Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 11/1/24**
(See policy history boxes for previous effective dates)

Title: Ingestible Capsule for Assessment of Gastrointestinal (Motility) Disorders

Description/Background

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, 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 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.

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.

Medical Policy Statement

Measurement of gastrointestinal transit times, including gastric emptying and colonic transit times, using an ingestible pH and pressure capsule is considered experimental and investigational for the evaluation of suspected gastroparesis, constipation, or other gastrointestinal motility disorders. The peer reviewed literature has not yet shown that the use of this capsule has sufficient diagnostic accuracy to provide clinically relevant information when compared to other available diagnostic testing, including gastric emptying scintigraphy.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

91112

Note: Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.

Rationale

Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

Wireless pH and Pressure Capsules

Clinical Context and Test Purpose

The purpose of diagnostic testing with an ingestible pH and pressure capsule in patients who have suspected disorders of gastric emptying or have suspected slow-transit constipation is to inform a decision whether to proceed to appropriate treatment.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with suspected disorders of gastric emptying or with suspected slow-transit constipation.

Interventions

The test being considered is diagnostic testing with an ingestible pH and pressure capsule.

Comparators

The following tests are currently being used to diagnose suspected disorders of gastric emptying or slow-transit constipation: scintigraphy and radiopaque markers.

Although scintigraphy is considered the reference standard for evaluating gastric emptying, several issues complicate its use as a reference test. Until recently, there has been a lack of test standardization.[1] Significant day-to-day variability in the rate of gastric emptying has also been noted.[2]

Due to a lack of standardization and small sample sizes referenced in published studies, the capability of the gastric emptying test to discriminate between healthy individuals and those with known gastroparesis is uncertain. In a study by Tougas et al (2000), 123 healthy subjects were assessed to determine the normal period required for nearly complete evacuation of a standardized meal from the stomach.[3] The authors suggested that the threshold of normality

for gastric retention at 4 hours is 10% meal retention. The cutoff point was set to include 95% of normal persons. However, it appears to be unknown if this same threshold adequately identifies persons who would otherwise be classified as having gastroparesis and who are candidates or responders to treatment.

Outcomes
The general outcomes of interest are reductions in gastrointestinal discomfort and pain and improvements in quality of life. Comparisons between the ingestible capsule and scintigraphy could be done concurrently.

Technically Reliable
Assessment of technical reliability focuses on specific tests and operators and requires review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review and alternative sources exist. This evidence review focuses on the clinical validity and clinical utility.

Clinically Valid
A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Gastric Emptying

Systematic Reviews
A few published studies have evaluated the ingestible capsule in relation to another diagnostic measure of gastric emptying. A systematic review of 12 studies on the ingestible capsule was published by the Agency for Healthcare Research and Quality (AHRQ; Table 1).[4] Studies that included only healthy participants were excluded from the review; instead, AHRQ looked for studies with comparison groups consisting of healthy, asymptomatic (ie, without symptoms of gastroparesis or constipation) participants as controls. Among these studies, 5 were only available as meeting presentations, and the overall strength of evidence favoring the ingestible capsule was low. Diagnostic accuracy with the ingestible capsule was considered comparable to gastric scintigraphy in 7 studies, 3 of which were in abstracts only. There was a moderate correlation between the ingestible capsule and gastric emptying scintigraphy on transit data and device agreement in 5 studies.

Table 1. Characteristic and Results of Systematic Reviews

Study	Studies Included	Study Populations Included	Study Designs Included	Study Reference Standards Included	Sens, %	Spec, %	SOE
Stein et al (2013)[4], (AHRQ)	12	Patients with gastroparesis or constipation or healthy controls	7 studies were prospective, 5 of 7 were multicenter	Scintigraphy	59-86	64-81	Low

AHRQ: Agency for Healthcare Research and Quality; Sens: sensitivity; SOE: strength of evidence; Spec: specificity.

