Diaphragm Pacing Stimulation

Diaphragm pacing stimulation (also known as phrenic nerve stimulation) using an FDA-approved device may be MEDICALLY NECESSARY for patients with amyotrophic lateral sclerosis (ALS) who meet all of the following criteria:

- Both hemidiaphragms are stimulatable as demonstrated by voluntary contraction or phrenic nerve conduction studies, and
- Are experiencing chronic hypoventilation but have not progressed to an FVC less than 45% predicted, and
- Are 21 years of age or older.

Note: Chronic hypoventilation can be detected by one of the following methods:
- Pulmonary function tests measuring FVC or Maximum Inspiratory Pressure (MIP)
- Arterial blood gas measurement
- Oxygen saturation (SaO2) levels during sleep.

Criteria for hypoventilation include:
- FVC < 50% predicted
- MIP less than 60 cm H2O
- PCO2 >= 45 mm Hg
- SaO2 < 88% for 5 consecutive minutes during sleep.
Diaphragm pacing stimulation using an FDA-approved device may be **MEDICALLY NECESSARY** for patients with stable, high spinal cord injuries with stimulatable diaphragms who lack control of their diaphragms. All of the following criteria must be met:

- Patients must be 18 years of age or older
- Device must allow patients to breathe without the assistance of a mechanical ventilator for at least 4 continuous hours per day.

Diaphragm pacing stimulation is **INVESTIGATIONAL** for all other uses.

**Prior Authorization Information**

Pre-service approval is required for all inpatient services for all products. See below for situations where prior authorization may be required or may not be required for outpatient services.

- Yes indicates that prior authorization is required.
- No indicates that prior authorization is not required.
- N/A indicates that this service is primarily performed in an inpatient setting.

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<th>Outpatient</th>
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<td>Medicare HMO Blue&lt;sup&gt;SM&lt;/sup&gt;</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**

Amyotrophic lateral sclerosis (ALS) is a progressive neurodegenerative disease which invariably results in respiratory insufficiency and failure, requiring non-invasive mechanical ventilation and ultimately invasive mechanical ventilation to prolong survival. Several studies have demonstrated that electrical stimulation of the diaphragms by an electronic pacemaker can be an alternative treatment for progressive respiratory insufficiency. The studies indicate that the rate of decline in respiratory function can be reduced from 2.4% prior to implantation of the device to 0.9% per month, which extrapolates to an additional 24 months of ventilator-free survival. On the basis of these studies, two devices have been approved by the FDA under the Humanitarian Device Exemption for patients with ALS, as well as for ventilator-dependent patients with high spinal cord injuries when the latter patients can achieve freedom from the respirator for four consecutive hours per day. The devices are the Mark IV Breathing Pacemaker System (Avery Biomedical Device, Inc., Commack, NY) and the NeuRx DPS RA/4 Respiratory Stimulation System (Synapse Biomedical Inc., Oberlin, OH). The medical necessity criteria for implantation of these systems for the indications described are based on the criteria noted in the FDA approval documents.

**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

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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
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References


Endnotes

1 Based on expert opinion