



Clinical Policy Title: Gastroparesis evaluations

Clinical Policy Number: 08.01.11

Effective Date: March 1, 2018
Initial Review Date: January 11, 2018
Most Recent Review Date: February 6, 2018
Next Review Date: February 2019

Policy contains:

- Gastroparesis.
- Radiolabeled scintigraphy.
- Wireless motility capsule.

Related policies:

CP# 08.01.02 Capsule endoscopy

ABOUT THIS POLICY: 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

AmeriHealth Caritas considers the use of evaluations of gastrointestinal motility to be clinically proven and, therefore, medically necessary when the following criteria are met (Camilleri, 2013; Stein, 2013; Camilleri, 2008; Camilleri 2016, Hayes, 2017, Butler 2017):

- Presence of symptoms of gastroparesis, including, but not limited to, nausea, vomiting, early satiety, postprandial fullness, bloating, and upper abdominal pain in the absence of demonstrable mechanical obstruction of the gastric outlet.

Approved modalities for evaluating gastroparesis include, but are not limited to:

- Antropyloroduodenal manometry.
- Stable isotope breath tests.
- Scintigraphy of a radiolabeled solid meal.

Limitations:

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

Alternative covered services:

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

Background

Historically, gastroparesis is characterized by delayed gastric emptying of fluids and/or solids without evidence of a mechanical gastric outlet obstruction (Saliakellis, 2013). It is suspected on the presence of symptoms indicating gastric dysmotility, such as nausea, vomiting, early satiety, postprandial fullness, bloating, weight loss, and upper abdominal pain. Gastroparesis may be confirmed on the demonstration of delayed gastric emptying on scintigraphy of a radiolabeled solid meal. Tests of gastric, small intestinal, and colonic motor function may provide relevant physiologic information and are useful adjuncts for diagnosing and guiding the management of gastrointestinal dysmotilities.

Searches

AmeriHealth Caritas searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality's National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on December 4, 2017. Search terms were: "gastroparesis evaluation," "intestinal motility," and "wireless endoscopy."

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

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 percent to 86 percent and specificity ranged from 64 percent to 81 percent. 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 pre-selecting those individuals most likely to be affirmed with positive findings for wireless motility 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.

The American Neurogastroenterology and Motility Society (Camilleri, 2008) consensus statement on intraluminal measurement of gastrointestinal and colonic motility in clinical practice noted that combined wireless pressure and pH capsules provide information on the amplitude of contractions as they traverse the stomach and small intestine. In children with intractable constipation, colonic phasic pressure measurements can identify patterns suggestive of neuropathy and predict success of antegrade enemas via cecostomy. In adults, these assessments may be used to document severe motor dysfunction (colonic inertia) prior to colectomy. Thus, intraluminal pressure measurements may contribute to the management of patients with disorders of gastrointestinal and colonic motility.

Camilleri (2013), writing on behalf of the American College of Gastroenterology, urged greater awareness and identification of clinical symptoms and documentation of delayed gastric emptying in clinical practice. Symptoms from gastroparesis include nausea, vomiting, early satiety, postprandial fullness, bloating, and upper abdominal pain. Moreover, clinical management of gastroparesis should include assessment and correction of the nutritional state, relief of symptoms, improvement of gastric emptying, and, in patients with diabetes, glycemic control.

Camilleri (2016) in a narrative review of gastric transit cited gamma camera scintigraphy as the most widely used test for the assessment of gastric motility. A standard, 2 percent fat meal consisting of 4 ounces of Eggbeaters (Conagra Foods, Omaha, NE) or equivalent egg white substitute, 2 slices of bread, strawberry jam (30 gm), and 120 mL water (total 240 kcal) is radiolabeled with 0.5–1 mCi 99mTc-sulfur colloid may not reliably induce symptoms in patients with functional dyspepsia, although it is useful for diagnosing gastroparesis.

Hayes (2017) has established the following ratings for gastroparesis evaluation by wireless motility capsule:

- C: For assessing gastrointestinal motility with the wireless motility capsule system in adult patients without contraindications to use. This rating reflects limited, low-quality evidence that the system may be as accurate as conventional methods for detecting gastroparesis and delayed motility but no reliable evidence that information from the system improves patient management or health outcomes.
- D2: For assessing gastrointestinal motility with a wireless capsule endoscopy system in adult patients without contraindications to use. This rating reflects the small body of low-quality evidence on clinical performance, the paucity of studies, and the impact on patient management and health outcomes.
- D2: For assessing gastrointestinal motility by wireless motility capsule in pediatric and adolescent patients. This rating reflects the paucity of evidence in this patient population.

