



# Cigna Medical Coverage Policy

**Subject Diaphragmatic/Phrenic Nerve Stimulation**

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### INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna companies. Coverage Policies are intended to provide guidance in interpreting certain **standard** Cigna benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supersedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations. Proprietary information of Cigna. Copyright ©2014 Cigna

## Coverage Policy

**Cigna covers diaphragmatic/phrenic (D/P) nerve stimulation with the Mark IV™ Breathing Pacemaker System as an alternative to invasive mechanical ventilation as medically necessary for an individual with severe, chronic respiratory failure requiring mechanical ventilation for EITHER of the following:**

- alveolar hypoventilation, either primary or secondary to a brainstem disorder
- interruption of neuronal conduction at the upper cervical level, at or above the C3 vertebral level

**AND when ALL of the following criteria are met:**

- There is integrity of the intrathoracic section of the phrenic nerve.
- Diaphragmatic function is sufficient to accommodate chronic stimulation.
- Baseline estimated pulmonary function test is known, or likely, to be adequate.
- Individual has normal chest anatomy, normal level of consciousness, and the ability to participate in and complete the training and rehabilitation associated with the use of the device.

**Cigna covers the NeuRx DPS™ RA/4 Respiratory Stimulation System as medically necessary for an individual age 18 years or older with either a stable, high spinal cord injury and a stimlatable diaphragm or an individual age 21 years or older with amyotrophic lateral sclerosis (ALS) when provided in accordance with the Humanitarian Device Exemption (HDE) specifications of the U.S. Food and Drug Administration (FDA).**

**Cigna does not cover D/P stimulation for ANY other indication because it is considered experimental, investigational or unproven.**

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## General Background

Patients with high-level, vertebrae C1-C3 spinal cord injuries typically experience respiratory muscle paralysis leading to chronic ventilatory insufficiency. The standard therapy for these patients is chronic mechanical ventilation via tracheostomy. Non-invasive ventilation (NIV) such as positive pressure ventilation or bilevel positive airway pressure is currently the first line treatment for amyotrophic lateral sclerosis (ALS) patients experiencing symptoms of respiratory insufficiency. At some point, ALS affects the respiratory muscles so severely that bulbar paresis is combined with severe expiratory and inspiratory muscle weakness. There is a significant risk of impending respiratory failure or death and invasive ventilation becomes the only option for survival.

Diaphragmatic/phrenic (D/P) nerve pacing is an alternative to mechanical ventilation for a select subgroup of patients. D/P pacing, also referred to as phrenic pacing, phrenic nerve stimulation, diaphragm pacing, or electrophrenic respiration, is the electrical stimulation of the diaphragm via the phrenic nerve, the major nerve supply to the diaphragm that controls breathing. The two FDA approved D/P pacing systems 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). Prior to implantation, patients may undergo diaphragm electromyography (EMG), pulmonary function studies and/or polysomnography (i.e., sleep study).

### **Mark IV™ Breathing Pacemaker System**

The Mark IV system is connected to the phrenic nerve by electrodes in the neck or chest area (i.e. thoracotomy approach). The device consists of surgically implanted receivers and electrodes which are connected to an external transmitter. Implantation is indicated in patients with alveolar hypoventilation due to primary or secondary brainstem disorders or interruption of neuronal conduction at the upper cervical level, at or above the C3 vertebral level. Diagnoses of patients who may be candidates for Mark IV pacing include: complete or incomplete quadriplegia, congenital central hypoventilation syndrome (i.e., Ondine's curse), diaphragmatic paralysis, central sleep apnea, brainstem stroke, brain tumor, brain injury or Arnold-Chiari malformation.

For Mark IV pacing to be effective, candidates must have an intact phrenic nerve, a functional diaphragm, normal chest anatomy, and uncompromised lung function. The patient should be alert, mentally competent, motivated and able to complete the training and rehabilitation needed for a successful outcome.

