NO. 91572-R8

GASTROPARESIS TESTING AND TREATMENT

Effective date: 03/01/2026 **Last reviewed**: 02/2026

Instructions for use: This document is for informational purposes only. Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable. Eligibility and benefit coverage are determined in accordance with the terms of the member's plan in effect as of the date services are rendered. It is not an authorization, certification, explanation of benefits, or contract. Receipt of benefits is subject to satisfaction of all terms and conditions of coverage. Priority Health's medical policies are developed with the assistance of medical professionals and are based upon a review of published and unpublished information including, but not limited to, current medical literature, guidelines published by public health and health research agencies, and community medical practices in the treatment and diagnosis of disease. Because medical practice, information, and technology are constantly changing, Priority Health reserves the right to review and update its medical policies at its discretion. Priority Health's medical policies are intended to serve as a resource to the plan. They are not intended to limit the plan's ability to interpret plan language as deemed appropriate. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment they choose to provide.

Policy scope: This medical policy addresses the diagnosis and treatment of gastroparesis, including interventions such as gastric electrical stimulation (gastric pacing) and gastric peroral endoscopic myotomy (G-POEM).

Related Policies:

- Stimulation Therapy and Devices # 91468
- Category III Current Procedural Terminology (CPT®) Codes # 91636
- Experimental/Investigational/ Unproven Care/Benefit Exceptions # 91117

SUMMARY OF CHANGES – R8

Deletions:
- Removed exclusion of Gastric peroral endoscopic pyloromyotomy or myotomy (G-POEM)

Additions:
- Added gastric peroral endoscopic pyloromyotomy or myotomy (G-POEM) to background section
- Gastric Peroral Endoscopic Myotomy (G-POEM) procedure for refractory gastroparesis is considered medically necessary when medical policy criteria is met.

Changes:
- Prior version of this policy (R7) excluded gastric peroral endoscopic pyloromyotomy or myotomy (G-POEM) for treatment of gastroparesis. With this version of this policy (R8), this exclusion has been removed—G-POEM is now considered medically necessary for treatment of refractory gastroparesis.

I. MEDICAL NECESSITY CRITERIA

A. The following are medically necessary for the purpose of evaluation, diagnosis or treatment of gastroparesis:
    1. Dietary manipulation and administration of antiemetic and prokinetic agents
    2. Gastric emptying scintigraphy (GES)
    3. Gastric pacing (gastric pacemaker) and gastric electrical stimulation are medically necessary according to InterQual® criteria when provided in accordance with the Humanitarian Device Exemption (HDE) specifications of the U.S. Food and Drug Administration (FDA): Humanitarian Device Exemption (HDE) Gastric pacing (gastric pacemaker) and gastric electrical stimulation is considered to be experimental and investigational for all other reasons.
    4. Gastroduodenal manometry for patients who have evidence of gastric stasis by a scintigraphic study without an identifiable cause are medically necessary.
    5. Upper endoscopy is medically necessary to confirm the presence of gastric stasis by the finding of retained food after an overnight period of fasting or to exclude mechanical obstruction or mucosal disease as a cause of impaired gastric emptying.
    6. The Gastric Peroral Endoscopic Myotomy (G-POEM) procedure for refractory gastroparesis is considered medically necessary when **all** of the following criteria are met:
        a. A 4-hour solid-phase gastric emptying scan (GES) demonstrates delayed gastric emptying, preferably with >20% retention at 4 hours.
        b. Member is 18 years of age or older.
        c. An esophagogastroduodenoscopy (EGD) confirms no mechanical gastric outlet obstruction.
        d. Moderate to severe symptoms have persisted for at least 6–12 months, including nausea, vomiting, and/or postprandial fullness.
        e. Documented failure of standard treatment, including **all** of the following:
            i. Dietary modification
            ii. Prokinetic agents
            iii. Anti-emetic therapy

B. The following are NOT medically necessary for evaluation and diagnosis of gastroparesis as they are considered to be experimental and investigational:
    1. Cutaneous electrogastrogram (EGG)
    2. Electronic barostat
    3. MRI
    4. Wireless capsule monitoring system (i.e., Smart pill)

C. The following are NOT medically necessary for the treatment of gastroparesis due to insufficient quality evidence in the published clinical literature to support long-term effectiveness of the technology on health outcomes:

1. Use of botulinum toxin for the treatment of gastroparesis

II. CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) COVERAGE DETERMINATION

Any applicable federal or state mandates will take precedence over this medical coverage policy.

