Cohere Medicare Advantage Policy - Diaphragmatic/Phrenic Nerve Electrical Stimulators

Clinical Guidelines for Medical Necessity Review

Version: 1
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Important Notices

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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: Sleep Medicine
Guideline Name: Cohere Medicare Advantage Policy - Diaphragmatic/Phrenic Nerve Electrical Stimulators

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Type: [**X**] Adult (18+ yo) | [_] Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Diaphragmatic/Phrenic Nerve Electrical Stimulators

Benefit Category

Prosthetic Devices

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.[1]

Related CMS Documents

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

- National Coverage Determination (NCD). Phrenic Nerve Stimulator (160.19)

Recommended Clinical Approach

The phrenic nerve controls the movement of the diaphragm to facilitate respiration by allowing air to move into the lungs. Electrical stimulation of the phrenic nerve may be achieved by the implantation of a device that can detect cessation of breathing and trigger contraction of the diaphragm to simulate natural respiration. These devices have been used for short-term daily respite from mechanical ventilation in patients with high-level (C3 and higher) spinal cord injuries (SCI) as well as conditions affecting respiration such as central alveolar hypoventilation syndrome.[2-3] Clinical studies are ongoing related to proposed use in central sleep apnea (CSA), amyotrophic lateral sclerosis (ALS), and difficult-to-wean mechanically ventilated individuals.[4-7]

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 diaphragmatic/phrenic nerve electrical stimulators. 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:

- If the patient does not have an intact diaphragm and phrenic nerve, an implanted phrenic nerve stimulator will not be effective.[1]
- The stimulator may not work if there is nerve injury to the patient during the implantation procedure.[1]
- The device may not be effective for the patient, which could result in the patient returning to full-time mechanical ventilation for survival.[1]
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- Diaphragmatic/phrenic nerve electrical stimulation has been used for several conditions that have resulted in hypoventilation including spinal cord and brain stem injuries.[1]
- Potential for temporary daily ventilator weaning (approximately 4 hours/day)which can improve quality of life for patients who require invasive or noninvasive mechanical ventilation.[1]
- 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

- ➔ **Diaphragmatic/phrenic nerve electrical stimulation** is considered appropriate if **ALL** of the following are **TRUE**[1, 2-3, 8]:
  - The patient has an intact diaphragm and phrenic nerve; **AND**
  - Partial or complete respiratory insufficiency is present; **AND**
  - Intermittent or permanent use of a mechanical ventilator is required.

Non-Indications

- ➔ **Diaphragmatic/phrenic nerve electrical stimulation** is not considered appropriate if **ANY** of the following is **TRUE**:
  - Central sleep apnea (e.g, remedē)[4, 9-11]; **OR**
  - Amyotrophic lateral sclerosis (ALS)[5,12]; **OR**
  - Temporary respiratory insufficiency or difficult-to-wean patients on mechanical ventilation[6,13]; **OR**
  - Denervation of the diaphragm.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
33276	Insertion of phrenic nerve stimulator system (pulse generator and stimulating lead[s]), including vessel catheterization, all imaging guidance, and pulse generator initial analysis with diagnostic mode activation, when performed
33277	Insertion of phrenic nerve stimulator transvenous sensing lead (List separately in addition to code for primary procedure)
33278	Removal of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed;

	system, including pulse generator and lead(s)
33279	Removal of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; transvenous stimulation or sensing lead(s) only
33280	Removal of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; pulse generator only
33281	Repositioning of phrenic nerve stimulator transvenous lead(s)
33287	Removal and replacement of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; pulse generator
93150	Therapy activation of implanted phrenic nerve stimulator system, including all interrogation and programming
93151	Programming device evaluation of implanted neurostimulator pulse generator system for central sleep apnea; single session
93152	Interrogation and programming of implanted phrenic nerve stimulator system during polysomnography
93153	Interrogation without programming of implanted phrenic nerve stimulator system