A contemporary systematic review (n = 378) looked at the relevance of psychopathology in the context of disrupted gastric and colonic motility and found that combined anxiety and depression were present in 24 percent of the gastroparesis cohort, severe anxiety in 12.4 percent, depression in 21.8 percent to 23 percent, and somatization in 50 percent (Woodhouse, 2017). A clear, positive relationship with gastroparesis symptom severity was evident. The authors concluded that gastroparesis is associated with significant psychological distress and poor quality of life.

Summary of clinical evidence:

Citation	Content, Methods, Recommendations
<p>Butler (2017)</p> <p>Stable Isotope Techniques for the Assessment of Host and Microbiota Response During Gastrointestinal Dysfunction</p>	<p>Key points:</p> <ul style="list-style-type: none"> • 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.

Citation	Content, Methods, Recommendations
	<ul style="list-style-type: none"> • 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.
<p>Woodhouse (2017)</p> <p>Psychological controversies in gastroparesis: a systematic review</p>	<p>Key points:</p> <ul style="list-style-type: none"> • A contemporary systematic review (n = 378) looked at the relevance of psychopathology in the context of disrupted gastric and colonic motility and found that combined anxiety and depression were present in 24 percent of the gastroparesis cohort, severe anxiety in 12.4 percent, depression in 21.8 percent to 23 percent, and somatization in 50 percent. • A clear, positive relationship with gastroparesis symptom severity was evident. • The authors concluded that gastroparesis is associated with significant psychological distress and poor quality of life.
<p>Hayes (2017)</p> <p>Wireless capsule systems for diagnosis of gastroparesis and monitoring of gastrointestinal motility</p>	<p>Key points:</p> <p>Hayes (2017) has established the following ratings for gastroparesis evaluation by wireless motility capsule:</p> <ul style="list-style-type: none"> • C: For assessing gastrointestinal motility with the wireless motility capsule system in adult patients without contraindications to use. This rating reflects limited, low-quality evidence that the system may be as accurate as conventional methods for detecting gastroparesis and delayed motility but no reliable evidence that information from the system improves patient management or health outcomes. • D2: For assessing gastrointestinal motility with a wireless capsule endoscopy system in adult patients without contraindications to use. This rating reflects the small body of low-quality evidence on clinical performance, the paucity of studies, and the impact on patient management and health outcomes. • D2: For assessing gastrointestinal motility by wireless motility capsule in pediatric and adolescent patients. This rating reflects the paucity of evidence in this patient population.
<p>Camilleri (2016)</p> <p>Measurement of Gastrointestinal and Colonic Motor Functions in Humans and Animals.</p>	<p>Key points:</p> <ul style="list-style-type: none"> • Narrative review of gastric transit cited gamma camera scintigraphy as the most widely used test for the assessment of gastric motility. • A standard, two percent fat meal consisting of four ounces of Eggbeaters (Conagra Foods, Omaha, NE) or equivalent egg white substitute, two slices of bread, strawberry jam (30 gm), and 120 mL water (total 240 kcal) radiolabeled with 0.5–1 mCi ^{99m}Tc-sulfur colloid may not reliably induce symptoms in patients with functional dyspepsia, although it is useful for diagnosing gastroparesis.
<p>Camilleri (2013)</p> <p>American College of Gastroenterology clinical guideline: management of gastroparesis</p>	<p>Key points:</p> <ul style="list-style-type: none"> • American College of Gastroenterology urged greater awareness and identification of clinical symptoms and documentation of delayed gastric emptying in clinical practice. • Symptoms from gastroparesis include nausea, vomiting, early satiety, postprandial fullness, bloating, and upper abdominal pain.

