MEDICAL POLICY

POLICY TITLE	INGESTIBLE PH AND PRESSURE CAPSULE
POLICY NUMBER	MP 5.047

CLINICAL BENEFIT	☒ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☐ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**5/1/2024**

I. POLICY

Measurement of gastrointestinal transit times, including gastric emptying and colonic transit times, using an ingestible pH and pressure capsule is considered **investigational** for the evaluation of suspected gastroparesis, constipation, or other gastrointestinal motility disorders. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-reference:

MP 2.017 Esophageal pH Monitoring
MP 5.033 Wireless Capsule Endoscopy to Diagnose Disorders of the Small Bowel, Esophagus, and Colon

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital BlueCross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO: Refer to FEP Medical Policy Manual. The FEP Medical Policy Manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

III. DESCRIPTION/BACKGROUND

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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 (GI) 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, 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

Scintigraphic gastric emptying (SGE) 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, and 4 hours postprandially, 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 radio-opaque markers and colonic transit scintigraphy. In the radio-opaque markers test, small markers are ingested over 1 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.

Wireless motility capsule (WMC) is a method of assessing regional (gastric emptying, small bowel transit, and colonic transit) and whole gut transit times. The WMC also provides information about gastrointestinal (GI) contractility, such as the frequency of contraction, amplitude of contractions, and motility indexes, for which reference values are available for the gastric and proximal small bowel regions. It is particularly useful for testing individuals with suspected alterations of GI motility in multiple regions.

The WMC is an ingestible, wireless capsule (26 x 13 mm) with a battery life of at least five days that measures pressure, pH, and temperature as it traverses the GI tract. Gastric emptying of the wireless motility capsule appears to occur with the Phase III migrating motor complex, signifying completion of the postprandial phase and return of the fasting state. It assesses small bowel transit time by a sharp increase in pH on entry into the duodenum and by a fall in pH at the ileocecal junction. However, in 15 percent of patients, this pH drop is not observed, and this may be related to the ileocecal valve incompetence.

The sensitivity and specificity of the WMC is comparable to radiopaque marker test and scintigraphic gastric emptying in diagnosing slow transit constipation and delayed gastric emptying, respectively. WMC is well tolerated, has good compliance, and avoids the risks of radiation exposure. However, the WMC is expensive, and it is not clear that it provides added clinical value in most patients.

Societal Guidance

The Joint American Nuclear Medicine Society and American Neurogastroenterology and Motility Society state “Because the wireless motility capsule, an inanimate object, identifies the phase III activity front of the migrating motor complex rather than overall gastric emptying, a meal-based

test provides better physiological assessment of gastric emptying and is thus recommended as the first-line test of gastric emptying over the wireless motility capsule." This guidance is referenced in the Clinical Practice Update for the Management of Medically Refractory Gastroparesis by the American Gastroenterological Association.

The American College of Gastroenterology have a conditional recommendation with low quality of evidence that the "wireless motility capsule testing may be as an alternative to SGE assessment for the evaluation of gastroparesis in patients with upper GI symptoms."

Regulatory Status

In 2006, an ingestible capsule (SmartPill® 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.

IV. RATIONALE

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Summary of Evidence

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 accuracy and 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 and colonic transit times. This evidence primarily consists of assessments of concordance with available tests. Because the available tests (e.g., 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. 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.

V. DEFINITIONS

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SCINTIGRAPHY refers to the injection and subsequent detection of radioactive isotopes to create images of body parts and identify body functions and diseases.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

The following codes are investigational when used to report measurement of gastrointestinal transit times, including gastric emptying and colonic transit times, using an ingestible pH and pressure capsule outlined in the policy statement:

Procedure Codes								
91112								

IX. REFERENCES

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11. *Camilleri M. Gastroparesis: Etiology, clinical manifestations, and diagnosis. In: UpToDate, Talley N (Ed), UpToDate, Waltham, MA. Updated August 15, 2022. Literature review current through December 2023.*
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17. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 2.01.81, Ingestible pH and Pressure Capsule. Archived January 2021*

X. POLICY HISTORY

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MP 5.047	**11/22/11 New policy**. Adopt BCBSA. Considered investigational. FEP variation added.
	01/28/2013 Admin review. New 2013 code added
	07/18/2013 Admin review
	09/24/2013 Consensus review. References updated but no changes to the policy statements. Rationale added.
	07/22/2014 Consensus review. No changes to the policy statements. References and rationale updated.
	07/21/2015 Consensus review. No change to policy statements. References and rationale updated. Coding reviewed
	07/26/2016 Consensus review. No change to policy statements. References and rationale updated. Coding reviewed**.**
	11/09/2016 Admin review. Variation Reformatting
	07/25/2017 Consensus review. No change to policy statements. References and rationale updated. Code reviewed.
	05/07/2018 Consensus review. No change to policy statement. References and background reviewed. Rationale condensed.
	03/29/2019 Consensus review. No change to policy statement. References updated.
	03/10/2020 Consensus review. No change to policy statement. Coding reviewed; references updated.
	05/28/2021 Consensus review. No change to policy statement. Coding and references reviewed.
	01/24/2022. Consensus review. No changes to policy statement. References

	updated.
	05/01/2023 Consensus review. No changes to policy statement. Coding and references reviewed.
	01/18/2024 Consensus review. No changes to policy. Update background and references.

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