Medicare: Refer to the CMS Online Manual System (IOMs) and Transmittals.
For the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA) refer to CMS Medicare Coverage Database.

The information below is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. MAC jurisdiction for purposes of local coverage determinations is governed by the geographic service area where the Medicare Advantage plan is contracted to provide the service. Please refer to the Medicare Coverage Database website for the most current applicable NCD, LCD, LCA, and CMS Online Manual System/Transmittals.

National Coverage Determinations (NCDs)	
None Identified	
Local Coverage Determinations (LCDs)	
CGS Administrators, LLC	LCD - Botulinum Toxins (L33949) LCD - Wireless Gastrointestinal Motility Monitoring Systems (L33455)
First Coast Service Options, Inc.	LCD - Diagnostic and Therapeutic Esophagogastroduodenoscopy (L33583) LCD - Botulinum Toxins (L33274)
National Government Services, Inc.	LCD - Botulinum Toxins (L33646)
Noridian Healthcare Solutions	LCD - Botulinum Toxin Types A and B (L35172)
Novitas Solutions, Inc.	LCD - Upper Gastrointestinal Endoscopy (Diagnostic and Therapeutic) (L35350) LCD - Botulinum Toxins (L38809)
Palmetto GBA	LCD - Upper Gastrointestinal Endoscopy and Visualization (L34434) LCD - Chemodenervation (L33458) LCD - Wireless Gastrointestinal Motility Monitoring Systems (L33455)
WPS Insurance Corporation	LCD - Botulinum Toxin Type A & Type B (L34635)

III. BACKGROUND

Gastroparesis (delayed gastric emptying) is a digestive disorder in which the motility of the stomach is either abnormal or absent. Clinical symptoms that suggest gastroparesis include nausea, vomiting, and postprandial abdominal fullness.

The diagnosis of gastroparesis is based on the presence of appropriate symptoms/signs, delayed gastric emptying, and the absence of an obstructing structural lesion in the

stomach or small intestine. Primary treatment of gastroparesis includes dietary manipulation and administration of antiemetic and prokinetic agents. Other medications include unapproved medications or off-label indications such as domperidone, erythromycin, and centrally acting antidepressants used as symptom modulators.

Gastric Electrical Stimulation (GES)
Current approved treatment options, including metoclopramide and gastric electrical stimulation (GES) approved on a humanitarian device exemption. A humanitarian device is a medical device specially designated by the US Food and Drug Administration (FDA) for use in the treatment of a rare medical condition (fewer than 8000 new cases per year in the United States). The FDA requires that any physician who wishes to use the device to treat a patient must first obtain approval from the hospital's institutional review board. Two types of electrical stimulation have been used for gastroparesis. One type is referred to as a long-pulse duration and applies pulses with duration in milliseconds (usually few hundreds), at a frequency of a few cycles per minute. The second type of stimulus is referred to as a short pulse duration, and applies pulses with duration in microseconds, at a hertz frequency (cycle/sec), hence also referred to as high-frequency stimulation or low energy stimulation. Pulses can be delivered continuously, or in groups (trains). GES with trains of high frequency, short-duration pulses is currently the only type in clinical use for gastroparesis. An example of a GES is the Enterra Therapy system (Medtronic) which is authorized for use in treatment of chronic intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology. GES may relieve symptoms, including weekly vomiting frequency, and the need for nutritional supplementation, based on open-label studies.

Second-line approaches include venting gastrostomy or feeding jejunostomy; intrapyloric botulinum toxin injection was not effective in randomized controlled trials. Most of these treatments are based on open-label treatment trials and small numbers.

