Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: AmeriHealth Caritas Pennsylvania	**Submission Date**: 02/22/2023
Policy Number: CCP.1357	**Effective Date:** 3/2018 **Revision Date:** February 1, 2023
Policy Name: Gastroparesis evaluations	

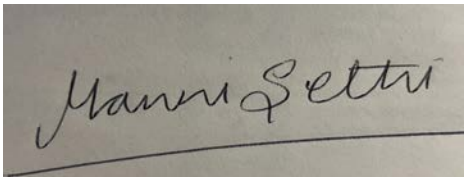
Type of Submission – Check all that apply:

- ☐ **New Policy**
- **X Revised Policy***
- ☐ **Annual Review – No Revisions**
- ☐ **Statewide PDL**

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any clarifying information for the policy below:

Please see revisions with tracked changes below.

Name of Authorized Individual (Please type or print): Manni Sethi, MD,MBA, CHCQM	**Signature of Authorized Individual:** 

Gastroparesis evaluations

Clinical Policy ID: CCP.1357

Recent review date: 2/2023

Next review date: 6/2024

Policy contains: Gastric emptying breath test; gastric emptying scintigraphy; gastroparesis; wireless motility capsule.

AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by AmeriHealth Caritas when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas' clinical policies are not guarantees of payment.

Coverage policy

Gastroparesis evaluation is clinically proven and, therefore, medically necessary when all of the following criteria are met (Camilleri, 2013; Rao, 2011; Schol, 2021; Stein, 2013; Usai-Satta, 2020):

- Presence of symptoms of suspected gastroparesis, including, but not limited to, nausea, vomiting, early satiety, postprandial fullness, bloating, and upper abdominal pain.
- Absence of demonstrable mechanical obstruction of the gastric outlet.
- Non-diagnostic basic clinical investigations, including upper endoscopy.
- Documentation of delayed gastric emptying by either:
    - Gastric emptying scintigraphy of a radiolabeled solid meal.
        - If gastric emptying scintigraphy is contraindicated or not feasible, a wireless motility capsule (e.g., SmartPill™ Motility Testing System, Medtronic Inc., Minneapolis, Minnesota) or stable isotope breath test may be used.
- Evaluation by a gastroenterologist trained to use and interpret the results.

Limitations

All other modalities of verification of delayed gastric emptying in the absence of demonstrable mechanical obstruction of the gastric outlet are not medically necessary.

Contraindications to the wireless motility capsule include a history of gastric bezoar, swallowing disorders, dysphagia, suspected strictures/fistulae in the gastrointestinal tract, physiologic gastrointestinal obstruction, gastrointestinal surgery within the previous three months, Crohn's disease, diverticulitis, or those who have an implanted electromechanical medical device (such as pacemaker or infusion pump) (Centers for Medicare & Medicaid Services, 2019, 2021; Rao, 2011).

The wireless motility capsule is not medically necessary in pediatric members, as it has not been approved for use in this population (U.S. Food and Drug Administration, 2017).

Alternative covered services

Routine patient evaluation and management by a network health care provider.

Background

Gastroparesis is a gastric motility disorder characterized by delayed gastric emptying of fluids and/or solids without evidence of a +mechanical gastric outlet obstruction (Saliakellis, 2013). Roughly three of four cases of gastroparesis are idiopathic or related to diabetes mellitus (Ye, 2021). Among individuals with diabetes, the pathogenic changes in gastrointestinal functions can damage the enteric nervous system leading to gastrointestinal motility disorders and increased disease morbidity (Rodrigues, 2012). Gastroparesis is associated with significant psychological distress and poor quality of life (Woodhouse, 2017).

Individuals typically present with nonspecific symptoms that may indicate several possible gastric disorders. These symptoms include nausea, vomiting, early satiety, postprandial fullness, bloating, weight loss, and upper abdominal pain. The differential diagnosis can be particularly challenging in children, in whom the most common symptoms are typically age-dependent (Camilleri, 2013). For example, nausea and abdominal pain are more frequent in older children and adolescents, while vomiting is more frequent in younger children.

Evaluation and management of suspected gastroparesis requires documentation of delayed gastric emptying and exclusion of other potential causes (Camilleri, 2013). Scintigraphy using Technecium-99 is considered the gold standard for diagnosing gastroparesis, with C13 breath testing a safe and effective alternative. Wireless capsules are promising, but limited by lack of availability and high cost (Usai-Satta, 2020). An upper gastrointestinal barium contrast study and esophagogastroduodenoscopy can rule out mechanical obstruction. Tests of gastric, small intestinal, and colonic motor function may provide adjunctive physiologic information for diagnosing and guiding the management of gastrointestinal dysmotilities.

Findings

Butler (2017) in a narrative review noted that breath tests (e.g., the 13C urea breath test for the diagnosis and monitoring of Helicobacter pylori) are an excellent gastric diagnostic tool, particularly for studying children, as testing is painless and noninvasive. Several stable isotope breath tests for assessing gastric emptying have been designed and validated against scintigraphic methods. These tests have also been combined with nonabsorbable carbohydrates, such as lactulose, using hydrogen molecule measurements in exhaled breath to determine orocecal transit time. However, as the tracer target moves more distally away from the stomach, there may be variations in transit time that reduce the sensitivity and specificity of the test.

Stein (2013) in a systematic review identified the wireless motility capsule as an effective modality for diagnosing gastric and colonic motility disorders when compared with other tests of gastric and colonic motility; however, the quality of evidence regarding its ability to detect gastroparesis or slow-transit constipation was graded as low. Seven studies evaluated diagnosis of gastric emptying delay and found the wireless motility capsule comparable to scintigraphy for diagnostic accuracy, accuracy of motility assessment, effect on treatment

decisions, and effect on resource utilization. Sensitivity of the wireless motility capsule compared with gastric scintigraphy ranged from 59% to 86% and specificity ranged from 64% to 81%.

