin-sized capsule containing a miniaturized wireless video camera, light, transmitter and batteries."[1] As the capsule moves through the gastrointestinal tract, propelled by peristalsis, it transmits video and/or pictures to an external receiver. The video and images are then stored and can later be downloaded to a computer for review in real time. Depending on the specific device, it is either designed to take video and/or pictures of the small-bowel (PillCam™ SB 3 system or ENDOCAPSULE EC-10 System), colon (PillCam™ COLON 2), or esophagus (PillCam™ UGI system).

Wireless Gastrointestinal Patency Capsule

To ensure the device used for wireless capsule endoscopy will pass safely through the gastrointestinal tract, a patency capsule was developed to test for the presence of strictures that might trap a capsule endoscopy device.[2] The patency capsule contains a radiofrequency identification tag, which allows it to

be detected with a handheld scanner, or it can also be visualized on x-rays. "If the capsule becomes lodged in the small intestine, it is designed to dissolve in 20 to 100 hours, allowing it to pass spontaneously."[2]

PillSense™ System

The PillSense™ System is a diagnostic tool intended for the detection of blood in the upper gastrointestinal (GI) tract in hemodynamically stable adults with suspected upper GI bleeding (UGIB). It consists of a single-use, nonsterile capsule equipped with an optical sensor that identifies the presence of blood or hematin. The capsule transmits data wirelessly to a reusable, nonsterile external receiver for interpretation and reporting. The system is designed to support early identification of UGIB and may assist in clinical decision-making and triage. PillSense is not intended to replace endoscopic evaluation

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

Wireless Small-bowel Endoscopy Capsules

There are two FDA-approved capsule endoscopy systems for imaging the small bowel: the PillCam™ SB 3 system by Medtronic, Inc. (previously the Given Diagnostic Imaging System by Given Imaging Ltd.) and the ENDOCAPSULE EC-10 System by Olympus America Inc. (previously the EnteroPRO Endo Capsule).[3,4] Both devices are intended to provide visualization of the small-bowel.

Colon Endoscopy Capsule

There is one FDA-approved capsule endoscopy system for imaging of the colon: PillCam™ COLON 2 Capsule Endoscopy System.[5] The PillCam™ COLON 2 capsule endoscopy system is intended to provide visualization of the colon.

Esophageal Endoscopy Capsule

There is one FDA-approved capsule endoscopy system for imaging of the esophagus: PillCam™ UGI Capsule Endoscopy System.[6] The PillCam™ UGI capsule endoscopy system is intended for visualization of the upper gastrointestinal tract (esophagus, stomach, duodenum).

Wireless Gastrointestinal Patency Capsule

The following regulatory information was obtained from the Hayes evidence review (archived) on the AGILE™ Patency System:

"The Given Diagnostic® System is regulated by the FDA as a Class II device that has been categorized as a wireless, gastrointestinal, capsule imaging system. This device was granted 510(k) market clearance on August 1, 2001 for visualization of the small bowel. On May 8, 2006, the Given AGILE Patency System received Food and Drug Administration (FDA) 510(k) approval (K053639) as an optional accessory to the PillCam™ video endoscopy device. The patency system consists of the dissolvable Agile Patency capsule, handheld Agile Patency scanner, and a TesTag interference scanner. The PillCam™ product line was formerly called the M2A® Capsule and no other imaging systems have been approved in the same FDA category as the PillCam."[2]

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

Gastrointestinal Bleeding

In 2017, Hayes conducted an evidence review to evaluate capsule endoscopy of the small bowel for obscure gastrointestinal bleeding.[1] The literature review identified 25 studies as eligible for inclusion. Sample sizes ranged from 50 to 911 patients and the longest average follow-up across studies was 18 months. The primary outcome of interest was diagnostic performance (i.e., accuracy, sensitivity, specificity, positive predictive value [PPV], and negative predictive value [NPV]). Additional outcomes included diagnostic yield (defined as identification of bleeding source), impact on patient management and health outcomes, rate of complete small bowel imaging, and complications.

The diagnostic performance for capsule endoscopy was as follows:

- Sensitivity: 89% to 100%
- Specificity: 48% to 100%
- PPV: 62% to 100%
- NPV: 83% to 100%.