Wireless Capsule Monitoring Systems (SmartPill GI Monitoring System)
Wireless capsule monitoring systems directly measure conditions in the gastrointestinal (GI) tract. One example of these systems is the SmartPill GI Monitoring System, also known as a wireless motility capsule. The patient ingests the capsule and wears or keeps a data receiver nearby to collect the information transmitted by the capsule. The capsule is usually eliminated in the stool in 10 to 73 hours. After data collection is complete, the data receiver is returned to the physician for downloading and analysis of the pH, temperature, and pressure data. Gastroparesis is detected based on prolonged gastric transit time, which is detected based on the increase in acidity while in the stomach and subsequent decrease in acidity upon small bowel entry (Hayes, 2023). The SmartPill GI Monitoring System includes a capsule activation device, laptop computer with docking station, and software for data display and analysis (Lee et al., 2014; Bekkelund et al., 2021); it does not have a camera for collection of images. There is a risk that the capsule will become lodged in the small bowel and require another procedure to dislodge or remove it. Furthermore, the wireless capsule is a single relatively large unit and its movement does not appear to accurately reflect the emptying of liquid and small solid caloric contents from the stomach (Grover et al., 2019).

Botulinum Toxin
Botulinum toxin is an inhibitor of cholinergic neuromuscular transmission and has been used to treat spastic disorders of both striated and smooth muscles by local injection into affected muscles. Botulinum toxin inhibits cholinergic neurotransmission by irreversibly

interfering with acetylcholine release. For gastroparesis, botulinum toxin is typically delivered endoscopically as an intrapyloric injection usually under direct visualization. Two randomized controlled trials (Arts, 2007; Friedenberg, 2008) evaluated the effect of botulinum toxin in gastroparesis patients. Although symptoms and gastric emptying improved after treatment with botulinum toxin, no significant difference was seen compared to placebo. Furthermore, neither trial measured pyloric function after botulinum toxin injection, therefore it is unclear if botulinum toxin truly had the anticipated physiologic effect, aside from the hypothesized clinical effect. A systematic review of the literature published by Bai (2010) concluded available studies could not showed that intrapyloric botulinum toxin injection significantly relieves subjective symptoms and improve objective measurement in patients with gastroparesis. In addition, the American College of Gastroenterology (ACG) clinical guidelines on the management of gastroparesis currently does not recommend botulinum toxin injections for patients with gastroparesis (Camilleri, 2022). Currently, there is no high-quality evidence to support the use of botulinum toxin in clinical practice for patients with gastroparesis (Pasricha, 2020).

Gastric Peroral Endoscopic Pyloromyotomy or Myotomy (G-POEM)
Gastric peroral endoscopic pyloromyotomy or myotomy (G-POEM) is a minimally invasive treatment of refractory gastroparesis. Refractory gastroparesis can be defined as gastroparesis with poor response to greater than 6 months of dietary modifications and trial of maximally tolerated doses of prokinetic medications. G-POEM was first reported on a human patient in 2013 (Khashab, 2013). G-POEM works like the original POEM procedure which is performed on the valve between the esophagus and stomach to treat achalasia and related conditions. The process of G-POEM involves submucosal injection, mucosal incision, submucosal tunnel creation, myotomy, and closure of mucosal entry site with clips of endoscopic suturing. A meta-analysis (Kamal et al, 2021) included 10 studies and 482 patients. The pooled rate of clinical success at 1 year following G-POEM was 61% and the pooled rate of adverse events was 8%. However, some of the studies included in this analysis were different types and defined clinical success differently. A randomized controlled trial (Martinek, 2022) that included 41 patients with severe gastroparesis, symptomatic improvement at 6 months was achieved in 71% of the patients after G-POEM compared with 22% after the sham procedure. Moreover, 75% of the patients achieved symptomatic improvement 6 months after cross-over G-POEM, which was offered to patients without treatment success after the sham procedure. However, the trial was not sufficiently powered to assess the effectiveness of GPOEM in the etiology subgroups and results cannot be considered as fully conclusive in patients with idiopathic and postsurgical etiologies.

The studies reported that the procedure was safe and somewhat effective for gastroparesis. G-POEM is generally safe when performed by trained and/or experienced endoscopists, and adverse events (AE) are uncommon (McCurdy et al, 2023). However, serious AEs can occur and have been reported. A sizable minority of patients undergoing G-POEM for refractory gastroparesis will not achieve a clinically satisfactory response. Redo G-POEM can be very challenging due to dense fibrosis from the first procedure (Khashab, 2023).

