Priority Health

MEDICAL POLICY
No. 91572-R7

GASTROPARESIS TESTING AND TREATMENT

Effective Date: February 21, 2024

Date of Origin: February 10, 2010

Review Dates: 2/10, 2/11, 2/12, 2/13, 2/14, 2/15, 2/16, 2/17, 2/18, 2/19, 2/20, 2/21, 2/22, 2/23, 2/24, 2/25

Status: Current

I. POLICY/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): http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/HDEApprovals/ucm161827.htm
   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.

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
2. Gastric peroral endoscopic pyloromyotomy or myotomy (G-POEM)

II. MEDICAL NECESSITY REVIEW

Prior authorization for certain drug, 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, please refer to the Priority Health Provider Manual.
To access InterQual criteria: Log into Priority Health Prism → Authorizations → Authorization Criteria Lookup.

III. APPLICATION TO PRODUCTS

Coverage is subject to 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) and/or the Evidence of Coverage (EOC); 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 located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, the Michigan Medicaid Provider Manual will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.***

IV. DESCRIPTION

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) and 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 G-POEM 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 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% 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).

There is limited evidence on long-term outcomes of G-POEM. A pilot and feasibility trial of G-POEM for gastroparesis to assess safety, physiological mechanisms and efficacy is currently in the recruitment phase. The purpose of this research is to evaluate the 12-month treatment effect of G-POEM vs. sham surgery in patients with gastroparesis that is not helped by medications and to analyze factors that may predict the outcome of the surgery. The evidence is

insufficient to determine the effects of the technology on health outcomes. Several clinical trials are in progress for the G-POEM.

V. CODING INFORMATION

ICD-10 Codes that may apply:

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)

Prior authorization required

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

No prior authorization required

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.)*

See also: Stimulation Therapy and Devices Medical Policy #91468

VI. REFERENCES

1. Camilleri M, Kuo B, Nguyen L, Vaughn VM, Petrey J, Greer K, Yadlapati R, Abell TL. ACG Clinical Guideline: Gastroparesis. Am J Gastroenterol. 2022 Aug
2. Parkman HP, Hasler WL, Fisher RS. American Gastroenterological Association Medical Position Statement: Diagnosis and Treatment of Gastroparesis. Gastroenterology. 2004 Nov;127(5):1589-91.

Botulinum toxin

3. Arts J, Holvoet L, Caenepeel P, Bisschops R, Sifrim D, Verbeke K, Janssens J, Tack J. Clinical trial: a randomized-controlled crossover study of intrapyloric injection of botulinum toxin in gastroparesis. Aliment Pharmacol Ther. 2007 Nov 1;26(9):1251-8. PMID: 17944739.
4. Bai Y, Xu MJ, Yang X, Xu C, Gao J, Zou DW, Li ZS. A systematic review on intrapyloric botulinum toxin injection for gastroparesis. Digestion. 2010;81(1):27-34. Epub 2009 Dec 22. PMID: 20029206.
5. Camilleri M, Parkman HP, Shafi MA, Abell TL, Gerson L; American College of Gastroenterology. Clinical Guideline: Management of Gastroparesis. Am J Gastroenterol 2013; 108:18–37; doi: 10.1038/ajg.2012.373).
6. Lacy BE, Tack J, Gyawali CP. AGA Clinical Practice Update on Management of Medically Refractory Gastroparesis: Expert Review. Clin Gastroenterol Hepatol. 2022 Mar;20(3):491-500. Epub 2021 Oct 29. PMID: 34757197.
7. Pasricha TS, Pasricha PJ. Botulinum Toxin Injection for Treatment of Gastroparesis. Gastrointest Endosc Clin N Am. 2019 Jan;29(1):97-106. doi: 10.1016/j.giec.2018.08.007. Epub 2018 Sep 28. PMID: 30396531; PMCID: PMC6223662.

Endoscopy

8. Martinek J, Hustak R, Mares J, Vackova Z, Spicak J, Kieslichova E, Buncova M, Pohl D, Amin S, Tack J. Endoscopic pyloromyotomy for the treatment of severe and refractory gastroparesis: a pilot, randomised, sham-controlled trial. Gut. 2022 Nov;71(11):2170-2178. Epub 2022 Apr 25. PMID: 35470243; PMCID: PMC9554080.
9. U.S. Food and Drug Administration. Center for Devices and Radiological Health. Enterra Therapy System- H990014. Mar 31, 2000. Updated Aug 22, 2000. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfhde/hde.cfm?id=H990014 (Accessed January 12, 2025).
10. U.S. Food and Drug Administration. Center for Devices and Radiological Health. Humanitarian Use Devices. Available at URL address: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfHDE/HDEInformation.cfm (Accessed January 12, 2025).

