Cohere Medical Policy - Gastric Pacing/Electrical Stimulation

Clinical Guidelines for Medical Necessity Review

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Important Notices

Notices & Disclaimers:

GUIDELINES ARE SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION-MAKING OF END USERS.

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Other Notices:

Guideline Information:

Specialty Area: Gastroenterology/Urology/Disorders of the Musculoskeletal System
Guideline Name: Cohere Medical Policy - Gastric Pacing/Electrical Stimulation
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Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17 yo)

Table of Contents

Important Notices **2**
Medical Necessity Criteria **4**
Service: Gastric Pacing/Electrical Stimulation **4**
Recommended Clinical Approach 4
Medical Necessity Criteria 5
Indications 5
Non-Indications 6
Level of Care Criteria 7
Procedure Codes (CPT/HCPCS) 7
Medical Evidence **8**
References **10**
Clinical Guideline Revision History/Information **13**

Medical Necessity Criteria

Service: Gastric Pacing/Electrical Stimulation

Recommended Clinical Approach

Electrical stimulation is a treatment modality that modulates the inappropriate or excessive activity of nerves through the surgical implantation of a device that generates an electrical pulse to stimulate the nerves of a specific region. Several types of neurostimulators exist.

- Gastric electrical stimulation (GES) is an advanced treatment for gastroparesis, a condition that manifests as delayed movement of food from the stomach to the small intestine. This may result in chronic nausea, vomiting, abdominal pain, bloating, and nutritional deficiency. Although gastroparesis may be well-controlled through less invasive methods, including dietary modification and medical therapy, a small percentage of patients experience refractory gastroparesis that causes intractable nausea and vomiting. Among such patients, gastric electrical stimulation is indicated, wherein a neurostimulator device is surgically placed beneath the skin to direct electrical impulses to the smooth muscle of the stomach. For appropriately selected patients, this often confers an improvement in symptoms and an overall improved quality of life.
- More than one-fifth of adults in the United States suffer from chronic pain. Peripheral nerve stimulation is approved by the US Food & Drug Administration for the treatment of chronic pain affecting the lower back, extremities, trunk, head, and face. A neurostimulator device is implanted in the appropriate area, and electrodes are placed near the affected peripheral nerves (i.e., nerves located outside of the brain and spinal cord). It is reserved for patients who have not attained adequate pain control through conventional treatment. Although the evidence base is growing, there is not yet enough research to validate this tool as an effective, safe means to control pain. This service is clinically unproven and not medically necessary at this time.
- Fecal incontinence and urinary complications are the primary indications for sacral neurostimulation. The neurostimulator device is positioned to deliver electrical impulses to the sacral nerves, which

control bowel and bladder function. It is an advanced tool for patients who have failed conventional, conservative therapy. Patient outcomes and quality of life are improved among appropriately selected patients.

Medical Necessity Criteria

Indications

- ➔ **Electrical neurostimulation** is considered appropriate if **ANY** of the following is **TRUE**:
  - ◆ **Gastric electrical stimulation (GES)** is considered appropriate if **ALL** of the following are **TRUE**[1-3]:
    - Documented confirmation of gastroparesis (gastric emptying delay with >10% tracer retention at 4 hours) on a 4-hour scintigraphic gastric emptying test; **AND**
    - Predominant symptom is nausea or vomiting; **AND**
    - Other anatomic/organic cause for symptoms has been excluded with upper endoscopy and selective imaging, if clinically indicated; **AND**
    - Failure of **ALL** of the following:
      - Dietary modification (adoption of a small particle diet); **AND**
      - Over-the-counter (OTC) therapy; **AND**
      - Anti-emetics; **AND**
      - Prokinetics; **OR**
  - ◆ **Sacral nerve stimulation** is considered appropriate if **ALL** of the following are **TRUE**[4,5]:
    - Successful stimulation trial/test period of sacral nerve stimulation with at least a 50% reduction in symptoms compared to baseline; **AND**
    - **ANY** of the following:
      - **ALL** of the following:
        - ◆ Chronic fecal incontinence, as indicated by the uncontrolled passage of fecal materials for a duration of at least 3 months; **AND**
        - ◆ Failure of dietary modifications, physical therapy, bowel management program, and medication; **OR**
      - Urinary retention or incomplete bladder emptying (including drug-induced retention) when sacral

nerve stimulation is considered as an alternative to intermittent self-catheterization; **OR**

- **ALL** of the following:
  - Failure of behavioral modifications, physical therapy/biofeedback, and pharmacotherapy (e.g., anti-cholinergic or beta-agonist medications); **AND**
  - **ANY** of the following:
    - Neurogenic lower urinary tract dysfunction; **OR**
    - Overactive bladder; **OR**
    - Urinary symptoms for incomplete SCI without posterior rhizotomy; **OR**
    - Urge incontinence; **OR**
    - Urinary frequency; **OR**
    - Urinary urgency; **OR**

- **Removal, revision, or replacement** of an existing neurostimulation device that is nonfunctioning, has a depleted battery, or is damaged (fractured leads or other damage).[1,2,4,5]

