Medical Policy

Diaphragmatic/Phrenic Nerve Stimulation and Diaphragm Pacing Systems

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Policy Number: 593
BCBSA Reference Number: NA
NCD/LCD: National Coverage Determination (NCD) for Phrenic Nerve Stimulator (160.19)

Related Policies
None

Policy
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 BlueSM and Medicare PPO BlueSM Members**

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

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

**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.**

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<tr>
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<th>Outpatient</th>
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<tr>
<td>Commercial Managed Care (HMO and POS)</td>
<td>Prior authorization is not required.</td>
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<tr>
<td>Commercial PPO and Indemnity</td>
<td>Prior authorization is not required.</td>
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<tr>
<td>Medicare HMO BlueSM</td>
<td>Prior authorization is not required.</td>
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<tr>
<td>Medicare PPO BlueSM</td>
<td>Prior authorization is not required.</td>
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**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.

A new device that is currently conducting its initial Phase II trial, in an effort to seek FDA clearance to market in the U.S. is the Remedē® System (Respircardia®, Inc., Minneapolis, MN) which, according to the manufacturer:

Is an implantable pacemaker-like device that was designed for improving central sleep apnea (CSA) using Respidrive™, a Respiratory Rhythm Management™ algorithm. The Remedē system delivers electrical pulses via a proprietary, novel transvenous implantable lead to one of the body's two phrenic nerves. The Remedē system therapy is intended to stimulate the diaphragm to restore a more natural, less disrupted, breathing pattern.

The manufacturer sponsored, Phase II trial entitled, the Respircardia, Inc. Pivotal Trial of the Remedē System, has an estimated completion date of December 2017. At present, this device and its phrenic nerve stimulation technology has not been cleared to market in the U.S. by the FDA.

**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**

<table>
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<tr>
<th>Date</th>
<th>Action</th>
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<tr>
<td>9/2018</td>
<td>National Coverage Determination (NCD) for Phrenic Nerve Stimulator (160.19) added. 9/1/2018</td>
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<tr>
<td>9/2017</td>
<td>MPA review: policy statements unchanged. 9/1/2017</td>
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<tr>
<td>8/2015</td>
<td>Coding information clarified.</td>
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**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
References


Endnotes

1 Based on expert opinion