OHCA Guideline

Medical Procedure Class:	**Diaphragmatic / Phrenic Nerve Stimulators**
Initial Implementation Date:	March 8, 2024
Last Review Date:	N/A
Effective Date:	March 8, 2024
Next Review/Revision Date:	March 2027

* This document is not a contract, and these guidelines do not reflect or represent every conceived 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.

☒ New Criteria ☐ Revision of Existing Criteria

Summary

Purpose:	To provide guidelines to assure medical necessity and consistency in the prior authorization process.

Definitions

Amyotrophic Lateral Sclerosis (ALS): a fatal type of motor neuron disease characterized by progressive degeneration of nerve cells in the spinal cord and brain.

Central Alveolar Hypoventilation Syndrome: a disorder of impaired ventilatory response to elevated carbon dioxide in blood and low level of oxygen in blood; it may be congenital, acquired, or idiopathic.

Central Sleep Apnea: a type of sleep apnea that occurs when the brain periodically fails to communicate with the muscles that are necessary for breathing.

Hypoventilation: a state in which an abnormally low amount of air enters the lungs.

Phrenic nerve: provides the primary motor supply to the diaphragm, the major respiratory muscle.

Description

The phrenic nerve stimulator provides electrical stimulation of the patient's phrenic nerve to contract the diaphragm rhythmically and produce breathing in patients who have hypoventilation. The device has been used successfully to treat hypoventilation caused by a variety of conditions, including respiratory paralysis resulting from lesions of the brain stem and cervical spinal cord, and chronic pulmonary disease with ventilatory insufficiency.

The phrenic nerve stimulator is intended to be an alternative to management of patients with respiratory insufficiency who are dependent upon the usual therapy of intermittent or permanent use of a mechanical ventilator as well as maintenance of a permanent tracheotomy stoma.

An implanted phrenic nerve stimulator can be effective only if the patient has an intact phrenic nerve and diaphragm.

CPT Codes Covered Requiring Prior Authorization (PA)

33276: insertion of phrenic nerve stimulator generator and stimulating lead(s)

33277: insertion of phrenic nerve stimulator sensing lead

33287: removal and replacement of phrenic nerve stimulator pulse generator

33288: removal and replacement of phrenic nerve stimulator stimulation or sensing leads

Approval Criteria

I. GENERAL

A. Medical necessity must be met. All documentation submitted to request services or substantiate previously provided services must demonstrate through adequate objective medical records, evidence sufficient to justify the member's needs for the service in accordance with the OAC 317:30-3-1(f).

B. All documentation must be easily legible and images must be of diagnostic quality.

II. INDICATIONS

Diaphragmatic/phrenic nerve stimulation with an FDA-approved device is considered medically necessary as an alternative to invasive mechanical ventilation for members for the following indications:

1. The member has ventilatory failure from stable, non-acute high spinal cord injury at or above C-3 **OR** ventilatory failure from central alveolar hypoventilation syndrome (member with central alveolar hypoventilation syndrome **must** be 18 years of age or over); **and**
    a. The member cannot breathe spontaneously for 4 continuous hours or more without use of a mechanical ventilator; **and**
    b. Diaphragm movement with stimulation is visible under fluoroscopy or by other radiologic techniques such as ultrasound; **and**
    c. Intact and sufficient function in the phrenic nerve, lungs, and diaphragm; **and**
    d. Stimulation of the diaphragm either directly or through the phrenic nerve results in sufficient muscle activity to accommodate independent breathing without the support of a ventilator for at least 4 continuous hours a day; **and**
    e. Bilateral clinically acceptable phrenic nerve function is demonstrated with electromyography recordings and nerve conduction times; **and**
    f. The member has normal chest anatomy, a normal level of consciousness, and has the ability to participate in and complete the training and rehabilitation associated with the use of the device.
2. The member has a diagnosis of amyotrophic lateral sclerosis (ALS); **and**
    a. The member is 21 years of age or over; **and**
    b. The member is experiencing chronic hypoventilation; **and**
    c. Has intact phrenic nerve function; **and**
    d. Diaphragm movement with stimulation is visible under fluoroscopy or by other radiographic techniques such as ultrasound; **and**
    e. Diaphragmatic pacing is used as an alternative to mechanical ventilation.

Replacement Criteria

Replacement of a diaphragmatic/phrenic stimulation system is considered medically necessary if the original diaphragmatic/phrenic stimulation system met criteria as medically necessary and is no longer under warranty and cannot be repaired.

Additional Information

Diaphragmatic/phrenic nerve stimulation devices are considered not medically necessary for central sleep apnea.

References

Aetna, Medical Clinical Policy; Functional Electrical Stimulation and Neuromuscular Electrical Stimulation, coverage policy #0067, effective 09/25/2023.

Amerigroup, Medical Policy; Diaphragmatic/Phrenic Nerve Stimulation and Diaphragm Pacing Systems, clinical UM guideline #CG-MED-79, effective 12/28/2023.

Centene, Clinical Policy; Diaphragmatic/Phrenic Nerve Stimulation, coverage policy #CP.MP.203, effective 08/2023.

Centers for Medicare & Medicaid Services. (2024). National coverage determination (NCD): Prosthetic Devices: Phrenic Nerve Stimulator (160.19). Retrieved from https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=244&ncdver=1&bc=AAAAQAAAAAAA

Cigna, Medical Coverage Policy; Diaphragmatic/Phrenic Nerve Stimulation, coverage policy #0391, effective 09/15/2023.

Humana, Medical Coverage Policy; Electrical Stimulators-Diaphragmatic/Phrenic Nerve, Functional and Neuromuscular, coverage policy #HUM-0399-023, effective 01/01/2024.

Wellmark, Medical Policy; Diaphragmatic/Phrenic Nerve Stimulation and Diaphragm Pacing Systems, coverage policy #07.01.77, effective 08/2023.

Louisiana Medicaid. (2022). Medical Clinical Policy: Diaphragmatic/Phrenic Nerve Stimulation. Retrieved from https://ldh.la.gov/assets/medicaid/MCPP/11.30.22/1109_LHCC_LA.CP.MP.203_Diaphragmatic_Phrenic_Nerve_Stimulation_10.22.pdf

BCBS Michigan. (2023). Medical Policy: Phrenic Nerve Stimulation and Diaphragm Pacing. Retrieved from https://www.bcbsm.com/amslibs/content/dam/public/mpr/mprsearch/pdf/2018918.pdf

SelectHealth of South Carolina. (2023). Clinical Policy: Phrenic (diaphragmatic) Nerve Stimulation. Retrieved from https://www.selecthealthofsc.com/pdf/provider/policies-20230208/ccp1041-phrenic-diaphragmatic-nerve-stimulation.pdf