The diagnostic yield ranged from 30% to 88% for capsule endoscopy compared with:

- 30% to 67% for double-balloon enteroscopy
- 30% to 67% for CT
- 5% to 24% for push enteroscopy
- 7% for SBFT
- 20% for angiography.

A total of 10 studies evaluated capsule endoscopy and its impact on patient management and health outcomes. "Across studies, when capsule endoscopy guided treatment, the bleeding problem resolved in 70% to 100% of patients."[1] Thirteen studies evaluated rates of incomplete small bowel imaging and found that capsule endoscopy failed to reach the colon in 4% to 34% of procedures. In 0.6% to 9.7% of procedures the capsule failed completely due to technical difficulties. Capsule endoscopy was found to be relatively safe. Capsule retention was the most common procedure-related complication and occurred in 0.2% to 5% of procedures.

The quality of evidence was determined to be moderate, and study limitations included small sample sizes, lack of blinding, and lack of well-defined reference standards. The evidence review concluded that "capsule endoscopy has good diagnostic yield and is sensitive for the investigation of the bleeding source in patients who are referred for small bowel investigation following a negative or nondiagnostic upper gastrointestinal (GI) endoscopy and colonoscopy. Capsule endoscopy had an immediate impact on treatment with overall positive impact on health outcomes."[1] The following Hayes Ratings were assigned:

- B (some proven benefit) – For video capsule endoscopy in adult patients with obscure GI bleeding, when upper GI endoscopy and colonoscopy are negative or nondiagnostic.
- D1 (no proven benefit) – For video capsule endoscopy in adult patients with specific contraindications, including the presence of known or suspected intestinal obstruction, fistulas, or strictures, since these abnormalities may hinder passage of the capsule.

Crohn's Disease

In 2021, Hayes updated a technology assessment of capsule endoscopy (CE) for the diagnosis of small bowel Crohn's disease (CD).[7] The evidence review identified 9 prospective or retrospective cohort studies and 8 prospective or retrospective cross-section studies as eligible for inclusion. Sample sizes ranged from 41 to 674 patients and follow-up times varied from no follow-up to 36 months. Outcome measures included diagnostic yield, reclassification of CD, sensitivity, specificity, positive predictive value, negative predictive value, alteration of patient management, and health outcomes after alteration of management.

In patients with suspected CD, the diagnostic yield ranged from 6% to 65% (a wide range is expected because it is highly dependent on disease prevalence) and sensitivity ranged from 64% to 100% and specificity ranged from 89% to 93%. "In patients with a prior diagnosis of CD, CE had a diagnostic yield of 54% to 100% for detection of active or recurrent disease."[7] In the evaluation of clinical utility, studies reported that CE findings led to changes in patient management in 6% to 70% of 41 to 187 patients who were assessed with CE for CD. Overall, CE was safe and capsule retention was the most serious complication occurring in 0% to 10% of patients.

The quality of evidence was determined to be moderate for the assessment of clinical validity and low for the assessment of clinical utility. The following Hayes Ratings were assigned:

- "B (some proven benefit)—For use of capsule endoscopy (CE) in symptomatic adult patients with a confirmed history of small bowel Crohn's disease (CD) and suspected recurrence of CD, and where there are no contraindications to the procedure.
- B (some proven benefit) —For use of CE to diagnose small bowel CD in symptomatic adult patients in whom CD is suspected and conventional diagnostic tests are inconclusive, and where there are no contraindications to the procedure."[7]

Esophageal Varices

In 2018, a systematic review and meta-analysis was published by McCarty and colleagues on the use of wireless capsule endoscopy for the diagnosis and grading of esophageal varices in patients with portal hypertension.[8] Seventeen studies from 2005 to 2015 were included in this meta-analysis (n=1,328). The

diagnostic accuracy of wireless capsule endoscopy was 90% (95% CI, 0.88–0.93). The diagnostic pooled sensitivity and specificity were 83% (95% CI, 0.76 – 0.89) and 85% (95% CI, .75–0.91), respectively. The diagnostic accuracy of wireless capsule endoscopy for the grading of medium to large varices was 92% (95% CI, 0.90–0.94). The pooled sensitivity and specificity were 72% (95% CI, 0.54–0.85) and 91% (95% CI, 0.86–0.94), respectively, for the grading of medium to large varices. The use of capsule demonstrated only mild adverse events. A sensitivity analysis limited to only high quality studies revealed similar results.

