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# Wireless Capsule for Gastrointestinal Motility Monitoring

MEDICAL POLICY NUMBER: 80

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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, Providence Plan Partners, and Ayin Health Solutions 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.

### \*\*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

Gastrointestinal motility monitoring using a wireless capsule (i.e., SmartPill® GI Monitoring System) is considered **investigational and is not covered** for all indications.

Link to [Evidence Summary](#)

## POLICY CROSS REFERENCES

- [Wireless Capsule Endoscopy, MP134](#)

The full Company portfolio of current Medical Policies is available online and can be [accessed here](#).

## POLICY GUIDELINES

### BACKGROUND

#### Gastroparesis

Gastroparesis is a gastrointestinal motility disorder, not due to an obstruction, where the stomach empties slower than normal causing bloating, nausea, vomiting, and weight loss. The cause of gastroparesis is usually unknown; however, it is common in patients with diabetes and may also be due to certain medications. Gastroparesis can also affect the small and large intestines leading to a diagnosis of irritable bowel syndrome.

## Wireless Capsule for Gastrointestinal Motility Monitoring (SmartPill™)

The SmartPill™ Motility Capsule (Medtronic) is part of the SmartPill™ motility testing system. The capsule technology is a self-contained electronic device that wirelessly measures gastrointestinal pH, temperature, and pressure. The patient ingests the capsule and a data receiver nearby collects the data transmitted by the capsule. After data collection, the receiver is returned to the physician for downloading and analysis.

## 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.

The SmartPill® GI Monitoring System was approved under the FDA's 510(k) process as a class II device and assigned the product code NYV.<sup>1</sup> SmartPill cleared 7/2006 (K053547) and version 2.0 cleared 10/2009 (K092343). SmartPill GI Monitoring System is indicated for use in evaluating patients with suspected delayed gastric emptying.

## CLINICAL EVIDENCE AND LITERATURE REVIEW

### EVIDENCE REVIEW

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of a wireless capsule (i.e., SmartPill®) for gastrointestinal motility monitoring. Below is a summary of the available evidence identified through December 2022.

### Systematic Reviews

In 2017 (updated 2021), Hayes published a health technology assessment of wireless capsule systems for the diagnosis of gastroparesis and monitoring of gastrointestinal (GI) motility.<sup>2</sup> The technology assessment was last updated in November 2019. The literature review identified 13 nonrandomized studies (3 cross-sectional comparative studies, 7 prospective case-control studies, and 3 retrospective pretest/posttest studies) as eligible for inclusion. Sample sizes ranged from 21 to 196 patients with known or suspected GI motility disorders. Outcome measures included sensitivity, specificity, and accuracy of motility disorder detection.

Although 13 studies were evaluated, “these studies provide limited evidence concerning the accuracy of the wireless capsule systems and no reliable evidence that use of these systems improves patient outcomes.”<sup>2</sup> Five studies evaluated the use of the SmartPill wireless motility capsule (WMC) to detect gastroparesis; however, these studies, “provided limited evidence of the accuracy of WMC.” Six studies reviewed the SmartPill WMC for the detection of delayed colonic transit. Studies compared WMC to

conventional techniques (e.g., radiopaque markers), and although agreement between WMC and these techniques was generally good, “the reported measures of test agreement are not precise indicators of the accuracy of WMC relative to conventional testing methods.” Three studies evaluated the clinical utility of WMC testing to improve patient management. Due to their poor quality (retrospective, no follow-up), these studies provided no reliable evidence that information from WMC testing improves patient management.

The overall quality of evidence was determined to be low due to individual study limitations, including lack of randomization, small study size, retrospective analysis, lack of follow-up, and incomplete testing of enrolled patients. The Hayes review concluded that additional studies are needed to determine the accuracy of wireless capsule systems relative to standard testing for the detection of GI motility disorders. “Additional studies are also needed to demonstrate that the information obtained with wireless capsule systems can be used to improve the management and health outcomes of patients who have GI motility disorders.” The following Hayes ratings were assigned for wireless capsule monitors to assess GI motility:

- C (potential but unproven benefit): For assessment of gastrointestinal (GI) motility with the SmartPill wireless motility capsule (WMC) system in adult patients without contraindications to use.
- D2 (insufficient evidence): For assessment of GI motility with a wireless capsule endoscopy (WCE) system in adult patients without contraindications to use.
- D2 (insufficient evidence): For assessment of GI motility with the SmartPill WMC system or a WCE system in pediatric and adolescent patients.

## **CLINICAL PRACTICE GUIDELINES**

### National Institute for Health and Care Excellence (NICE)

The 2014 evidence-based NICE guideline for assessing motility of the gastrointestinal tract using a wireless capsule recommended the following:<sup>3</sup>

“The evidence on assessing motility of the gastrointestinal tract using a wireless capsule raises no major safety concerns. There is evidence of efficacy in measuring gastrointestinal function but uncertainty about the clinical benefit of this, and about patient selection. Therefore, this procedure should be used only with special arrangements for clinical governance, consent and audit or research... NICE encourages further research into the use of a wireless capsule to assess motility of the gastrointestinal tract. Studies should include clear details of patient selection. They should report on the diagnostic accuracy of the procedure in different parts of the gastrointestinal tract, and should provide data on the clinical benefits of the procedure for patients.”

