Cohere Medicare Advantage Policy - Gastric Pacing/Electrical Stimulation

Clinical Guidelines for Medical Necessity Review

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Important Notices

Notices & Disclaimers:

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Other Notices:

Guideline Information:

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

Table of Contents

Medical Necessity Criteria

Service: Gastric Pacing/Electrical Stimulation

Benefit Category

Prosthetic devices.

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Related CMS Documents

Please refer to the CMS Medicare Coverage Database for the most current applicable CMS National Coverage.[1-5]

- National Coverage Determination (NCD) 160.7: Electrical Nerve Stimulators
- National Coverage Determination (NCD) 230.18: Sacral Nerve Stimulation for Urinary Incontinence
- Local Coverage Determination (LCD) L39543: Sacral Nerve Stimulation for the Treatment of Urinary and Fecal Incontinence
- Local Coverage Determination (LCD) L34328: Peripheral Nerve Stimulation
- Local Coverage Determination (LCD) L37360: Peripheral Nerve 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.[6,7]

- More than one-fifth of adults in the United States suffer from chronic pain.[8] 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.
- 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.[6,7,9,10]

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of electrical stimulation. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Device-associated risks are possible with the implantation of nerve stimulators. These complications include infection, pain at the stimulation site, erosion of the device through the skin or stomach wall, excessive bleeding, and inadequate treatment of symptoms.
- Risks with inappropriate surgical procedures include infection, bleeding, injury to neurovascular structures, lead migration, anesthetic risk, and the need for repeat or additional procedures. If a patient has an inappropriate surgical procedure, this can lead to additional

complications, necessitating further invasive management; therefore, careful patient selection is in the patient's best interest.
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The potential clinical benefits of using these criteria include:
- Nerve stimulators may offer symptom relief for patients who have exhausted other treatment options, including patients with intractable vomiting or recurrent incontinence. Non-opioid treatment of chronic pain may be possible with peripheral nerve stimulators.
- As compared to traditional treatment, including major procedures such as urostomy/colostomy formation for chronic incontinence, nerve stimulators are relatively less invasive and less expensive. Minimally invasive procedures confer a better patient safety profile and tend to require a shorter recovery period and a minimal (or eliminated) hospital stay.
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

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:

- Documented confirmation of gastroparesis (gastric emptying delay with >10% tracer retention at 4 hours) on a 4-hour scintigraphic gastric emptying test[6,9]; **AND**
- Predominant symptom is nausea or vomiting[6,9]; **AND**
- Other anatomic/organic cause for symptoms has been excluded with upper endoscopy and selective imaging, if clinically indicated[6,9]; **AND**
- Failure of **ALL** of the following:
  - Dietary modification (adoption of a small particle diet)[6,9]; **AND**
  - Over-the-counter (OTC) therapy[6,9]; **AND**
  - Anti-emetics[6,9]; **AND**
  - Prokinetics[6,9]; **OR**

◆ **Peripheral nerve stimulation** is considered appropriate if **ALL** of the following are **TRUE**:

- Chronic, severe pain for at least 3 months; **AND**
- Failure of less invasive treatment modalities and medications[1,4,5]; **AND**
- Appropriate surgical candidate (no infection or relevant medical risks)[1,4,5]; **AND**
- Appropriate proper patient education, discussion and disclosure of risks and benefits[1,4,5]; **AND**
- No active substance abuse[1,4,5]; **AND**
- Formal psychological screening by a mental health professional[1,4,5]; **AND**
- Successful stimulation trial with greater than or equal to 50% reduction in pain intensity or 50% reduction in analgesic use before permanent implantation[1,4,5]; **OR**

◆ **Sacral nerve stimulation** is considered appropriate if **ALL** of the following are true:

- **ANY** of the following:
  - Urinary urge incontinence[2,3]; **OR**
  - Urinary frequency syndrome[2,3]; **OR**
  - Urinary retention[2,3]; **OR**
  - Chronic fecal incontinence with greater than 2 incontinent episodes on average per week for a duration of more than 6 months[3]; **AND**

- Failure or intolerance of conventional therapy (behavioral, pharmacologic, dietary, or surgical corrective therapy)[2,3]; **AND**
- Appropriate surgical candidate (no infection or relevant medical risks)[2,3]; **AND**
- Ability to record voiding diary data such that clinical results of the implant procedure may be properly evaluated[2,3]; **AND**
- Successful stimulation trial with greater than or equal to 50% sustained (more than 48 hours) reduction in symptoms[2,3]; **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).[1-7]

Non-Indications

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

◆ **Gastric pacing/gastric neurostimulation** is not considered appropriate if **ANY** of the following is true:
- Current opioid use[6,9]; **OR**
- Cannabinoid hyperemesis[6,9]; **OR**
- Predominant symptom of gastroparesis is abdominal pain, bloating, or discomfort[6,9]; **OR**
- Cyclic vomiting syndrome in absence of other criteria[6,9]; **OR**
- Diabetes mellitus in absence of other criteria[6,9]; **OR**
- Obesity in absence of other criteria[6,9]; **OR**
- Eating disorder in absence of other criteria[6,9]; **OR**
- Psychogenic vomiting in absence of other criteria[6,9]; **OR**
- Functional dyspepsia in absence of other criteria[6,9]; **OR**
- Congenital hypertrophic pyloric stenosis in absence of other criteria[6,9]; **OR**

◆ **Peripheral neurostimulation** is not considered appropriate if **ANY** of the following is true:
- Fibromyalgia[1,4,5]; **OR**
- Phantom limb pain[1,4,5]; **OR**
- Diffuse polyneuropathy[1,4,5]; **OR**
- Nociceptive pain in trunk or lower back[1,4,5]; **OR**
- Angina pectoris[1,4,5]; **OR**

- **Sacral neurostimulation** is not considered appropriate if **ANY** of the following is true:
  - Stress incontinence[2,3]; **OR**
  - Urethral obstruction or stricture[2,3]; **OR**
  - Diabetes with peripheral nerve involvement[2,3]; **OR**
  - Multiple sclerosis[2,3]; **OR**
  - Benign prostatic hypertrophy[2,3]; **OR**
  - Chronic constipation[2,3]; **OR**
  - Fecal incontinence that is related to rectal intussusception[14,15]; **OR**
  - Chronic pelvic pain in the absence of other criteria[2,3]; **OR**
  - Fecal incontinence that is related to anorectal malformation[2,3]; **OR**
  - Fecal incontinence that is related to peripheral neuropathy or complete spinal cord injury.[2,3]

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

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

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.[6] 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.[9] 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. At one year following 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.[11]

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 appropriate 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").[12-13]

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.[7,10]

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Clinical Guideline Revision History/Information

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