The authors concluded, "Wireless esophageal capsule endoscopy is well tolerated and safe in patients with liver cirrhosis and suspicion of portal hypertension. The sensitivity of capsule endoscopy is not currently sufficient to replace EGD as a first exploration in these patients, but given its high accuracy, it may have a role in cases of refusal or contraindication to EGD."[8]

Non-Medically Necessary Indications for Wireless Capsule Endoscopy

Lynch Syndrome (Hereditary Non-polyposis Colorectal Cancer)

The evidence evaluating capsule endoscopy (CE) for surveillance of patients with Lynch syndrome is limited to two nonrandomized studies.[9,10]

Haanstra et al. conducted a nonrandomized study using video capsule endoscopy (VCE) to determine the prevalence of small-bowel neoplasia in asymptomatic patients with Lynch syndrome (LS). A total of 200 patients with proven mutations were included. A small-bowel neoplasia was detected using VCE in two patients. In one patient, a neoplasia was diagnosed 7 months after a negative VCE, which was considered a lesion missed by VCE. Of note, all three neoplasias were within reach of a conventional gastroduodenoscope. The prevalence of small-bowel neoplasia in asymptomatic patients with LS was 1.5%.[9]

Saurin et al. conducted a prospective, blinded, comparative study to evaluate the diagnostic yield of CE versus CT enteroclysis for diagnosis of small-bowel adenocarcinoma in Lynch syndrome patients. Thirty-five asymptomatic patients with genetically confirmed Lynch syndrome were enrolled. CE identified small-bowel neoplasms in three patients compared to only one diagnosed by CT enteroclysis. However, the authors concluded that, "(t)he clinical usefulness of systematic small-bowel screening in these patients should be confirmed through large prospective studies."[10]

Although these studies showed CE may detect small-bowel neoplasms in asymptomatic Lynch syndrome patients, there remains insufficient evidence to determine whether evaluation with CE improves disease management and health outcomes in this patient population.

Colon Capsule Endoscopy

- In 2023, Hayes published an "evolving evidence review" assessing the safety and efficacy of the PillCam Patency Capsule to assess small bowel patency.[11] A review of full-text clinical studies suggests minimal support for using the PillCam patency capsule for verifying small bowel patency in adult patients with known or suspected strictures prior to video capsule endoscopy. Studies were of very poor or poor quality and retrospective in nature - 3 out of 4 studies did not have comparison groups and compared pretest-posttest metrics only. Findings were generally

positive for verification of functional patency; however, some results were confounded due to confirmatory radiographic imaging use in some protocols, even with a passing patency capsule screen.

- In 2020, the ECRI Institute updated an evidence review to evaluate the PillCam Colon 2 Capsule Endoscopy System (Medtronic, Inc.) for detecting colon polyps.[12] The literature review identified two systematic reviews (seven studies, n = 2,420; five studies, n = 361), four prospective diagnostic cohort studies (n = 53, n = 126, n = 66, n = 51), and one RCT (n = 236)) as eligible for inclusion.

  The evidence review concluded that PillCam Colon 2 may be useful in patients unable or unwilling to undergo colonoscopy and that it can detect polyps with sufficient accuracy. However, ECRI concluded that these conclusions, "require further validation in randomized studies."[12] Serious device-related injury or death is, "possible, but rare". Two FDA MAUDE reports of injury were identified. Both involved capsule retention and one case required surgical intervention.

  The ECRI Evidence Bar™ concluded that the balance of evidence is somewhat favorable for the PillCam Colon 2 Capsule Endoscopy System for detecting colon polyps.[12]

- In 2019 (updated 2022), Hayes conducted a health technology assessment of colon capsule endoscopy (CCE) for colorectal cancer screening, diagnosis, and surveillance.[13] The review included 12 studies, 10 of which were prospective cohort studies, one retrospective cohort study, and one case series. Of the 12 studies, 9 assessed CCE in asymptomatic and symptomatic individuals at higher risk of colorectal cancer, 2 studies evaluated CCE for screening average-risk individuals, and one study evaluated the clinical utility of CCE after incomplete conventional colonoscopies.

