



# Louisiana

## Ingestible pH and Pressure Capsule

**Policy #** 00470

**Original Effective Date:** 06/17/2015

**Current Effective Date:** 07/13/2020

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

*Note: Wireless Capsule Endoscopy as a Diagnostic Technique in Disorders of the Small Bowel, Esophagus, and Colon is addressed separately in medical policy 00137.*

## Services Are Considered Investigational

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers measurement of gastrointestinal transit times, including gastric emptying and colonic transit times, using an ingestible pH and pressure capsule for the evaluation of suspected gastroparesis, constipation, or other gastrointestinal motility disorders to be **investigational**.\*

## Background/Overview

### **Gastroparesis and Constipation**

Gastroparesis is a chronic disorder characterized by delayed gastric emptying in the absence of mechanical obstruction. Symptoms of gastroparesis are often nonspecific and may mimic other gastrointestinal tract disorders. It can be caused by many conditions; most commonly it is idiopathic, diabetic, or postsurgical.

Constipation is a chronic disorder involving infrequent bowel movements, a sensation of obstruction, and incomplete evacuation. Many medical conditions can cause constipation, such as mechanical obstruction, metabolic conditions, myopathies, and neuropathies. Diagnostic testing for constipation can aid in distinguishing between 2 categories of disorders, slow-transit constipation and pelvic floor dysfunction.

### **Diagnosis**

Gastric emptying scintigraphy is considered the reference standard for diagnosing gastroparesis. The patient ingests a radionuclide-labeled standard meal and subsequent imaging is performed at 0, 1, 2,

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and 4 hours post prandially, to measure how much of the meal has passed beyond the stomach. A typical threshold to indicate abnormal gastric emptying is more than 10% of the meal remaining at 4 hours after ingestion.

Standard tests used in the evaluation of constipation include ingestion of radiopaque markers and colonic transit scintigraphy. In the radiopaque markers test, small markers are ingested over one or several days, and abdominal radiographs are performed at 4 and/or 7 days. The number of remaining markers correlates with the colonic transit time. In colonic transit scintigraphy, a radio-labeled meal is ingested, followed by scintigraphic imaging at several time intervals. The location of the scintigraphic signals correlates with colonic transit times.

## **FDA or Other Governmental Regulatory Approval**

### **U.S. Food and Drug Administration (FDA)**

In 2006, an ingestible capsule (SmartPill<sup>®</sup> ‡ GI Monitoring System; Given Imaging) was cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process, for evaluation of delayed gastric emptying. Gastric emptying is signaled when the pH monitor in the capsule indicates a change in pH from the acidic environment of the stomach to the alkaline environment of the small intestine. For example, an increase of 2 or more pH units usually indicates gastric emptying, and a subsequent decrease of 1 or more pH units usually indicates a passage to the ileocecal junction. While SmartPill does not measure 50% emptying time, it can be correlated with scintigraphically measured 50% emptying time. The capsule also measures pressure and temperature during its transit through the entire gastrointestinal tract, allowing calculations of total gastrointestinal tract transit time. In 2009, the Food and Drug Administration expanded the use of the SmartPill to determine colonic transit time for the evaluation of chronic constipation and to differentiate between slow- and normal- transit constipation. When colonic transit time cannot be determined, small and large bowel transit times combined can be used instead. The SmartPill is not for use in pediatric patients.

## **Rationale/Source**

An ingestible pH and pressure-sensing capsule (SmartPill GI Monitoring System) measures pH, pressure, and temperature changes to signify the passage of the capsule through portions of the gastrointestinal tract. It is proposed as a means of evaluating gastric emptying for diagnosis of gastroparesis, and colonic transit times for the diagnosis of slow-transit constipation.