### American College of Gastroenterology (ACG)

The 2013 ACG evidence-based clinical practice guideline for the management of gastroparesis stated “(a)lternative approaches for assessment of gastric emptying include wireless capsule motility testing and C breath testing using octanoate or spirulina incorporated into a solid meal; they require further validation before they can be considered as alternates to scintigraphy for the diagnosis of gastroparesis.

(Conditional recommendation, moderate level of evidence).”<sup>4</sup> The guideline also states “scintigraphic measurement of gastric emptying of solid food is the standard method for diagnosis of gastroparesis.”

In addition to the evidence-based clinical practice guidelines above, four position statements were identified, and all conclude a lack of sufficient evidence for wireless gastrointestinal motility capsules.<sup>5-8</sup>

## EVIDENCE SUMMARY

Although the evidence suggests the wireless motility capsule (i.e., SmartPill) may be useful in diagnosing gastrointestinal (GI) motility disorders, the quality of evidence is low. Additional studies of good methodological quality are required to confirm the clinical validity and clinical utility of wireless capsule GI motility monitoring compared to standard GI motility testing (e.g., gastric emptying study). Furthermore, both the National Institute for Health and Care Excellence and American College of Gastroenterology do not recommend a wireless capsule for gastrointestinal motility monitoring. Therefore, wireless motility capsules are considered investigational for gastrointestinal motility monitoring.

## MEDICARE ADVANTAGE

**Note:** The Company policy for *PHA Medicare Medical Policy Development and Application* (MP50) provides details regarding Medicare’s definition of medical necessity and the hierarchy of Medicare references and resources during the development of medical policies, as well as the Plan’s use of evidence-based processes for policy development.

As of 2/2022, no specific Medicare coverage policy or guidance (e.g., manual, national coverage determination [NCD], local coverage determination [LCD] article [LCA], etc.) was identified which addresses wireless capsule use for gastrointestinal motility monitoring. In the absence of a NCD, LCD, or other Medicare policy, Medicare regulatory guidelines do allow Medicare Advantage Organizations (MAOs) to make their own coverage determinations, as long as the MAO applies an objective, evidence-based process, based on authoritative evidence. (*Medicare Managed Care Manual, Ch. 4, §90.5*) Thus, the Company medical policy criteria may be applied for medical necessity decision-making.

Following an evidence-based assessment of current peer-reviewed medical literature, the Company may consider certain medical services or technologies to be “investigational.” The term “investigational” is not limited to devices or technologies which have not received the appropriate governmental regulatory approval (e.g., U.S. Food and Drug Administration [FDA]), but rather may also mean the procedure, device, or technology does not meet all of the Company’s technology assessment criteria, as detailed within the Company policy for *Definition: Experimental/Investigational* (MP5). For Medicare, only medically reasonable and necessary services or items which treat illness or injury are eligible for Medicare coverage, as outlined in *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. Thus, services which lack scientific evidence regarding safety and efficacy because they are investigational are “not medically reasonable or necessary” for Medicare Plan members. (*Medicare Claims Processing Manual, Ch. 23, §30 A*)

## BILLING GUIDELINES AND CODING

CODES*		
CPT	91112	Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report

### \*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.

## REFERENCES

1. U.S. Food and Drug Administration. 510(k) Premarket Notification. Smart Pill GI Monitoring System. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K092342>. Accessed 12/7/2022.
2. Hayes Inc. Wireless Capsule Systems for Diagnosis of Gastroparesis and Monitoring of Gastrointestinal Motility. Archived 10/20/2022. <https://evidence.hayesinc.com/report/dir.capsulegastroparesis1419>. Accessed 12/7/2022.
3. National Institute for Health and Care Excellence. Assessing motility of the gastrointestinal tract using a wireless capsule. <https://www.nice.org.uk/guidance/ipg502/chapter/1-Recommendations>. Published 2014. Accessed 12/7/2022.
4. Camilleri M, Parkman HP, Shafi MA, Abell TL, Gerson L, American College of G. Clinical guideline: management of gastroparesis. *Am J Gastroenterol*. 2013;108(1):18-37; quiz 38. <https://www.ncbi.nlm.nih.gov/pubmed/23147521>
5. Bharucha AE, Dorn SD, Lembo A, Pressman A. American Gastroenterological Association medical position statement on constipation. *Gastroenterology*. 2013;144(1):211-217.
6. Camilleri M, Bharucha AE, di Lorenzo C, et al. American Neurogastroenterology and Motility Society consensus statement on intraluminal measurement of gastrointestinal and colonic motility in clinical practice. *Neurogastroenterology and motility : the official journal of the European Gastrointestinal Motility Society*. 2008;20(12):1269-1282.
7. Camilleri M, Parkman HP, Shafi MA, Abell TL, Gerson L. Clinical guideline: management of gastroparesis. *Am J Gastroenterol*. 2013;108(1):18-37; quiz 38.
8. Rao SS, Camilleri M, Hasler WL, et al. Evaluation of gastrointestinal transit in clinical practice: position paper of the American and European Neurogastroenterology and Motility Societies.

## **POLICY REVISION HISTORY**

<b>DATE</b>	<b>REVISION SUMMARY</b>
2/2023	Converted to new policy template.