Diagnostic Studies
A study by Green et al (2013) assessed SmartPill and gastric emptying scintigraphy in 22 pediatric patients with severe upper gastrointestinal (GI) symptoms.[5] Of 20 evaluable patients

who had both tests, 9 patients had delayed gastric emptying identified by scintigraphy. SmartPill was 100% sensitive and 50% specific for delayed gastric emptying. Patients also underwent antroduodenal manometry to detect motor abnormalities. SmartPill identified motor abnormalities in 17 patients compared with 10 detected by antroduodenal manometry. However, because there does not appear to be a reference standard for motor abnormalities, it cannot be determined whether SmartPill is more sensitive or whether it has a higher false-positive rate for detection of motor abnormalities.

Section Summary: Clinical Validity for Gastric Emptying
The data present several shortcomings on the use of the SmartPill in diagnosing gastroparesis; as a result, the diagnostic accuracy is not well defined. The current reference test (gastric emptying scintigraphy) is an imperfect criterion standard, and this creates difficulties in defining the sensitivity and specificity of SmartPill. Studies included healthy asymptomatic subjects as part of a control group. Although there was a moderate correlation between SmartPill gastric emptying time and scintigraphy, scintigraphy itself has limited reliability. Although the areas under the curve between SmartPill and scintigraphy are similar, the modest correlation between the 2 tests indicates that there are often discordant results.

Constipation
Few studies have evaluated the use of SmartPill for assessing colonic transit times. In the systematic review Stein et al (2013) conducted for AHRQ, the strength of evidence in available studies on the ingestible capsule was found to be low overall.[4] No studies were identified that compared the SmartPill to colonic scintigraphy. Accuracy of the ingestible capsule in diagnosing slow-transit constipation was similar to tests using radiopaque markers. A moderate correlation between colonic transit times with the ingestible capsule and tests with radiopaque markers was shown in 5 studies (*r* range, 0.69-0.71).

Section Summary: Clinical Validity for Colonic Transit Time
Although the studies included in the AHRQ systematic review showed moderate correlations between SmartPill and other methods for assessing colonic transit times, they should be interpreted cautiously. The diagnostic capability of SmartPill for detecting slow-transit constipation is unknown.

Clinically Useful
A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence
Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials. No randomized controlled trials were identified.

Gastric Emptying and Colonic Transit Times
The 2013 AHRQ review found that there was a lack of evidence on the clinical utility of testing with the ingestible capsule.[4] The review found 3 studies, including 1 abstract, on management

changes following use of the SmartPill. Kuo et al (2011)[6] and Rao et al (2011)[7] reported that wireless motility capsule testing resulted in a new diagnosis in about 50% of patients. Due to the limited data, AHRQ reviewers considered the evidence insufficient to determine the impact of testing results of the ingestible capsule on treatment and management decisions.

Chain of Evidence

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

Because the clinical validity of an ingestible pH and pressure capsule has not been established, a chain of evidence supporting the clinical utility of the device cannot be constructed.

Section Summary: Clinically Useful

Evidence on the clinical utility of a wireless pressure capsule is very limited, consisting of 3 retrospective analyses describing outcomes of patients undergoing testing with SmartPill. These studies lacked control subjects diagnosed without the test or with alternative tests. This evidence is insufficient to determine the clinical utility of SmartPill for either indication; higher quality studies are still needed to measure the impact of SmartPill on patient management and improved health outcomes.

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 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 versus 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

In 2011, the American and European Neurogastroenterology and Motility Societies issued a position paper on the evaluation of gastrointestinal transit.[8] 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
In 2013, the American Gastroenterological Association's 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.[9] Gastric emptying scintigraphy was considered the best-accepted method to test for delays in gastric emptying.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Ongoing and Unpublished Clinical Trials