  Compared to conventional colonoscopy, CCE had a 79%-97% sensitivity and 64% to 97% specificity for detection of polyps or lesions ≥ 6 millimeters (mm) in size. For larger polyps or lesions (size, ≥ 9 mm or ≥ 10 mm), CCE had 77% to 100% sensitivity and 89% to 99% specificity. Hayes found that a number of studies potentially overestimated the sensitivity and specificity of CCE, measuring detection per-patient, rather than per lesion. Further limitations of the evaluation of clinical utility in these studies included a high rate of incomplete imaging by CC, ranging from 0% to 46% of procedures in the 7 studies that reported incomplete imaging rates.
  The only study that evaluated clinical utility of CCE found that CCE was able to image regions colorectal regions that conventional colonoscopy could not in 89 out of 96 patients, and in 43 patients (45%), the additional images by CCE changed medical management. Yet this study did not compare CCE with computed tomography colonography, no rationale for delayed use of modified colonoscopy after initial complete colonoscopy, and no follow-up to determine if patient management effected health outcomes.

  Hayes found that the available research does not provide clear evidence to determine the accuracy and efficacy of CCE relative to conventional colonoscopy of CTC. Hayes gave the following ratings:

- "C: For use of colon capsule endoscopy (CCE) for diagnosis or surveillance in adults with signs or symptoms of colorectal cancer (CRC) and risk factors for the disease. This Rating reflects an overall low-quality body of evidence suggesting that CCE is relatively safe and can detect most colorectal lesions and CRC. CCE may be a suitable alternative for patients who cannot tolerate or refuse to undergo conventional colonoscopy (CC) and for patients with an incomplete CC. However, uncertainty exists regarding the accuracy of CCE versus CC and versus computed tomography colonography. This Rating also reflects a paucity of evidence regarding the clinical utility of CCE for this indication.
- D: For use of CCE for screening for CRC in asymptomatic individuals at average risk of the disease. This Rating reflects very-low-quality evidence that is insufficient to draw conclusions regarding the clinical validity, clinical utility, and safety of CCE for screening for CRC in this patient population. Substantial uncertainty exists due to the lack of well-designed, long-term comparative studies of the effectiveness of CCE relative to established standards, particularly CC, and the role of this test in reducing CRC morbidity and mortality."[13]

Esophageal Capsule Endoscopy

In 2017, McCarty et al. conducted a systematic review and meta-analysis to evaluate the use of esophageal capsule endoscopy (ECE) for the diagnosis and grading of esophageal varices in patients with portal hypertension.[8] Independent reviewers systematically identified relevant literature, assessed quality, and extracted data. The primary outcome of interest was diagnostic accuracy (i.e., sensitivity and specificity).

A total of 17 studies encompassing 1,328 patients were identified as eligible for inclusion. The diagnostic accuracy of ECE for the diagnosis of esophageal varices was 90%. The diagnostic pooled sensitivity and specificity was 83% and 85%, respectively. The diagnostic accuracy of ECE for the grading of esophageal varices was 92% and the pooled sensitivity and specificity was 72% and 91%, respectively. No major adverse events were reported.

Strengths of this study include the systematic review of evidence by independent authors, the inclusion of a large number of studies and a large patient population, and the evaluation of heterogeneity prior to conducting meta-analyses. However, limitations are present due to the poor quality of included studies (e.g., lack of randomization, small sample sizes, lack of follow-up). The authors concluded that although ECE is safe, "the sensitivity of capsule endoscopy is not currently sufficient to replace EGD (endogastroduodenoscopy) as a first exploration in these patients."[8]

In 2014, Colli et al. conducted a Cochrane systematic review to determine the diagnostic accuracy of capsule endoscopy for the diagnosis of esophageal varices in children or adults with chronic liver disease or portal vein thrombosis.[14] Following Cochrane guidelines, several reviewers identified literature, extracted data, and assessed quality. The primary outcome of interest was the pooled estimate of sensitivity and specificity.