In the 2022 American College of Gastroenterology (ACG) Clinical Guideline: Gastroparesis, ACG gives a conditional recommendation for G-POEM as treatment for patients with gastroparesis with symptoms refractory to medical therapy. Overall, open-label studies of G-POEM suggest there is benefit in terms of symptom improvement and

improved GE, though most studies were of only 3–6 months' duration. A 12-month study showed 56% of patients improved at 1 year (Camilleri et al, 2022). The American Gastroenterological Association (AGA) Clinical Practice Update on Management of Medically Refractory Gastroparesis, states that although intriguing, G-POEM should not be considered first-line therapy and should only be performed at tertiary care centers using a team approach of experts (motility specialists, advanced endoscopists) with extensive experience in treating refractory gastroparesis patients (Lacy, 2022).

A systematic review and network meta-analysis **(**Eckhardt, 2025**)** review of 55 studies compared G-POEM, pyloroplasty, gastric electrical stimulation (GES), and botulinum toxin A in adults with confirmed gastroparesis. All interventions improved symptoms short-term; G-POEM showed the greatest short-term benefit and improved gastric emptying. At intermediate follow-up (>3–36 months), GES had the highest efficacy. Long-term data (>36 months) were available only for G-POEM. Sham-controlled trials confirmed GES superiority over placebo.

A systematic review and meta-analysis (Dolan,2025) of 20 studies (797 patients) found G-POEM achieved technical success of 98% and significant symptom improvement (mean GCSI reduction: –1.56; P<0.001). Gastric emptying improved by ~50% (43% to 23% retention at 4 hours; P<0.001). Functional lumen imaging probe (FLIP) measurements showed increased pyloric diameter and distensibility post-procedure. Adverse events occurred in ~11% of patients, generally minor. This review concluded that the G-POEM is highly effective for refractory gastroparesis, improving symptoms and gastric emptying with acceptable safety.

A randomized, double-blind study (Gonzalez, 2024) compared G-POEM to pyloric botulinum toxin injection (BTI) in patients with refractory gastroparesis confirmed by gastric emptying scintigraphy. At 3 months, clinical success (≥1-point Gastroparesis Cardinal Symptom Index (GCSI) reduction) was higher with G-POEM (65%) versus BTI (40%), though not statistically significant. One-year success rates were 60% vs. 40%, respectively. G-POEM showed greater improvement in gastric emptying (72% vs. 50%) and had only minor adverse events.

A review of 5 studies (Canakis A, et al. 2023) (560 patients; mean follow-up 38 months) found clinical success at 3 years was 75% (95% CI: 68–81). Symptom scores (GCSI) improved significantly at 36 months. Technical success was 98.6%. Adverse events were uncommon: perforation 0.7%, bleeding 4.1%, pain 0.9%, and other minor events 3.4%. Mean hospital stay was ~3 days. This study concludes that G-POEM provides durable long-term symptom improvement with high technical success and low complication rates.

IV. GUIDELINES / POSITION STATEMENTS

Medical/Professional Society	Guideline
American College of Gastroenterology (ACG)	American College of Gastroenterology (ACG) Clinical Guideline: Gastroparesis. Official journal of the American College of Gastroenterology | ACG
American Gastroenterological Association (AGA)	Clinical Guidance on the Management of Gastroparesis- Clinical guidance on the

	management of gastroparesis - American Gastroenterological Association
American Academy of Family Physicians (AAFP)	Gastrointestinal Complications of Diabetes Mellitus
United European Gastroenterology (UEG) and European Society for Neurogastroenterology and Motility (ESNM)	United European Gastroenterology (UEG) and European Society for Neurogastroenterology and Motility (ESNM) consensus on gastroparesis

V. REGULATORY (US FOOD AND DRUG ADMINISTRATION)

See U.S. Food & Drug Administration (FDA) Medical Device Databases for the most current information.

