Policy Title:	Policy – Gastric Neurostimulator	Number & Version:	UM-GAST_Stim
Functional Unit:	Utilization Management	Effective Date:	07/10/2023
Policy Owner (Title):	Director, Utilization Management	Page Number:	1 of 4

I. POLICY STATEMENT and PURPOSE

The purpose of this policy is to describe the circumstances under which a Gastric Neurostimulator would or would not be considered medically necessary for members under the guidelines used for clinical review of organizational determinations.

II. BACKGROUND

Gastroparesis is a gastrointestinal motility disorder characterized by delayed gastric emptying in the absence of physical obstruction. It is a condition that slows or stops the movement of food from the stomach to the small intestine. After swallowing food, the muscles in the wall of the stomach grind the food into smaller pieces and push them into the small intestine to continue digestion. With gastroparesis, the stomach muscles work poorly or not at all. The stomach is delayed in emptying its contents. The main symptoms include nausea, vomiting, early satiety, distension/bloating, and epigastric pain (ACG, 2021) (Hayes, 2022) (NIDDK, 2018 - Definition).

Gastroparesis is not common; however, it is more likely to occur in people with diabetes, a history of surgery on the esophagus, stomach, or small intestine, which may injure the vagus nerve, or have had certain cancer treatments, e.g., radiation therapy to the chest or stomach area (NIDDK, 2018).

Diet and medication are first line treatments for gastroparesis. Treatment is based on the cause of the condition (NIDDK, 2018 – Treatment).

A Gastric Neurostimulator (also known as a Gastric Electrical Stimulation (GES) device) uses an implanted electrical device with electrodes attached to the stomach to stimulate the coordinated contractions that enable stomach emptying (Hayes, 2022).

III. SCOPE

This Policy applies to Gastric Neurostimulators, also known as Gastric Electrical Stimulation devices (GES).

IV. DEFINITIONS

Gastroparesis - A gastrointestinal motility disorder characterized by delayed gastric emptying without evidence of physical obstruction (Hayes, 2022).

Gastric Neurostimulator or Gastric electrical stimulation (GES) – An implanted electrical device with electrodes attached to the stomach to stimulate the coordinated contractions that enable stomach emptying (Hayes, 2022).

Medically Necessary – Covered Services rendered by a Health Care Provider that the Plan determines are:

1) Safe and effective
2) Not experimental or investigational
3) Appropriate for patients,
   a) including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is—
      i) furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member,
      ii) furnished in a setting appropriate to the patient's medical needs and condition,
      iii) ordered and furnished by qualified personnel,
      iv) one that meets, but does not exceed, the patient's medical need; and
      v) is at least as beneficial as existing and available medically appropriate alternatives.

V. OWNERSHIP & TRAINING

The Director of Utilization Management is responsible for administration, oversight, and training regarding performance under this Policy.

VI. PROTOCOLS / COVERAGE POLICY

Gastric Neurostimulation is currently considered medically necessary under specific conditions. Those conditions are:

- Treatment of nausea and vomiting from chronic gastroparesis that has been confirmed by gastric emptying scintigraphy, AND
- Does not respond to medical management that includes dietary changes, antiemetics, and prokinetic medications (Camilleri, 2013), OR
- Replacement or revision of a previously approved implant that resulted in complications of gastric stimulation such as bowel obstruction, infection, lead dislodgement, lead erosion, or gastric wall perforation.

(Anand, 2007) (Brody, 2015)

VII. REGULATORY REFERENCES / CITATIONS

CMS National Coverage Determinations (NCDs) None
CMS Local Coverage Determinations (LCDs) None

VIII. PROFESSIONAL REFERENCES / CITATIONS

1. American College of Gastroenterology (ACG). Gastroparesis. June 2021. Accessed at: http://patients.gi.org/topics/gastroparesis on June 7, 2023.

2. Anand C, Al-Juburi A, Familoni B, et al. Gastric electrical stimulation is safe and effective: a long-term study in patients with drug-refractory gastroparesis in three regional centers. Digestion. 2007;75(2-3):83-89. Accessed at: https://pubmed.ncbi.nlm.nih.gov/17519527/ on June 7, 2023.

3. Brody F, Zettervall SL, Richards NG, et al. Follow-up after gastric electrical stimulation for gastroparesis. J Am Coll Surg. 2015;220(1):57-63. Accessed at: https://pubmed.ncbi.nlm.nih.gov/25458798/ on June 7, 2023.

4. Camilleri M, Parkman HP, Shafi MA, Abell TL, Gerson L; American College of Gastroenterology. Clinical guideline: management of gastroparesis. Am J Gastroenterol. 2013;108(1):18-38. Accessed at: https://pubmed.ncbi.nlm.nih.gov/23147521/ on June 7, 2023.

5. Hayes. Health Technology Assessment. "Gastric Electrical Stimulation For Gastroparesis" Dec. 7, 2022. Accessed at: https://evidence.hayesinc.com/report/dir.gast0001 on June 7, 2023.

6. National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). Health Information, Digestive Diseases, Gastroparesis, Definition & Facts. January 2018. Accessed at: https://www.niddk.nih.gov/health-information/digestive-diseases/gastroparesis/definition-facts on June 7, 2023.

7. National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). Health Information, Digestive Diseases, Gastroparesis, Treatment. January 2018. Accessed at: https://www.niddk.nih.gov/health-information/digestive-diseases/gastroparesis/treatment#:~:text=Metoclopramide%20link.,help%20relieve%20nausea%20and%20vomiting on June 7, 2023.

IX. RELATED POLICIES / PROCEDURES

None

X. ATTACHMENTS

None

APPROVALS:

	Printed Name	Signature
Senior Medical Director, UM:	Michael Fusco, MD	
Corporate Chief Medical Officer (QMMC Chair):	Debbie Zimmerman, MD	

VERSION HISTORY:

Version #	Date	Author	Purpose/Summary of Major Changes
01	06/07/2023	Gina Vehige	Original
02	06/14/2023	Gina Vehige	Revised based on clinical feedback; FINAL Approved by MMC 6/30/2023; Effective 07/10/2023