The literature review identified 16 studies encompassing 936 patients as eligible for inclusion. The pooled estimate of sensitivity and specificity was 84.8% and 84.3%, respectively. Seven studies included only people with suspected but unknown varices and were at a low risk of bias. The pooled estimate of sensitivity and specificity for these low-bias studies was 79.7% and 86.1%, respectively. "Six studies

assessed the diagnostic accuracy of capsule endoscopy for the diagnosis of large oesophageal varices, associated with a higher risk of bleeding; the pooled sensitivity was 73.7% (95% CI 52.4% to 87.7%) and of specificity 90.5% (95% CI 84.1% to 94.4%)."[14]

Strengths of this study include the systematic identification of literature, extraction of data, and quality assessments following Cochrane guidelines. A significant limitation of this systematic review is that almost all included studies were determined to be at high risk of bias. The authors concluded, "(w)e cannot support the use of capsule endoscopy as a triage test in adults with cirrhosis, administered before oesophago-gastro-duodenoscopy, despite the low incidence of adverse events and participant reports of being better tolerated. Thus, we cannot conclude that oesophago-gastro-duodenoscopy can be replaced by capsule endoscopy for the detection of oesophageal varices in adults with cirrhosis."[14]

Wireless Gastrointestinal Patency Capsule

In 2014, Zheng et al. conducted a systematic review and meta-analysis to evaluate the diagnostic utility of the patency capsule (PC).[15] Independent reviewers systematically identified eligible studies, assessed quality, and extracted data. Study authors were also contacted, if necessary, for additional information or data. The primary outcomes of interest were sensitivity, specificity, likelihood ratios, and area under the receiver operating characteristic curve (AUROC).

The authors identified five single-center prospective studies as eligible for inclusion (n=203). The pooled data indicated the PC had a sensitivity of 97%, specificity of 83%, and AUROC of 0.9557. However, the validity of these results is significantly limited by the poor quality of included studies and small sample size of the meta-analysis. Ultimately, the authors concluded that PC may be of diagnostic value in confirming the GI tract patency before capsule endoscopy. However, further studies of good methodological quality are required to establish the diagnostic accuracy and clinical utility of PC.

PillSense™ System

- In 2025, ECRI published a report evaluating the PillSense™ System, an ingestible capsule designed to detect upper gastrointestinal bleeding (UGIB) in adults prior to endoscopy.[16] The assessment is based on a single, manufacturer-sponsored, prospective diagnostic cohort study (n=126), which reported high diagnostic accuracy: sensitivity of 92.9%, specificity of 90.6%, and a negative predictive value of 97.8%. No adverse events were reported. However, ECRI rates the confidence in this evidence as very low, citing several limitations: the study was conducted at a single center, used fasting protocols not aligned with the device's intended use, and lacks independent replication. The report concludes that while PillSense may offer logistical advantages—such as rapid results and use outside the endoscopy suite—it does not provide visual diagnostic information or therapeutic capability like esophagogastroduodenoscopy (EGD). The potential impact on cost, infrastructure, training, and care processes is rated as small, with moderate potential to reduce downstream resource use. ECRI emphasizes the need for additional independent studies to validate the findings and better understand the device's role in clinical workflows. Overall, the current evidence is insufficient to support strong conclusions about PillSense's clinical utility or cost-effectiveness.

- In 2025, Hayes evaluated the PillSense™ System.[17] Authors determined that the evidence base for the device is currently limited. Two clinical studies were identified: a cross-sectional study

(n=126) comparing PillSense to esophagogastroduodenoscopy (EGD), and a small feasibility study (n=10) involving healthy volunteers. The cross-sectional study reported high sensitivity (92.9%) and specificity (90.6%) for blood detection, suggesting strong diagnostic performance. The feasibility study confirmed the capsule's ability to detect blood following ingestion and demonstrated safe passage without adverse events. However, no studies have assessed the clinical utility of PillSense—specifically, whether its use improves patient outcomes or influences treatment decisions. Additionally, no economic evaluations or cost data were available, and no professional guidelines currently support its use. The device has received FDA de novo classification, indicating it is novel with no predicate. While early findings are promising, the report emphasizes the need for well-designed, comparative studies to establish the device's effectiveness, safety, and role in clinical practice.

