Diaphragmatic / Phrenic Nerve Stimulation

Policy Number: HS-185

Original Effective Date: 8/19/2010

Revised Date(s): 8/2/2011; 8/2/2012

DISCLAIMER

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member’s particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member’s benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member’s Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any. Note: The lines of business (LOB) are subject to change without notice; consult www.wellcare.com/Providers/CCGs for list of current LOBs.

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.
BACKGROUND

Diaphragmatic/phrenic nerve stimulator devices are indicated for certain ventilator-dependent individuals who lack voluntary control of their diaphragm muscles to enable independent breathing without the assistance of a mechanical ventilator for at least four continuous hours a day.

New FDA approval for distribution of the NeuRx DPS™ RA/4 Respiratory Stimulation System (Synapse Biomedical, Inc., Oberlin, OH) was granted under a Humanitarian Device Exemption (HDE) on June 17, 2008. The FDA-approved indications are: For use in patients with stable, high spinal cord injuries with stimulatable diaphragms, but lack control of their diaphragms. The device is indicated to allow the patients to breathe without the assistance of a mechanical ventilator for at least 4 continuous hours a day and is for use only in patients 18 years of age or older. This FDA approval is subject to the manufacturer developing an acceptable method of tracking device implantation to individual patient recipients (FDA, 2008).

The Avery Breathing Pacemaker System (i.e., the Mark IV™ Avery Biomedical Device, Inc., Commack, NY) is the only other diaphragmatic/phrenic stimulator system approved for use by the FDA in the United States. The pacemaker is classified as a Class III neurologic therapeutic device requiring premarket approval (PMA). The device is approved "For persons who require chronic ventilatory support because of upper motor neuron respiratory muscle paralysis (RMP) or because of central alveolar hypoventilation (CAH) and whose remaining phrenic nerve, lung, and diaphragm function is sufficient to accommodate electrical stimulation" (FDA, 2003). Clinical trials that have studied the efficacy of this device have been very limited and of small numbers of subjects.

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 patient to inhale. The DPS is lightweight and battery powered, eliminating the need for an external power source.

Hayes Review (2011)

A rating of B was given for diaphragmatic/phrenic nerve (D/P) pacing for the treatment of chronic ventilatory insufficiency in patients whose remaining phrenic nerve, lung, and diaphragm function are sufficient to accommodate electrical stimulation. This Rating reflects the ability of D/P pacing to achieve adequate ventilation in selected patients and to allow normal speech and mobility, despite the relatively high complication rate for this therapy.

A rating of D was given for D/P pacing in patients whose phrenic nerve, lung, or diaphragm function are not sufficient to achieve adequate diaphragm movement from electrical stimulation. This Rating is based on the fact that D/P pacing cannot be instituted if nerve, lung, and diaphragm function have not been preserved. D/P for this instance is considered experimental / investigational.

POSITION STATEMENT

Diaphragmatic/phrenic nerve stimulation is considered medically necessary if ALL of the following criteria are met:

- The device is FDA approved (i.e. NeuRx DPS™, Mark IV™); AND,
The stimulation is used as an alternative to invasive mechanical ventilation for members with severe, chronic respiratory failure requiring mechanical ventilation caused by brain or high cervical cord lesions; AND,

- Member is at least 18 years of age; AND,
- The member has ventilatory failure from stable, high spinal cord injuries OR central alveolar hypoventilation syndrome.

AND,

When all of the following criteria are met for direct or phrenic nerve stimulation:

- Diaphragm movement with stimulation is visible under fluoroscopy; AND,
- 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; AND,
- 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.

NOTE: If phrenic nerve stimulation is used, acceptable nerve function must be demonstrated with EMG recordings and nerve conduction times.