Non-Indications

➔ **Electrical neurostimulation** is not considered appropriate if **ANY** of the following is **TRUE**:

- Current pregnancy[1,2,4,5]; **OR**
- Active infection[1,2,4,5]; **OR**
- **Gastric pacing/gastric neurostimulation** is not considered appropriate if **ANY** of the following is **TRUE**[1-3]:
  - Current opioid use; **OR**
  - Cannabinoid hyperemesis; **OR**
  - Predominant symptom of gastroparesis is abdominal pain, bloating, or discomfort; **OR**
  - Cyclic vomiting syndrome in absence of other criteria; **OR**
  - Diabetes mellitus in absence of other criteria; **OR**
  - Obesity in absence of other criteria; **OR**
  - Eating disorder in absence of other criteria; **OR**
  - Psychogenic vomiting in absence of other criteria; **OR**
  - Functional dyspepsia in absence of other criteria; **OR**
  - Congenital hypertrophic pyloric stenosis in absence of other criteria; **OR**

- **Peripheral neurostimulation** is not considered appropriate if **ANY** of the following is **TRUE**[6,7]:
  - This procedure is clinically unproven and not medically necessary. There is inconclusive evidence of its effectiveness.
- **Sacral neurostimulation** is not considered appropriate if **ANY** of the following is **TRUE**[4,5]:
  - Stress incontinence; **OR**
  - Urethral obstruction or stricture; **OR**
  - Benign prostatic hypertrophy; **OR**
  - Fecal incontinence that is associated with constipation-predominant defecatory pattern; **OR**
  - Fecal incontinence that is related to rectal intussusception.[8,9]

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
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
64595	Revision or removal of gastric neurostimulator pulse generator
43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
43648	Laparoscopy, surgical; 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, antrum, open

Medical Evidence

Electrical nerve stimulation has been used to modulate pain, incontinence, vomiting, and other debilitating symptoms since the 1960s. At present, a range of devices exist to therapeutically stimulate the gastric, peripheral, and sacral nerves.

The American College of Gastroenterology (ACG) and the American Gastroenterological Association (AGA) have published guidance around the use of electrical stimulation for gastroparesis. The ACG endorses the treatment of medically refractory gastroparesis with gastric electrical stimulation. Importantly, this is a conditional recommendation made with low-quality evidence. The AGA's 2022 clinical practice guidelines encouraged clinicians to consider electrical stimulation only for those patients with intractable and refractory nausea and vomiting, provided that they had no success with conventional therapy and were not taking opioids. These professional guidelines underscore the importance of appropriate patient selection. Gastric pacing remains an advanced therapy for patients who have exhausted other treatment options. A 2024 systemic review and meta-analysis by Saleem et al. examined a total of 730 patients with gastric stimulators. One year after implantation, patients saw a significantly improved gastrointestinal total symptom score (TSS), reduced frequency in vomiting episodes, improved gastric emptying study, and improved quality of life. The authors concluded that gastric electrical stimulation remains a treatment option for gastroparesis that is refractory to traditional treatment, acknowledging gastroparesis as a high-burden disease with an associated elevated mortality rate.[1-3]

In 2024, the American Society of Interventional Pain Physicians (ASIPP) published evidence-based recommendations to guide the use of implanted peripheral nerve stimulators to manage chronic pain. Based on fair-quality evidence, they issued a recommendation of moderate strength for the use of peripheral stimulators in patients with chronic pain that is moderate or severe in nature, has failed two or more conventional treatments, and has successfully responded to a trial period with a test stimulation device. The authors note that the evidence base remains low-quality and heterogeneous, positing that this has impeded the field's ability to reach a definitive

consensus regarding use. In 2022, the American Society of Pain and Neuroscience (ASPN) published similar guidelines reviewing specific scenarios for peripheral nerve stimulation. All discussed scenarios received a recommendation of level B or C ("recommendable" or "neither recommendable nor inadvisable"). As in the ASIPP guidelines, the evidence base is not yet strong enough to make a robust recommendation for the safe, effective use of peripheral nerve stimulators. At present, this service is clinically unproven and, therefore, not medically necessary.[6,7]

Sacral nerve stimulation provides bladder and bowel control when it is absent or impaired. The American Society of Colon and Rectal Surgeons (ASCRS) issued practice guidelines in 2023 to aid in the treatment of fecal incontinence. Sacral neuromodulation was felt to be a conditional recommendation, and the authors noted the relative dearth of knowledge around sacral nerve stimulation as compared to other techniques. In their review of the literature, sacral nerve stimulation offers at least a 50% improvement in symptoms for many patients. Sacral neuromodulation may confer greater efficacy than optimal medical therapy for certain patients. The American Urological Association (AUA) has also published guidance for the use of electrical stimulation among patients with urinary dysfunction. A variety of common urological problems, including overactive bladder and urge incontinence, are improved with sacral nerve stimulation when patients have failed traditional therapy. An exception to this is urinary retention, which does not require failure of conservative therapy if sacral nerve stimulation is considered as an alternative to intermittent self-catheterization.[4,5]

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