Device	Premarket Approval, 513(f)(2)(De Novo), or 510(k) Number	Notice date
Enterra Therapy system (Medtronic)	H990014	03/31/2000
Smartpill GI Monitoring System	K092342	10/30/2009

VI. CODING

ICD-10 Codes that may support medical necessity

E08.43	Diabetes mellitus due to underlying condition with diabetic autonomic(poly) neuropathy
E09.43	Drug or chemical induced diabetes mellitus with neurological complications with diabetic autonomic (poly) neuropathy
E10.43	Type 1 diabetes mellitus with diabetic autonomic (poly) neuropathy
E11.43	Type 2 diabetes mellitus with diabetic autonomic (poly) neuropathy
E13.43	Other specified diabetes mellitus with diabetic autonomic (poly) neuropathy
K31.84	Gastroparesis
R11.0 - R11.2	Nausea and vomiting

CPT/HCPCS Codes

78264	Gastric emptying imaging study (eg, solid, liquid, or both);
78265	Gastric emptying imaging study (e.g., solid, liquid, or both); with small bowel transit
78266	Gastric emptying imaging study (e.g., solid, liquid, or both); with small bowel and colon transit, multiple days
91020	Gastric motility (manometric) studies
43235	Esophagogastroduodenoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)
43236	Esophagogastroduodenoscopy, flexible, transoral; with directed submucosal injection(s), any substance

43239	Esophagogastroduodenoscopy, flexible, transoral; with biopsy, single or multiple
43245	Esophagogastroduodenoscopy, flexible, transoral; with dilation of gastric/duodenal stricture(s) (e.g., balloon, bougie)
43253	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided transmural injection of diagnostic or therapeutic substance(s) (e.g., anesthetic, neurolytic agent) or fiducial marker(s) (includes endoscopic ultrasound examination of the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis)
43999	Unlisted procedure, stomach
J0585	Injection, onabotulinumtoxinA, 1 unit
J0586	Injection, abobotulinumtoxinA, 5 units
J0587	Injection, rimabotulinumtoxinB, 100 units
J0588	Injection, incobotulinumtoxinA, 1 unit
43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
43881	Implantation or replacement of gastric neurostimulator electrodes, antrum, open
64590	Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension
43648	Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum
43882	Revision or removal of gastric neurostimulator electrodes, antrum, open
64595	Revision or removal of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array
95980	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; intraoperative, with programming
95981	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; subsequent, without reprogramming
95982	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; subsequent, with reprogramming

Not Covered:

0868T	High-resolution gastric electrophysiology mapping with simultaneous patient-symptom profiling, with interpretation and report
43252	Esophagogastroduodenoscopy, flexible, transoral; with optical endomicroscopy (Covered for Medicare and Medicaid)
91112	Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report
91132	Electrogastrography, diagnostic, transcutaneous
91133	Electrogastrography, diagnostic, transcutaneous; with provocative testing
91299	Unlisted diagnostic gastroenterology procedure - when billed for electronic barostat (Explanatory notes must accompany claims billed with unlisted codes).

VII. MEDICAL NECESSITY REVIEW

Prior authorization for certain drugs, devices, services and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service or procedure is medically necessary. For more information, refer to the Priority Health Provider Manual.

To access InterQual guidelines: Log into Priority Health Prism → Authorizations → Authorization Criteria Lookup.

Individual case review may allow coverage for care or treatment that is investigational yet promising for the conditions described. Requests for individual consideration require prior plan approval. All determinations of coverage for experimental, investigational, or unproven treatment will be made by a Priority Health medical director or clinical pharmacist. The exclusion of coverage for experimental, investigational, or unproven treatment may be reviewed for exception if the condition is either a terminal illness, or a chronic, life threatening, severely disabling disease that is causing serious clinical deterioration.

VIII. APPLICATION TO PRODUCTS

Coverage is subject to the member's specific benefits. Group-specific policy will supersede this policy when applicable.

- **HMO/EPO**: This policy applies to insured HMO/EPO plans.
- **POS**: This policy applies to insured POS plans.
- **PPO**: This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.
- **ASO**: For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.
- **INDIVIDUAL**: For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.
- **MEDICARE**: Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.
- **MEDICAID/HEALTHY MICHIGAN PLAN**: For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan

Medicaid Fee Schedule. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

IX. REFERENCES

General Guidelines/Positions Statements

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Botulinum Toxin

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Wireless Motility Capsule

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