Gastric pacing (gastric pacemaker) and gastric electrical stimulation

11. Corvinus FM, Heinrich S, Neumann H, Hadzijusufovic E, Babic B, Lang H, et al. Minimally-invasive temporary gastric stimulation: A pilot study to predict the outcome of electronic gastric stimulation with the Enterra™ system. Dig Liver Dis. 2018 Oct;50(10):1030-1034.
12. Ducrotte P, Coffin B, Bonaz B, Fontaine S, Bruley Des Varannes S, Zerbib F, et al. Gastric Electrical Stimulation Reduces Refractory Vomiting in a Randomized Crossover Trial. Gastroenterology. 2020 Feb;158(3):506-514.e2.
13. Jayanthi NV, Dexter SP, Sarela AI; Leeds Gastroparesis Multi-Disciplinary Team. Gastric electrical stimulation for treatment of clinically severe gastroparesis. J Minim Access Surg. 2013 Oct;9(4):163-7.
14. Soffer EE. Gastric electrical stimulation for gastroparesis. J Neurogastroenterol Motil. 2012 Apr;18(2):131-7. doi: 10.5056/jnm.2012.18.2.131. Epub 2012 Apr 9. PMID: 22523722; PMCID: PMC3325298.

G-POEM

15. Kamal F, Khan MA, Lee-Smith W, Sharma S, Acharya A, Jowhar D, Farooq U, Aziz M, Kouanda A, Dai SC, Howden CW, Munroe CA. Systematic review with meta-analysis: one-year outcomes of gastric peroral endoscopic myotomy for refractory gastroparesis. Aliment Pharmacol Ther. 2022 Jan;55(2):168-177. Epub 2021 Dec 1. PMID: 34854102.
16. Khashab MA, Wang AY, Cai Q. AGA Clinical Practice Update on Gastric Peroral Endoscopic Myotomy for Gastroparesis: Commentary. Gastroenterology. 2023 Jun;164(7):1329-1335.e1. doi: 10.1053/j.gastro.2023.02.027. Epub 2023 Apr 20. PMID: 37086247.
17. Khashab MA, Stein E, Clarke JO, Saxena P, Kumbhari V, Chander Roland B, Kalloo AN, Stavropoulos S, Pasricha P, Inoue H. Gastric peroral endoscopic myotomy for refractory gastroparesis: first human endoscopic pyloromyotomy (with video). Gastrointest Endosc. 2013 Nov;78(5):764-8. PMID: 24120337.
18. McCurdy GA, Gooden T, Weis F, Mubashir M, Rashid S, Raza SM, Morris J, Cai Q. Gastric peroral endoscopic pyloromyotomy (G-POEM) in patients with refractory gastroparesis: a review. Therap Adv Gastroenterol. 2023 Mar 26;16:17562848231151289. PMID: 37007216; PMCID: PMC10052481.

Wireless motility capsule

19. Bekkelund M, Sangnes DA, Søfteland E, et al. Gastroparesis symptoms associated with intestinal hypomotility: an explorative study using wireless motility capsule. Clin Exp Gastroenterol. 2021;14:133-144.
20. Hayes. Wireless Capsule System for Diagnosis of Gastroparesis. Health Technology Assessment. Nov 27, 2023.
21. Chu H, Lin Z, Zhong L, et al. Treatment of high-frequency gastric electrical stimulation for gastroparesis. J Gastroenterol Hepatol. 2012 Jun;27(6):1017-26.

22. Friedenberg FK, Palit A, Parkman HP, Hanlon A, Nelson DB. Botulinum toxin A for the treatment of delayed gastric emptying. Am J Gastroenterol. 2008 Feb;103(2):416-23. doi: 10.1111/j.1572-0241.2007.01676.x. Epub 2007 Dec 5. PMID: 18070232.
23. Lee YY, Erdogan A, Rao SS. How to assess regional and whole gut transit time with wireless motility capsule. J Neurogastroenterol Motil. 2014;20(2):265-270.