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

Medical Evidence

Romero et al. (2012) completed a retrospective cohort study of cervical spinal cord injury (SCI) patients on permanent respiratory support. Potential for improved health-related quality of life (HRQL), long-term tolerability, and improved patient survival were indicators of effectiveness of the device. Of the 126 study participants, 38 patients received phrenic nerve stimulation (pacing) and 88 were mechanically ventilated. Patients included were those with high cervical SCI requiring volumetric mechanical ventilatory support from the moment of injury and exclusion criteria included active pulmonary infections, cancer, or other terminal illness. Mental disability and lack of family or caregiver support were not considered exclusions from the study. It was concluded that phrenic nerve stimulation, particularly in those younger members of the implant group, can impact long-term survival in patients with ventilator-dependent high SCI, with improved HRQL.[14]

Ataya and colleagues (2020) conducted the US-based RESCUE 1, multicenter, prospective open-label single treatment group feasibility study of adult patients. These were mechanical ventilation-dependent patients who had failed at least two weaning trials and who received temporary transvenous diaphragmatic neurostimulation (TTDN) in conjunction with the standard of care. Patients in this study were adults 18 years of age or older and medically stable, having been on mechanical ventilation for at least 7 days. Hypovolemia, neuromuscular disorder, known or suspected phrenic nerve paralysis, terminal illness, or body mass index greater than or equal to 40 were among the study exclusion criteria. The study number was small with 14 patients, 11 who remained throughout the study and 7 who received the TTDN treatment. Two patients were unable to have the device placed due to inability to thread the guidewire due to potential anatomical barriers. The overall conclusion was that TTDN is safe and feasible in patients who are difficult to wean from mechanical ventilation. Future studies with greater numbers of participants are recommended.[13]

The RESCUE II study results were presented by Dres et al. (2021) in the American Journal of Respiratory Critical Care Medicine (American Thoracic Society). The randomized, controlled, multi-center, open-label study focused

upon patients 18 years of age or older on mechanical ventilation for greater than or equal to 4 days, having failed at least 2 weaning attempts. There were 127 eligible participants, with 112 randomized to 57 in the treatment group with temporary transvenous diaphragm neurostimulation (TTDN) and 55 in the control group. It was concluded that TTDN combined with standard management did not increase the proportion of successful weaning from mechanical ventilation when compared to solely standard treatment. Further studies were recommended.[6]

The American Academy of Sleep Medicine (AASM) maintains a 2012 guideline (Aurora et al.) for treatment of central sleep apnea with practice parameters. The literature review and meta-analyses do not reference diaphragmatic/phrenic nerve stimulation for central sleep apnea treatment and no recommendations located on this society's website currently support the use of the device.[11]

Sagalow et al. (2022) conducted a systematic review published in the American Journal of Cardiology regarding transvenous phrenic nerve stimulation of central sleep apnea. There were 232 patients in the studies examined who were implanted with the device. While the device was found overall to be of benefit to patients, there were multiple limitations, including that the device is only active at night when patients are lying supine. CSA is present both at nighttime and in the daytime in heart failure patients in the form of Cheyne-Stokes respirations. This is indicative of a more serious prognosis. Patients with significant heart failure are unable to lie in a supine position due to orthopnea. A meta-analysis was unable to be completed due to a lack of consistent outcome measures in the articles. The authors recommend additional studies in the future focusing on long-term outcomes and complications which would be independent from the initial clinical trial results.[4]

A 2019 publication in The American Journal of Respiratory and Critical Care Medicine (Guimarães-Costa et al.) reviews findings of two clinical trials: DiPALS (Diaphragm Pacing in Patients with Amyotrophic Lateral Sclerosis) and RespiStimALS (Early Diaphragm Pacing in Patients with Amyotrophic Lateral Sclerosis). A diaphragm biopsy substudy of the RespiStimALS protocol was conducted on 39 patients, with 19 of these patients having left diaphragm

electrical activity recording. Two of the 19 patients were eventually excluded with a resulting 17 patients (active stimulation in 8 patients and sham in 9) with electrophysiological recordings for analysis. Through this mechanistic evaluation, it was concluded that electrical stimulation delays reinnervation of denervated muscle fibers in the diaphragm with resulting harmful effect.[12]

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Clinical Guideline Revision History/Information

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