The main limitations of the review were inconsistencies in reporting the performance of motility testing modalities. There is also a built-in bias in favor of the wireless motility capsule as subjects had undergone other testing suggestive of gastric emptying delay, in effect preselecting those individuals most likely to be affirmed with positive findings for wireless mobility capsule study. The authors noted that data are insufficient to determine the optimal timing of motility capsule testing in diagnostic algorithms, but the wireless motility capsule constitutes another viable and useful diagnostic modality. Capsule retention and obstruction are potential complications, but serious complications are rare. They are contraindicated in children and patients with a known history of esophageal stricture (Stein, 2013).

For gastric emptying the choice test for gastroparesis is scintigraghy which involves the consumption of a meal that has a radioactive substance in it, that can be visualized and track the digestion time for and rate of stomach emptying. It takes approximately two to four hours (International Foundation for Gastrointestinal disorders, 2021).

According to the American College of Gastroenterology, gastric emptying scintigraphy of a solid phase meal is the diagnostic standard for gastroparesis for its ability to provide a noninvasive, direct, and quantifiable measure of gastric emptying (Camilleri, 2013). While scintigraphic protocols vary among providers, the most reliable measure is gastric retention of solids at four hours, as studies of shorter duration or based on a liquid challenge are less sensitive for diagnosing gastroparesis. In professional guidance, the diagnostic value of wireless motility capsule and breath testing as alternatives to gastric emptying scintigraphy is controversial. They recommend further validation of wireless motility testing and breath testing before considering them as alternatives to gastric emptying scintigraphy.

In 2019, we added a consensus guideline from the American and European Neurogastroenterology and Motility Societies (Rao, 2011) and one narrative review (Bruno, 2013) to the policy, and deleted two studies from the policy. Limited evidence supports breath testing using 13C-octanoate or -spirulina as a safe, valid test that correlates well with gastric emptying scintigraphy for measuring the gastric emptying rate of solids (Bruno, 2013). There are no contraindications to the test, and it can be used in individuals with diabetes with suspected gastroparesis. However, technical factors such as concurrent diseases, the test meal used, the duration of breath collection, and the cut-off limits of the normative data can influence the results.

In 2022, we added a guideline from European experts, which stated that upper gastrointestinal endoscopy is mandatory for diagnosing gastroparesis. The guideline also states that scintigraphy, breath testing, wireless motility capsule assessment, and gastric ultrasound are all valid tests for diagnosing the condition (Schol, 2021).

According to the American and European Neurogastroenterology and Motility Societies, wireless motility capsules and breath tests are safe, validated, and radiation-free alternatives that offer advantages to individuals in whom gastric emptying scintigraphy is contraindicated or not feasible, such as pregnant women, breast-feeding women, and children (International Foundation for Gastrointestinal disorders, 2021; Rao, 2011). Scintigraphy and wireless motility capsules are capable of assessing regional and whole-gut transit and offer value for individuals with suspected alterations of gastrointestinal motility in multiple regions. Breath testing as a measure of orocecal transit time with lactulose provides semiquantitative assessment of small bowel transit, but its clinical use for whole-gut transit is unclear. Other tests such as transabdominal ultrasonography, magnetic resonance imaging, capsule endoscopy, radiopaque markers, and antroduodenal manometry may be used to evaluate small bowel and colonic transit, depending on availability and provider preferences.

We modified the policy to include the wireless motility capsule to the list of clinically proven methods for evaluating delayed gastric emptying, as it offers an acceptable alternative to scintigraphy, particularly in those whom gastric emptying scintigraphy is contraindicated or not feasible. The policy ID was changed from CP# 08.01.11 to CCP.1357.

In 2020, we identified no newly published, relevant literature to add to the policy. We modified the coverage to emphasize gastric emptying scintigraphy as the primary modality for evaluating gastric emptying and make wireless motility capsule and isotope breath tests medically necessary alternatives for those in whom gastric emptying scintigraphy is contraindicated or not feasible.

In 2021, we identified no newly published, relevant literature to add to the policy and deleted one older reference.

In 2022, we added a systematic review of 23 studies of persons with gastric emptying problems or upper gastrointestinal symptoms given promotility agents. Those who had optimal tests (scintigraphy, breath test, or solid meal > 2 hours duration) had significantly better improvements (P = .02) than those who had suboptimal tests (Vijayvargiya, 2019a). We also added a meta-analysis of 25 studies (n = 4,287) that documented an association between optimally measured (scintigraphy and breath tests) delayed gastric emptying and early satiety/fullness in patients with gastroparesis (Vijayvargiya, 2019b).

We also added a comparison of patients (n = 150) with gastroparesis symptoms tested with both scintigraphy, and wireless motility capsule. The latter resulted in more treatment changes (P < .0001), elimination of additional tests (P < .0001), and orders of prokinetics (P = .0007) and laxatives (P < .0001) (Hasler, 2019).

In 2023, no newly published relevant literature to add to the policy. No new testing for gastroparesis has been developed. All information is current and standard of care. No coverage changes are warranted.

References

On November 16, 2022, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “Gastroparesis/diagnosis” (MeSH), “Gastric Emptying” (MeSH), “Breath Tests” (MeSH), “gastroparesis evaluation,” “impedance,” “intestinal motility,” and “wireless endoscopy.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

1/2018: initial review date and clinical policy effective date: 3/2018

3/2019: Policy references updated. Wireless motility capsule added and policy ID changed.

2/2020: Policy references updated. Policy coverage modified.

2/2021: Policy references updated.

2/2022: Policy references updated.

2/2023: Policy references updated.