Citation	Content, Methods, Recommendations
	<ul style="list-style-type: none"> • Clinical management of gastroparesis should include assessment and correction of nutritional state, relief of symptoms, improvement of gastric emptying, and, in patients with diabetes, glycemic control.
<p>Stein (2013)</p> <p>Wireless motility capsule versus other diagnostic technologies for evaluating gastroparesis and constipation: a comparative effectiveness review</p>	<p>Key points:</p> <ul style="list-style-type: none"> • 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. • Sensitivity of the wireless motility capsule compared with gastric scintigraphy ranged from 59 percent to 86 percent, and specificity ranged from 64 percent to 81 percent. • The main limitations of the review were inconsistencies in reporting the performance of motility testing modalities. • 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.
<p>Camilleri (2008)</p> <p>American Neurogastroenterology and Motility Society consensus statement on intraluminal measurement of gastrointestinal and colonic motility in clinical practice</p>	<p>Key points:</p> <ul style="list-style-type: none"> • The American Neurogastroenterology and Motility Society (in a consensus statement on intraluminal measurement of gastrointestinal and colonic motility in clinical practice) noted that combined wireless pressure and pH capsules provide information on the amplitude of contractions as they traverse the stomach and small intestine. • In children with intractable constipation, colonic phasic pressure measurements can identify patterns suggestive of neuropathy and predict success of antegrade enemas via cecostomy. • In adults, these assessments may be used to document severe motor dysfunction (colonic inertia) prior to colectomy. • Thus, intraluminal pressure measurements may contribute to the management of patients with disorders of gastrointestinal and colonic motility.

References

Professional society guidelines/other:

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. *Neurogastroenterol Motil.* 2008 Dec;20(12):1269-82. doi: 10.1111/j.1365-2982.2008.01230.x. Review. PubMed PMID: 19019032.

Camilleri M, Linden DR. Measurement of Gastrointestinal and Colonic Motor Functions in Humans and Animals. *Cellular and Molecular Gastroenterology and Hepatology.* 2016;2(4):412-428. doi:10.1016/j.jcmgh.2016.04.003.

Camilleri M, Parkman HP, Shafi MA, Abell TL, Gerson L; American College of Gastroenterology. Clinical guideline: management of gastroparesis. *Am J Gastroenterol*. 2013 Jan;108(1):18-37; quiz 38. doi: 10.1038/ajg.2012.373. Epub 2012 Nov 13. PubMed PMID: 23147521; PubMed Central PMCID: PMC3722580.

Hayes Inc., Hayes Medical Technology Report. Wireless Capsule Systems for Diagnosis of Gastroparesis and Monitoring of Gastrointestinal Motility. Lansdale, Pa. Hayes Inc.; September, 2017

Stein E, Berger Z, Hutfless S, et al. *Wireless Motility Capsule Versus Other Diagnostic Technologies for Evaluating Gastroparesis and Constipation: A Comparative Effectiveness Review* [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2013 May. Available from <http://www.ncbi.nlm.nih.gov/books/NBK143974/> PubMed PMID: 23785726.

Peer-reviewed references:

Butler R, Kosek M, Krebs N, et al. Stable Isotope Techniques for the Assessment of Host and Microbiota Response During Gastrointestinal Dysfunction. *Journal of Pediatric Gastroenterology and Nutrition*. 2017; 64(1): 8–14. doi: 10.1097/MPG.0000000000001373

Saliakellis E, Fotoulaki M. Gastroparesis in children. *Ann Gastroenterol*.2013;26(3):204-211. Review. PubMed PMID: 24714281; PubMed Central PMCID: PMC3959432.

Woodhouse S, Hebbard G, Knowles SR. Psychological controversies in gastroparesis: A systematic review. *World J Gastroenterol*. 2017;23(7):1298-1309. doi: 10.3748/wjg.v23.i7.1298. Review. PubMed PMID: 28275310; PubMed Central PMCID: PMC5323455.

CMS National Coverage Determinations (NCDs):

100.2 Endoscopy. CMS website. <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=81&ver=1>. Accessed December 4, 2017.

A52384 Endoscopy by Capsule – Supplemental Instructions Article. CMS website. <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52384&ver=6>. Accessed December 4, 2017.

Local Coverage Determinations (LCDs):

L33774 Wireless Capsule Endoscopy. CMS website. <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33774&ver=3>. Accessed December 4, 2017.

L35089 Wireless Capsule Endoscopy. CMS website. <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35089&ver=10>. Accessed December 4, 2017.

Commonly submitted codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

CPT Code	Description	Comments
43235	Esophagogastroduodenoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)	
91010	Esophageal motility (manometric study of the esophagus and/or gastroesophageal junction) study with interpretation and report	
91020	Gastric motility (manometric studies)	
91120	Rectal sensation, tone, and compliance test (ie, response to graded balloon distention)	
91122	Anorectal manometry	

ICD-10 Code	Description	Comments
K30	Functional dyspepsia	
K31.84	Gastroparesis	
K56.0 – K56.7	Paralytic ileus and intestinal obstruction without hernia [includes chronic intestinal pseudo-hyphenobstruction]	
K59.8	Other specified functional intestinal disorders	
R11.0 – R11.2	Nausea and vomiting	

HCPCS Level II Code	Description	Comments
N/A	N/A	