Diaphragmatic/phrenic nerve stimulation is considered not medically necessary when:

- The member can breathe spontaneously for 4 hours or more without the use of a mechanical respirator; OR,
- The respiratory insufficiency is temporary; OR,
- Motor neuron disease, (i.e. amyotrophic lateral sclerosis [ALS]) is present; OR,
- Used in patients whose phrenic nerve, lung, or diaphragm function are not sufficient to achieve adequate diaphragm movement from electrical stimulation.

Diaphragmatic/phrenic nerve stimulation is considered experimental and investigational for all other indications not listed above.

Centers for Medicaid and Medicare Services (n.d.)

Therapy utilizing a phrenic nerve stimulator is covered by Medicare for selected patients with partial or complete respiratory insufficiency 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. It is intended as an alternative for patients with respiratory insufficiency who are dependent upon a mechanical ventilator as well as maintenance of a permanent tracheotomy stoma. The policy notes that phrenic nerve stimulators are not always effective, and that any patient considered for this technology must have an intact phrenic nerve and diaphragm. The policy does not specifically mention ventilatory support using stimulation provided by electrodes implanted into the diaphragm.

CODING

Covered CPT® Codes

- 64577 Incision for implantation of neurostimulator electrodes; autonomic nerve
- 64590 Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
- 64595 Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver
Covered ICD-9-CM Procedure Codes

04.92  Implantation or replacement of peripheral neurostimulator (leads)
86.94  Insertion or replacement of single array neurostimulator pulse generator not specified as rechargeable
86.95  Insertion or replacement of dual array neurostimulator pulse generator not specified as rechargeable
86.97  Insertion or replacement of single array neurostimulator pulse generator rechargeable
86.98  Insertion or replacement of dual array neurostimulator pulse generator rechargeable

Applicable HCPCS Codes

L8680  Implantable neurostimulator electrode, each
L8681  Patient programmer (external) for use with implantable programmable neurostimulator pulse generator
L8682  Implantable neurostimulator radiofrequency receiver
L8683  Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8685  Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686  Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
L8687  Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688  Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension

Covered ICD-9-CM Diagnosis Codes

327.24  Idiopathic sleep related nonobstructive alveolar hypoventilation
327.25  Congenital central alveolar hypoventilation syndrome
344.01  Quadriplegia and quadripareisis, C1-C4, complete
344.02  Quadriplegia and quadripareisis, C1-C4, incomplete
518.83  Chronic respiratory failure

Experimental/Investigational/Unproven/Not Covered:

Non-Covered CD-9-CM Diagnosis Codes – This list is not all inclusive

045.00 - 045.93  Acute poliomyelitis
138  Late effects of acute poliomyelitis
335.20  Amyotrophic lateral sclerosis (ALS)
344.00  Quadriplegia unspecified
359.0 - 359.29  Muscular dystrophies and other myopathies

Covered ICD-10 Diagnosis Codes

G47.34  Idiopathic sleep related nonobstructive alveolar hypoventilation
G47.35  Congenital central alveolar hypoventilation syndrome
G82.51  Quadriplegia and quadripareisis, C1-C4, complete
G82.52  Quadriplegia and quadripareisis, C1-C4, incomplete
J96.1 0  Chronic respiratory failure

Non-Covered ICD-10-CM Diagnosis Codes

A80.30 – A89.39  Acute paralytic poliomyelitis; unspecified, other
B91  Sequelae of poliomyelitis
G14  Postpolio syndrome
G12.21  Amyotrophic lateral sclerosis
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**HS-185**

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**G71.2** Congenital myopathies
**G72.0 – G72.9** Other and unspecified myopathies
**G82.50** Quadriplegia, unspecified

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**REFERENCES**

Peer Reviewed


**Government Agencies, Professional and Medical Organizations**


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**MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS**

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<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>8/2/2012</td>
<td>Approved by MPC. Added Hayes ratings (B, D) and CMS statement regarding coverage.</td>
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<tr>
<td>12/1/2011</td>
<td>New template design approved by MPC.</td>
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<tr>
<td>8/2/2011</td>
<td>Approved by MPC. No changes.</td>
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