CLINICAL PRACTICE GUIDELINES

Small-Bowel Wireless Capsule Endoscopy

American College of Radiology (ACR)

- The 2020 ACR evidence-based practice guidelines addressing the management of Crohn's Disease stated that " there is growing evidence that active inflammation can exist despite clinical resolution of symptoms and that complete mucosal healing represents a better treatment target for long-term outcomes than reliance on clinical symptoms. In this regard, both endoscopy and imaging are becoming central tools in CD to detect such inflammation."[18]

- The 2020 ACR evidence-based practice guidelines regarding radiologic management of lower gastrointestinal tract bleeding recommend the use of capsule endoscopy to evaluate intermittent or obscure non-localized recurrent bleeding when a prior adequate colonoscopy and upper GI endoscopy is negative.[19]

American College of Gastroenterology (ACG)

The 2013 ACG evidence-based practice guidelines regarding the diagnosis and management of celiac disease make the following recommendations regarding ancillary diagnostic testing:[20]

> "Capsule endoscopy should not be used for initial diagnosis except for patients with positive-celiac specific serology who are unwilling or unable to undergo upper endoscopy with biopsy (Strong recommendation, moderate level of evidence).
>
> Capsule endoscopy should be considered for the evaluation of small-bowel mucosa in patients with complicated CD (Strong recommendation, moderate level of evidence)."

American Society for Gastrointestinal Endoscopy (ASGE)

Suspected Small Bowel Bleeding

The 2017 ASGE evidence-based clinical practice guideline for endoscopy in the management of suspected small-bowel bleeding gave the following recommendations for wireless capsule endoscopy:

> "For hemodynamically stable patients with overt bleeding, after upper and lower endoscopic examinations with normal results, VCE (video capsule endoscopy) is recommended as the next diagnostic test.
>
> VCE is considered the first diagnostic step in the evaluation of small-bowel sources of occult bleeding once the upper GI tract and colon have been satisfactorily cleared as potential sources. A follow-up push enteroscopy or DAE is usually recommended for further management of positive results on VCE."[21]

Crohn's Disease

The 2015 ASGE evidence-based guideline evaluating endoscopy in inflammatory bowel disease gave the following recommendation for capsule endoscopy (CE):

> "We recommend CE to evaluate the small intestine in patients with suspected CD who have no obstructive symptoms and negative ileocolonoscopy results.
>
> We recommend CE in patients with known CD and unexplained symptoms only when abnormalities detected with CE will alter management."[22]

National Comprehensive Cancer Network (NCCN)

The NCCN guidelines for genetic/familial high-risk assessment: colorectal (v.3.2024) includes cancer risk and surveillance guidelines for peutz-jeghers syndrome (PJS).[23] The guidelines recommend small intestine screening beginning at approximately 8 to 10 years of age in PJS patients. The guidelines state small bowel visualization can be done using CT or MRI enterography or video capsule endoscopy with baseline at 8-10 y and follow-up interval based on findings but at least by age 18, then every 2-3 y, though this may be individualized, or with symptoms. The guideline also states, "High-level evidence to support routine small bowel screening distal to the duodenum is lacking. However, may consider small bowel visualization (eg, capsule endoscopy) or CT/MRI [for familial adenomatous polyposis], especially if advanced duodenal polyposis."

National Cancer Institute (NCI)

The NCI's PDQ® (Physician Data Query) for gastrointestinal (GI) carcinoid tumors recommends scintigraphy, computed tomography (CT), capsule endoscopy (CE), enteroscopy, or angiography for diagnostic imaging of GI carcinoids.[24]

National Institute for Health and Care Excellence

In 2019, NICE published a clinical practice guideline addressing the management of Crohn's Disease.[25] Investigators stated that "treatment with infliximab or adalimumab should only be continued if there is clear evidence of ongoing active disease as determined by clinical symptoms, biological markers and investigation, including endoscopy if necessary."[25]

Lynch Syndrome (Hereditary Non-Polyposis Colorectal Cancer)

No evidence-based clinical practice guidelines provide a recommendation for or against the use of capsule endoscopy for diagnostic surveillance of small-bowel malignancies in Lynch syndrome patients. This includes the American College of Gastroenterology guideline on the management of hereditary gastrointestinal cancer syndromes[26], the American Gastroenterological Association guideline on the management of lynch syndrome[27], and the National Comprehensive Cancer Network Guideline for genetic/familial high-risk assessment: colorectal[23].

Colon Capsule Endoscopy

No evidence-based clinical practice guidelines provide a recommendation for or against the use of colon capsule endoscopy.

Magnetically Controlled Capsule Endoscopy

No evidence-based clinical practice guidelines provide a recommendation for or against the use of magnetically controlled capsule endoscopy.

