



**DIAPHRAGMATIC / PHRENIC  
NERVE STIMULATION  
HS-185**



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*Harmony Behavioral Health of Florida, Inc.*

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**Diaphragmatic / Phrenic  
Nerve Stimulation**

**Policy Number: HS-185**

**Original Effective Date: 8/19/2010**

**Revised Date(s): 8/2/2011**

**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.

**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 stimlatable 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, 2002). 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.

## 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.

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

## **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  
**64590** Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling

### **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 quadriparesis, C1-C4, complete  
**344.02** Quadriplegia and quadriparesis, 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

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

\*Current Procedural Terminology (CPT) 2010 American Medical Association: Chicago, IL.®©

**REFERENCES**

**Peer Reviewed**

1. Hayes Inc. Hayes Medical Technology Directory. *Diaphragmatic/Phrenic Nerve Stimulation*. Lansdale, PA: Hayes, Inc; December 2, 2003. Search updated December 18, 2007. Archived November 12, 2008.
2. Ali A, Flageole H. Diaphragmatic pacing for the treatment of congenital central alveolar hypoventilation syndrome. *J Pediatr Surg*. 2008; 43(5):792-796.
3. Alshekhlee A, Onders RP, Syed TU, et al. Phrenic nerve conduction studies in spinal cord injury: applications for diaphragmatic pacing. *Muscle Nerve*. 2008; 38(6):1546-1552.
4. DiMarco AF, Onders RP, Ignagni A, et al. Phrenic nerve pacing via intramuscular diaphragm electrodes in tetraplegic subjects. *Chest*. 2005; 127(2):671-678.
5. Garrido-Garcia H, Mazaira Alvarez J, Martin Escribano P, Romero Ganuza J, La Banda F, Gambarrutta C, et al. Treatment of chronic ventilatory failure using a diaphragmatic pacemaker. *Spinal Cord*. 1998 May; 36(5):310-314.
6. Krieger LM, Krieger AJ. The Intercostal to Phrenic Nerve Transfer: An Effective Means of Reanimating the Diaphragm in Patients with High Cervical Spine Injury. Presented at the International Society of Reconstructive Microsurgery Annual Meeting, Los Angeles, California, June 22 through 26, 1999, and at the American Society for Reconstructive Microsurgery Annual Meeting, South Beach, Florida, January 8 through 11, 2000. *Plastic and Recon Surg*. 2000; 105(4):1255-1261.
7. Onders RP, Elmo MJ, Ignagni AR. Diaphragm pacing stimulation system for tetraplegia in individuals injured during childhood or adolescence. *J Spinal Cord Med*. 2007; 30 Suppl 1:S25-S29.
8. Onders RP, Elmo M, Khansarinia S, et al. Complete worldwide operative experience in laparoscopic diaphragm pacing: results and difference in spinal cord injured patients and amyotrophic lateral sclerosis patients. *Surg Endosc*. 2009; 23(7):1433-1440.
9. Shaul D, Danielson P, McComb J, Keens T. Thorascopic placement of phrenic nerve electrodes for diaphragmatic pacing in children. *J Pediatr Surg*. 2002 Jul; 37(7):974-978.

**Government Agencies, Professional and Medical Organizations**

1. Centers for Medicare and Medicaid Services. National Coverage Determination for Phrenic Nerve Stimulators. NCD 160.19. Longstanding coverage determination; Effective date not posted.
2. National Institute for Health and Clinical Excellence (NICE). Intramuscular diaphragm stimulation for ventilator-dependent chronic respiratory failure due to neurological disease. *Interventional Procedure Guidance 307*. London, UK: NICE; July 2009.
3. U.S. Food and Drug Administration. Center for Devices and Radiological Health (CDRH) 510(k) Premarket Notification Database. NeuRx DPS™ RA/4 Respiratory Stimulation System. Summary of Safety and Effectiveness. No. H070003. Rockville, MD: FDA. June 17, 2008.
4. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH) Premarket Approvals for the Avery Breathing Pacemaker System (Mark IV™ Avery Biomedical Device, Inc., Commack, NY).

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**HISTORY AND REVISIONS**

Date	Action
12/1/2011	• New template design approved by MPC.
8/2/2011	• Approved by MPC. No changes.