

## OHCA Guideline

<b>Medical Procedure Class:</b>	<b>Gastric Electrical Stimulation</b>
Initial Implementation Date:	July 1, 2014
Last Review Date:	April 2021
Effective Date:	September 2021
Next Review/Revision Date:	September 2024
* This document is not a contract, and these guidelines do not reflect or represent every conceivable situation. Although all items contained in these guidelines may be met, this does not reflect, or imply any responsibility of this agency or department to change the plan provision to include the stated service as an eligible benefit.	
<input type="checkbox"/> New Criteria <span style="float: right;"><input checked="" type="checkbox"/> Revision of Existing Criteria</span>	
<b>Summary</b>	
<b>Purpose:</b>	To provide guidelines to assure medical necessity and consistency in the prior authorization process.
<b>Definitions</b>	
<p><b>Gastroparesis</b> is a gastrointestinal motility disorder characterized by delayed gastric emptying without evidence of physical obstruction. Estimates of prevalence range from 1.8% to 4% within the United States. The disorder may be more common in women. Symptoms of gastroparesis include frequent nausea and vomiting, early satiety, bloating, postprandial fullness, and epigastric pain and burning, although symptoms do not correlate well with gastric emptying. The most common etiology of gastroparesis is idiopathic, followed by diabetes and postsurgical, often associated with vagotomy or vagal nerve injury during surgery. Less common causes include eating disorders, connective tissue disease, neurologic diseases (such as Parkinson's), metabolic and endocrine conditions, medications, and critical illness. If chronic nausea and vomiting are not controlled, dehydration, weight loss, and malnutrition can result. Patients with severe symptoms may be forced to withdraw from normal daily activities. Patients may eventually become bedridden from weakness or require hospitalization for fluid restoration and nutritional support.</p> <p><b>Gastric emptying scintigraphy (GES)</b> is commonly performed to evaluate patients with symptoms that suggest an alteration of gastric emptying (GE) and/or motility. It has become the standard for the measurement of gastric motility in clinical practice, because it provides a physiologic, noninvasive, and quantitative measurement of gastric emptying. Scintigraphy measures the motor function of the stomach by quantifying the emptying of a physiologic caloric meal. The technique involves incorporating a radioisotope tracer into a standard meal and tracking its passage through the stomach using a gamma camera. Images are typically gathered at 1, 2, 3, and 4 hours.</p>	
<b>Description</b>	
<p><b>Gastric electrical stimulation</b> involves implantation of a neuroelectrical stimulation device into the abdomen, connected to wires that are attached to the wall of lower stomach. The device sends high frequency, low energy electrical impulses to the stomach with the intention of alleviating chronic nausea and vomiting caused by gastroparesis by stimulating the smooth muscles of the stomach.</p>	
<b>CPT Codes Covered Requiring Prior Authorization (PA)</b>	
<p><b>43647</b> - Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum</p>	

- 43648** - Revision or removal of gastric neurostimulator electrodes, antrum
- 43881** - Implantation or replacement of gastric neurostimulator electrodes, antrum, open
- 43882** - Revision or removal of gastric neurostimulator electrodes electrodes, antrum, open
- 64590** - Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver
- 64595** - Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver

### Approval Criteria

#### INDICATIONS

Gastric electrical stimulation is considered medically necessary in the treatment of chronic intractable nausea and vomiting secondary to severe gastroparesis of diabetic or idiopathic etiology when **ALL** of the following criteria are met:

1. Patient has a diagnosis of at least “**severe**” gastroparesis as evidenced by a 4-hour gastric emptying study (scintigraphy). Grading for severity of delayed GE based on the 4-h value is:
  - Grade 1 (mild): 11–20% retention at 4 h;
  - Grade 2 (moderate): 21–35% retention at 4 h;
  - Grade 3 (severe): 36–50% retention at 4 h;
  - Grade 4 (very severe): >50% retention at 4 h.
2. Gastric anomalies/obstruction have been ruled out by endoscopy and/or contrast radiology; **AND**
3. Member with diabetes exhibits glycemic control with HbgA1C  $\leq$  7.0%; **AND**
4. Member has tried and failed pharmacological treatment with metoclopramide or erythromycin; **AND**
5. Member has experienced loss of 10% or more of usual body weight in 3-6 month period and/or repeated hospitalization for refractory symptoms.

Removal and replacement of the Gastric Electrical Stimulator is considered medically necessary when the following criteria are met:

1. If the device malfunctions, breaks, or becomes infected; **AND**
2. If the medical necessity criteria continue to be met; **AND**
3. If replacement is not part of the manufacturer warranty.

### Additional Information

Gastric electrical stimulation is considered **investigational and not medically necessary** in all other indications including but not limited to the treatment of obesity.

### References

1. Oklahoma Health Care Authority; Policies & Rules, OAC 317:30-3-1; 317:30-5-8.
2. Hayes Health Technology Assessment - *Gastric Electrical Stimulation for Gastroparesis*, March 9, 2021. <https://evidence.hayesinc.com/report/dir.gast0001>
3. Abell, T.L., et al, American Journal of Gastroenterology, 2008; 103:753-763, “Consensus Recommendations for Gastric Emptying Scintigraphy: A Joint Report of the American Neurogastroenterology and Motility Society and the Society of Nuclear Medicine”.
4. American Diabetes Association. (2021). *Diabetes Overview*. Retrieved from <https://www.diabetes.org/diabetes>
5. Medtronic - *Enterra Therapy for Gastroparesis Commonly Billed Codes*, Updated 2019 <http://professional.medtronic.com/pt/gastro/ges/rm-pm/coding-coverage/index.html>

6. Anthem BCBS Medical Policy – *Gastric Electrical Stimulation*, Updated 12/16/2020
7. Cigna Medical Coverage Policy – *Gastric Pacing/Gastric Electrical Stimulation*, Updated 11/15/2020
8. Humana Medical Coverage Policy – *Gastric Pacing*, Updated 01/22/2021
9. United HealthCare Medical Policy – *Gastrointestinal Motility Disorders, Diagnosis, and Treatment*, Updated 06/01/2020