Esophageal Capsule Endoscopy

American College of Gastroenterology (ACG)

The 2016 ACG evidence-based guideline for the diagnosis and management of Barrett's esophagus (BE) stated, "(e)sophageal video capsule endoscopy is a well-tolerated, patient-preferred, and noninvasive technique that allows visualization of the distal esophagus. However, because of inadequate accuracy (pooled sensitivity 78% and specificity 73%), it is currently not recommended for BE screening."[28]

Wireless Gastrointestinal Patency Capsule

No evidence-based clinical practice guidelines were identified that evaluate the use of wireless gastrointestinal (GI) patency capsules for assessing GI patency.

EVIDENCE SUMMARY

The use of wireless capsule endoscopy to evaluate the small-bowel for gastrointestinal bleeding, Crohn's disease, celiac disease, polyposis syndromes, and small-bowel tumors is supported by the peer-reviewed medical literature and evidence-based clinical practice guidelines. Therefore wireless capsule endoscopy is considered medically necessary for these conditions.

There is insufficient evidence to support the use of wireless capsule endoscopy for surveillance of small-bowel malignancies in Lynch syndrome patients. There are few studies investigating capsule endoscopy in this setting, none of which determine clinical utility, and they are limited by nonrandomized study design and small sample sizes. Additionally, no evidence-based clinical practice guidelines provide recommendations for capsule endoscopy surveillance in Lynch syndrome patients. Therefore, the use of

wireless capsule endoscopy is considered not medically necessary for surveillance of small-bowel malignancies in patients with Lynch syndrome.

There is insufficient evidence to establish the clinical validity and clinical utility of magnetically controlled capsule endoscopy, or of colon or esophageal capsule endoscopy. Studies lack comparator groups, do not address clinical utility, and lack long term follow up. Additionally, no evidence-based clinical practice guidelines recommend the use of colon capsule endoscopy and the American College of Gastroenterology does not recommend esophageal capsule endoscopy for Barrett's esophagus screening. Therefore, wireless capsule endoscopy is considered not medically necessary for screening and diagnosis of colon and esophageal diseases.

There is insufficient evidence to support the accuracy and validity of patency capsules for evaluation of gastrointestinal patency. Further studies of good methodological quality are required to establish the diagnostic accuracy and clinical utility of patency capsules for evaluating gastrointestinal patency prior to capsule endoscopy. Therefore, patency capsules for evaluation of gastrointestinal patency are considered not medically necessary.

HEALTH EQUITY CONSIDERATIONS

The Centers for Disease Control and Prevention (CDC) defines health equity as the state in which everyone has a fair and just opportunity to attain their highest level of health. Achieving health equity requires addressing health disparities and social determinants of health. A health disparity is the occurrence of diseases at greater levels among certain population groups more than among others. Health disparities are linked to social determinants of health which are non-medical factors that influence health outcomes such as the conditions in which people are born, grow, work, live, age, and the wider set of forces and systems shaping the conditions of daily life. Social determinants of health include unequal access to health care, lack of education, poverty, stigma, and racism.

The U.S. Department of Health and Human Services Office of Minority Health calls out unique areas where health disparities are noted based on race and ethnicity. Providence Health Plan (PHP) regularly reviews these areas of opportunity to see if any changes can be made to our medical or pharmacy policies to support our members obtaining their highest level of health. Upon review, PHP creates a Coverage Recommendation (CORE) form detailing which groups are impacted by the disparity, the research surrounding the disparity, and recommendations from professional organizations. PHP Health Equity COREs are updated regularly and can be found online here.

BILLING GUIDELINES AND CODING

CODES*		
CPT	0651T	Magnetically controlled capsule endoscopy, esophagus through stomach, including intraprocedural positioning of capsule, with interpretation and report
	0977T	Upper gastrointestinal blood detection, sensor capsule, with interpretation and report
	83993	Calprotectin, Fecal

	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
	91113	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), colon, with interpretation and report
	91299	Unlisted diagnostic gastroenterology procedure
HCPCS	None	

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

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POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.
4/2023	Changes in denial type from "investigational" to "not medically necessary."
7/2023	Annual update.
5/2024	Annual update. No changes to criteria.
5/2025	Annual update. No changes to criteria.
7/2025	Q3 2025 code set update.