**U.S. Food and Drug Administration (FDA):** The Mark IV™ Breathing Pacemaker System is approved by the FDA premarket approval (PMA) process as a Class III neurologic therapeutic device. The device is indicated "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, 2000).

**Literature Review:** Nonrandomized comparative studies, prospective case series and retrospective reviews have reported that the Mark IV device is a safe and effective alternative to invasive mechanical ventilation and is considered an established alternative therapy in appropriate candidates. Clinical trials with up to ten years follow-up reported success rates of 73%–94% and included adult and pediatric patients with spinal cord injuries, congenital central alveolar hypoventilation syndrome and other causes of respiratory failure (Hirschfeld, et al., 2008; Elefteriades, et al., 2002; Shaul, et al., 2002; Garrido-Garcia, et al., 1998).

### **NeuRx DPS™ RA/4 Respiratory Stimulation System**

The NeuRx system is laparoscopically connected at the phrenic nerve motor point region in the diaphragm (i.e., intramuscular diaphragm pacing, direct pacing, or laparoscopic D/P pacing). This approach avoids the need for cervical or thoracic access to the phrenic nerve and potential risks of phrenic nerve damage. The repetitive electrical stimulus by the pacer produces a rhythmic contraction of the diaphragm and a normal breathing pattern (i.e., inhalation upon electrical stimulation and exhalation on cessation of stimulation). The system includes four electrodes implanted in the diaphragm, a fifth electrode that completes the electrical circuit, a cable and an external pulse generator. Diaphragm stimulation devices are intended to lessen dependence on mechanical ventilators, increase mobility and independence, improve speech and sense of taste and smell, and

reduce secretions and risks of infection. The NeuRx system has been proposed in patients with stable, high spinal cord injuries and in amyotrophic lateral sclerosis (ALS) patients with a stimlatable diaphragm.

### **Spinal Cord Injury**

**U.S. Food and Drug Administration (FDA):** In June 2008, the NeuRx DPS™ RA/4 Respiratory Stimulation System received FDA approval under the Humanitarian Device Exemption (HDE) process for patients age 18 years and older. The device is “intended 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” (FDA, 2008).

In order to receive HDE approval, a manufacturer must first be granted a Humanitarian Use Device (HUD) exemption by demonstrating that the device is designed to treat or diagnose a disease or condition that affects fewer than 4,000 people in the U.S. per year. Although data demonstrating the safety and probable clinical benefit are required for HDE approval, clinical trials evaluating the effectiveness of the device are not required. Following HDE approval, the hospital or health care facility institutional review board (IRB) must also approve the use of the device at that institution before the device may be used in a patient.

**Literature Review Spinal Cord Injury:** As the FDA approval for the NeuRx device is an HDE, it is unlikely that there will be a sufficient body of evidence to conclusively demonstrate the safety and efficacy of this method. The available studies in the peer-reviewed published scientific literature are primarily in the form of case series and retrospective reviews. The studies (n=10-50) reported that a majority of the ventilatory dependant patients with spinal cord injuries were successfully transitioned to and paced with the NeuRx device from at least four hours and some patients up to 24 hours of the day. The available studies are limited by lack of a control or comparator group, small sample size, quality of life outcomes and long-term follow-up (Posluszny, et al., 2014, Onders, et al., 2009a; Alsheklee, et al., 2008; Onders, et al., 2007).