Several ongoing studies that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT06409182	A Prospective Pilot Study to Evaluate the Diagnostic Performance of a Wireless Sensor Capsule in Detection of UGIB (HemoPill)	30	5/30/25
NCT05326646	Efficacy of a Low FODMAP Diet According to Colonic pH in Irritable Bowel Syndrome Patients (FOSIIL)	50	August 2024
Completed with results			
NCT01469819	Lubiprostone Effect on Gastrointestinal Tract Transit Times Measured by Smartpill in Patients With Chronic Constipation	37	February 2015
NCT01102894	Pilot Study Using a Wireless Motility Capsule	10	April 2010
Completed			
NCT01551966	Esophageal Capsule Endoscopy in Children (PREVOCAP)	100	July 2013(no results)
NCT00702533	A New Method for Determining Gastric Acid Output Using a Wireless Capsule	80	Completed (no posted results)
NCT02219568	Efficacy of Wireless Capsule Endoscopy and CT Enterography in Obscure Gastrointestinal Bleeding	52	October 2010 (no posted results)

Government Regulations National/Local:

There is no national or local coverage determination on this topic.

The 2024 Medicare Physician Fee Schedule has fees for procedure code 91112.
An assigned fee is not a guarantee of coverage.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

Wireless Capsule Endoscopy to Diagnose Disorders of the Small Bowel, Esophagus, and Colon

References

1. Abell TL, Camilleri M, Donohoe K et al. Consensus recommendations for gastric emptying scintigraphy: a joint report of the American Neurogastroenterology and Motility Society and the Society of Nuclear Medicine. J Nucl Med Technol. Mar 2008;36(1):44-54. PMID 18287197
2. Parkman HP, Hasler WL, Fisher RS. American Gastroenterological Association technical review on the diagnosis and treatment of gastroparesis. Gastroenterology. Nov 2004; 127(5):1592-622. PMID 15521026
3. Tougas G, Eaker EY, Abell TL et al. Assessment of gastric emptying using a low fat meal: establishment of international control values. Am J Gastroenterol. Jun 2000;95(6):1456-62. PMID 10894578
4. Stein E, Berger Z, Hutfless S et al. Wireless Motility Capsule Versus Other Diagnostic Technologies for Evaluating Gastroparesis and Constipation: A Comparative Effectiveness Review. Rockville (MD): Agency for Healthcare Research and Quality; 2013.
5. Green AD, Belkind-Gerson J, Surjanhata BC, et al. Wireless motility capsule test in children with upper gastrointestinal symptoms. J Pediatr. Jun 2013;162(6):1181-1187. PMID 23290514
6. 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):2928-38. PMID 2165964
7. Rao SS, Mysore K, Attaluri A et al. Diagnostic utility of wireless motility capsule in gastrointestinal dysmotility. J Clin Gastroenterol. Sep 2011;45(8):684-90. PMID 21135705

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. Neurogastroenterol Motil. Jan 2011;23(1):8-23. PMID 21138500
9. Camilleri M, Parkman HP, Shafi MA et al. Clinical guideline: management of gastroparesis. Am J Gastroenterol. Jan 2013; 08(1):18-37; quiz 38. PMID 23147521

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 5/20/24, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
9/1/10	7/22/10	6/15/10	Joint policy established
1/1/11	10/12/10	10/27/10	Routine maintenance; code updates: 0242T added to policy; NOC code 91299 deleted
7/1/12	4/10/12	5/18/12	Routine maintenance
7/1/13	4/16/13	4/22/13	Routine review; code update- deleted 0242T and added 91112
9/1/14	6/20/14	6/23/14	Routine maintenance
11/1/15	8/24/15	9/14/15	Routine maintenance
11/1/16	8/16/16	8/16/16	Routine maintenance
11/1/17	8/15/17	8/15/17	Routine maintenance
11/1/18	8/21/18	8/21/18	Routine maintenance
11/1/19	8/20/19		Routine maintenance
11/1/20	8/18/20		Routine maintenance
11/1/21	8/17/21		Routine maintenance
11/1/22	8/16/22		Routine maintenance (ls)
11/1/23	8/15/23		Routine maintenance (jf) Vendor Managed: NA
11/1/24	8/20/24		Routine maintenance (jf) Vendor Managed: NA

Next Review Date: 3rd Qtr, 2025

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: INGESTIBLE CAPSULE FOR ASSESSMENT OF GASTROINTESTINAL (MOTILITY) DISORDERS

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not Covered
BCNA (Medicare Advantage)	See Government Regulations section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.