MASSACHUSETTS

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Medical Policy

Diaphragmatic/Phrenic Nerve Stimulation and Diaphragm Pacing Systems

Table of Contents

Policy Number: 593

BCBSA Reference Number: N/A
NCD/LCD: National Coverage Determination (NCD) for Phrenic Nerve Stimulator (160.19)

Related Policies

Phrenic Nerve Stimulation for Central Sleep Apnea, #955

Policy[1]

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Diaphragmatic/Phrenic Stimulation

Diaphragmatic/phrenic nerve stimulation with an FDA-approved device is considered **MEDICALLY NECESSARY** as an alternative to invasive mechanical ventilation for individuals who are 18 years of age or older when ALL of the following criteria are met:

a. The individual has ventilatory failure from stable, high spinal cord injury **or** ventilatory failure from central alveolar hypoventilation syndrome; **and**
b. The individual cannot breathe spontaneously for 4 continuous hours or more without use of a mechanical ventilator; **and**
c. Diaphragm movement with stimulation is visible under fluoroscopy; **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. Individual 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; **and**
f. Bilateral clinically acceptable phrenic nerve function is demonstrated with electromyography recordings and nerve conduction times.

Diaphragmatic Stimulation

Diaphragm stimulation with an FDA approved diaphragm pacing system is considered **MEDICALLY NECESSARY** as an alternative to invasive mechanical ventilation in individuals who are 18 years of age or older when ALL of the following criteria are met:

a. The individual has ventilatory failure from stable, high spinal cord injury **or** ventilatory failure from central alveolar hypoventilation syndrome **or** ventilatory failure from motor neuron disease, for example amyotrophic lateral sclerosis; **and**
b. The individual cannot breathe spontaneously for 4 continuous hours or more without use of a mechanical ventilator; **and**
c. Diaphragm movement with stimulation is visible under fluoroscopy; **and**
d. Stimulation of the diaphragm directly 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. Individual 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.

Diaphragmatic/phrenic nerve stimulation devices and Diaphragm Pacing Systems are considered **NOT MEDICALLY NECESSARY** when:

- The individual can breathe spontaneously for 4 continuous hours or more without use of a mechanical ventilator; **or**
- The respiratory insufficiency is temporary.

Diaphragmatic/phrenic nerve stimulation and Diaphragm Pacing Systems are considered **INVESTIGATIONAL** and **NOT MEDICALLY NECESSARY** for all other indications including, but not limited to:

- Underlying cardiac, pulmonary or chest wall disease is present which is significant enough to prevent spontaneous breathing off a ventilator for more than 4 hours even with the use of the phrenic nerve or diaphragm pacemaker device; **or**
- In individuals with intact phrenic nerve and diaphragm function; **or**
- For treatment of any other condition where the phrenic nerve and diaphragm are intact (for example, chronic obstructive lung disease, restrictive lung disease, singultus [hiccups]); **or**
- For adolescents, children and infants; **or**
- When the above criteria are not met.

Medicare HMO Blue[SM] and Medicare PPO Blue[SM] Members

Medical necessity criteria and coding guidance can be found through the link below.

National Coverage Determinations (NCDs)

National Coverage Determination (NCD) for Phrenic Nerve Stimulator (160.19)

Note: To review the specific NCD, please remember to click “accept” on the CMS licensing agreement at the bottom of the CMS webpage.

Medical necessity criteria and coding guidance for **Medicare Advantage members living in Massachusetts** can be found through the link below.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **not required**.
Commercial PPO and Indemnity	Prior authorization is **not required**.

Medicare HMO Blue℠	Prior authorization is **not required**.
Medicare PPO Blue℠	Prior authorization is **not required**.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes
There is no specific CPT code for this service.

Description

The NeuRx DPS RA/4 Respiratory Stimulation System is implanted through minimally invasive laparoscopic surgery and provides electrical stimulation to muscles and nerves that run through the diaphragm. This eliminates any direct contact with the phrenic nerve, allows all circuitry and electronics to remain outside the body, and provides direct, selective activation to each hemidiaphragm. According to manufacturer information, when stimulated by the NeuRx DPS, the diaphragm contracts, mimicking natural breathing and allowing air to fill the upper and lower parts of the lungs, rather than forcing air in with a mechanical ventilator. The device uses four electrodes implanted in the muscle of the diaphragm to electronically stimulate contraction; this stimulation allows the user to inhale. The DPS is lightweight and battery powered, eliminating the need for an external power source. Similar to the NeuRx DPS system, the Mark IV system is connected to the phrenic nerve by electrodes in the neck or chest area. The device consists of a surgically implanted receiver and electrodes which are connected to an external transmitter for transmitting the stimulating pulses across the skin to the implanted receiver.

Summary

Based on humanitarian device exemptions, diaphragmatic/phrenic nerve stimulation is considered medically necessary for patients with high spinal cord injuries to allow freedom from mechanical ventilation for at least 4 hours daily and is indicated for patients with ALS to delay the need for mechanical ventilation. Patients must meet the medical necessity criteria in the Policy section of this document.

Policy History

Date	Action
5/2020	Policy updated with literature review through April 2020, references added. Policy statements unchanged.
7/2019	Phrenic Nerve Stimulation for the treatment of central sleep apnea was transferred to policy #955.
4/2019	Local Coverage Determination (LCD): Transvenous Phrenic Nerve Stimulation in the Treatment of Central Sleep Apnea (L37929). Effective 4/1/2019
11/2018	MPA literature review. Investigational policy statements clarified. Policy statements unchanged.
9/2018	National Coverage Determination (NCD) for Phrenic Nerve Stimulator (160.19) added.
1/2018	Medically necessary criteria revised. Effective 1/1/2018.
9/2017	MPA literature review. Policy statements unchanged.
8/2015	Coding information clarified.
9/2013	New policy describing medically necessary and investigational indications. Effective 9/1/2013.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

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Endnotes

[1] Based on expert opinion