Posluszny et al. (2014) published results of a retrospective multicenter study of spinal cord injury patients considered for diaphragm pacing system (DPS) therapy using the NeuRX system (n=29). This study was conducted under institutional review board approval for humanitarian use device. A total of 16 sites of implantation were identified. Each site had the same database for data collection including sex, age, mechanism and level of injury, date of injury, date of diaphragm pacing (DP) surgery, surgical findings, and outcome of patient in respect to DP. Full patient comorbidities or ventilator management was unavailable in the limited database. The objectives were to report the present-day real-time use of DP in spinal cord injury patients early in their disease course, to review the reported surgical findings, and to discuss success at weaning from mechanical ventilation with regard to diagnostic laparoscopic diaphragm evaluation. A total of 22 patients had stimlatable diaphragms and had electrodes implanted. Sixteen (72.7%) were completely weaned from mechanical ventilation after an average of 10.2 days. For the remaining six patients, two had delayed weans of 180 days following implantation and two patients had partial weans, using DP for part of the day. One patient used DP with simultaneous mechanical ventilation by preference. The final patient was successfully implanted and discharged to a long-term acute care hospital but subsequently had life prolonging measures withdrawn. Eight patients (36%) had complete recovery of respiration, and DP wires were removed. Limitations of this study are the retrospective design, nonuniform data collection, selection bias by the surgeons at the implanting centers, and overall limited patient data from each of the sites. There was no standard weaning program or description before surgery. Patient spinal cord injury level was not verified by radiologic review or standardized neurologic examination. The weaning techniques with DP were not analyzed or standardized. In this study, patients with an intact phrenic system but without control of ventilation, DP can shorten the duration of mechanical ventilation and, in many instances, allow for complete independence from mechanical ventilation.

FDA HDE approval of the NeuRx device was based on a prospective, non-randomized, multicenter clinical trial (FDA Summary of Safety and Probable Benefit [SBSS], 2008; Onders, et al., 2009a). A total of 50 patients were enrolled in this study at five investigational sites beginning in the year 2000. Patients in this study group have all suffered from high spinal cord injury and were full-time dependant on positive pressure mechanical ventilation prior to enrollment. The age of enrolled patients was from 18-74 years of age. The primary endpoint was to assess the ability of the NeuRx device to provide clinically acceptable tidal volume for at least four continuous hours of pacing. The safety endpoint was to qualitatively assess the adverse event reports and compare these to a similar patient population. Secondary endpoints include reduction of dependence on mechanical ventilation and surgical implementation site independence.

Inclusion criteria:

- age 18 years or older;
- cervical spinal cord injury with dependence on mechanical ventilation;
- clinically stable following acute spinal cord injury;
- bilateral phrenic nerve function clinically acceptable as demonstrated with EMG recordings and nerve conduction times;
- diaphragm movement with stimulation visible under fluoroscopy;
- clinically acceptable oxygenation on room air (greater than 90% O<sub>2</sub> saturation);
- hemodynamically stable;
- no medical co-morbidities that would interfere with the proper placement or function of the device;
- committed primary caregiver;
- negative pregnancy test in females of child-bearing potential;
- informed consent from the device user or designated representative.

Exclusion criteria:

- co-morbid medical conditions that preclude surgery;
- active lung disease (obstructive, restrictive or membrane diseases);
- active cardiovascular disease or active brain disease;
- hemodynamic instability or low oxygen levels on room air;
- hospitalization for or a treated active infection, within the last 3 months;
- significant scoliosis or chest deformity;
- marked obesity;
- anticipated poor compliance with protocol by either the device user or primary caregiver;
- currently breastfeeding.

The authors reported average follow-up of 2.0±1.5 years (median 1.6 years, range 0.5–8.0 years). Overall, a total of 48 out of 50 patients enrolled were able to pace for longer than four consecutive hours while achieving tidal volumes greater than their basal metabolic requirements. At the end of the study period, a total of 44 patients were actively using the device for an unspecified period of time. About 50% of the patients had used the device for more than 24 continuous hours. Five deaths, which do not appear to be device-related, were reported during the study. Two deaths occurred during mechanical ventilation, and two deaths occurred during intramuscular diaphragm stimulation. One patient lost consciousness while the stimulator was functioning, and a second patient on the stimulator died of septic shock due to urosepsis. One patient was not able to be paced. There were eleven incidents of aspiration and three incidents of upper airway obstruction that occurred in three patients. Use of the device for periods greater than four continuous hours a day occurred after a period of diaphragmatic conditioning that ranged from one week to several months.