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For individuals who have suspected disorders of gastric emptying or suspected slow-transit constipation who receive diagnostic testing with an ingestible pH and pressure capsule, the evidence includes studies of test characteristics and case series of patients who have undergone the test. Relevant outcomes are test validity, other performance measures, symptoms, functional outcomes, and health status measures. The available studies have provided some comparative data on the SmartPill ingestible pH plus pressure-sensing capsule and other techniques for measuring gastric emptying. This evidence primarily consists of assessments of concordance with available tests. Because the available tests (eg, gastric emptying scintigraphy) are imperfect criterion standards, it is not possible to determine the true sensitivity and specificity of SmartPill. The results of the concordance studies have revealed a moderate correlation with alternative tests, but have provided only limited additional data on the true accuracy of the test in clinical care. Evaluation of cases with discordant results would be of particular value and, ideally, these studies should be linked to therapeutic decisions and to meaningful clinical outcomes. The evidence to date on the clinical utility of testing is lacking, consisting of a small number of retrospective studies. It is not possible to determine whether there is net improvement in health outcomes using SmartPill vs standard diagnostic tests. The evidence is insufficient to determine the effects of the technology on health outcomes.

## **Supplemental Information**

### **Practice Guidelines and Position Statements**

#### **American and European Neurogastroenterology and Motility Societies**

The American and European Neurogastroenterology and Motility Societies issued a position paper on the evaluation gastrointestinal transit in 2011. In it, the wireless motility capsule was recommended by consensus for assessing gastric emptying and small bowel, colonic, and whole-gut transit times in patients with suspected gastroparesis or gastrointestinal dysmotility in multiple regions. However, the position paper noted that the clinical utility of identifying delays in small bowel transit times is unknown.

#### **American Gastroenterological Association**

The American Gastroenterological Association's 2013 guidelines on gastroparesis diagnosis and treatment indicated wireless motility capsule testing requires validation before it can be considered as an alternative to scintigraphy for diagnosing gastroparesis. Gastric emptying scintigraphy was considered the best-accepted method to test for delays in gastric emptying.

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### U.S. Preventive Services Task Force Recommendations

Not applicable.

### Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

### Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

| NCT No.                  | Trial Name  | Planned Enrollment | Completion Date                                 |
|--------------------------|---|--------------------|---|
| Unpublished              |   |                    |   |
| NCT02022826 <sup>a</sup> | Clinical Management With SmartPill Motility Monitoring System and Validation of the SmartPill Five Hour Cutoff in Patients With Symptoms of Gastroparesis | 167                | Dec 2016 (terminated-sponsor internal decision) |

NCT: national clinical trial.

<sup>a</sup> Denotes industry-sponsored or cosponsored trial.

## References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, “Ingestible pH and Pressure Capsule”, 2.01.81, 12:2019.
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3. Parkman HP, Hasler WL, Fisher RS. American Gastroenterological Association technical review on the diagnosis and treatment of gastroparesis. *Gastroenterology.* Nov 2004;127(5):1592-1622. PMID 15521026.

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7. Kuo B, Maneerattanaporn M, Lee AA, et al. Generalized transit delay on wireless motility capsule testing in patients with clinical suspicion of gastroparesis, small intestinal dysmotility, or slow transit constipation. *Dig Dis Sci*. Oct 2011;56(10):2928-2938. PMID 21625964.
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## **Policy History**

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- |            |   |
|------------|---|
| 06/04/2015 | Medical Policy Committee review   |
| 06/17/2015 | Medical Policy Implementation Committee approval. New policy.                           |
| 08/03/2015 | Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed. |
| 06/02/2016 | Medical Policy Committee review   |
| 06/20/2016 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged.       |
| 01/01/2017 | Coding update: Removing ICD-9 Diagnosis Codes   |
| 06/01/2017 | Medical Policy Committee review   |
| 06/21/2017 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged.       |
| 06/07/2018 | Medical Policy Committee review   |
| 06/20/2018 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged.       |

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06/06/2019 Medical Policy Committee review

06/19/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

06/04/2020 Medical Policy Committee review

06/10/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 06/2021

### Coding

*The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2019 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.*

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

| Code Type | Code  |
|-----------|-------|
| CPT       | 91112 |

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|                  |                       |
|------------------|-----------------------|
| HCPCS            | No codes              |
| ICD-10 Diagnosis | All related diagnoses |

\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
  1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
  2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
  3. Reference to federal regulations.

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**NOTICE:** If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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