The most frequent reported adverse event attributable to this device was capnothorax. A total of 42% of the patients enrolled in the clinical study experienced this complication in association with implantation of the

electrodes in the diaphragm. While no patients experienced compromised pulmonary gas exchange or hemodynamic instability as a result of the capnothorax, affected patients required treatment with a chest tube, for up to two days in one patient, and an extended hospital stay of five days, in one patient. The manufacturer addressed this risk in the labeling and training procedure provided with this device. This study did not report quality of life outcomes such as mobility, speech, comfort levels, and sense of taste and smell. This study lacked a control or comparator group.

To assess diaphragm viability in 26 chronic high-cervical quadriplegics, Alsheklee et al. (2008) conducted a case series study evaluating the preoperative phrenic nerve conduction studies simultaneously with fluoroscopic observation of diaphragm excursions. The patients, age 18 years and older, were totally dependent on mechanical ventilation via tracheostomy prior to implantation. Preoperatively there was no spontaneous abdominal or chest wall muscle movement in any of the patients. The mean diaphragm compound muscle action potential (CMAP) amplitudes of the patients with intact phrenic nerves and diaphragms were within normal limits (i.e.,  $0.32 \pm 0.16$  millivolts [mV] on the right and  $0.37 \pm 0.18$  mV on the left). CMAP was present when diaphragm movement was concurrently seen on fluoroscopy which was consistent with preserved phrenic motor neurons, and indicated that these patients were candidates for D/P pacing. Following implantation, 25 patients were able to pace and stay off the ventilator. Fourteen patients achieved full-time pacing, six maintained pacing for 12–23 hours, and five were still conditioning at the time of data analysis. The median number of days to achieve four or more hours of pacing ranged from 26–142. The study is limited by the small, heterogeneous patient population, lack of a control or comparison group and no long-term follow-up.

Onders et al. (2007) retrospectively reviewed the outcomes of implantation of the NeuRx diaphragmatic pacing system in tetraplegic patients (n=10) with spinal cord injuries sustained prior to age 18 years, but who did not receive implantation until ages 18–34 years. The length of time from injury to implantation ranged from 0.8–19 years. Following implantation, all patients who had completed pacing conditioning (n=8) obtained tidal volumes above the expected basal rate by 5%–100%. Four patients successfully utilized pacing continuously, four patients used pacing during the daytime only, and two patients were still conditioning. The time it took to achieve four hours of continuous pacing ranged from 0.7–5.9 weeks. All patients preferred D/P pacing, reported less secretions, less need for suctioning, and increased mobility. One patient with a cardiac pacemaker showed no adverse interaction with the NeuRx. There were no reported complications. The study is limited by the small, heterogeneous patient population and lack of a control or comparison group.

### **Amyotrophic Lateral Sclerosis (ALS)**

**U.S. Food and Drug Administration (FDA):** In September 2011, the NeuRx DPS™ RA/4 Respiratory Stimulation System received FDA approval under the HDE process for patients age 21 years and older. The device is “indicated for use in amyotrophic lateral sclerosis (ALS) patients with a stimlatable diaphragm (both right and left portions) as demonstrated by voluntary contraction or phrenic nerve conduction studies, and who are experiencing chronic hypoventilation (CH), but not progressed to an FVC < 45% predicted”. According to the FDA Summary of Safety and Probable Benefit, data from one unpublished trial was considered in the HDE approval process. The NeuRx Diaphragm Pacing Stimulation (DPS™) System of Motor-Point Stimulation for Conditioning the Diaphragm of Patients with Amyotrophic Lateral Sclerosis (ALS) trial was a prospective study at nine clinical centers in the U.S. and France. The study enrolled 144 patients. A total of 106 patients were implanted with the DPS therapy between 2005 and 2009. Primary outcome measure was the DPS System will slow the decline of pulmonary function, as defined by percent predicted forced vital capacity (FVC) to 30% of normal, by approximately 12 months. According to the FDA summary, this HDE was not taken to a meeting of the Neurological Devices Advisory Panel because it was determined that the preclinical and clinical issues raised by the HDE did not require panel review for the proposed indication.” The FDA summary reported that “the Center for Devices and Radiological Health (CDRH) has determined that based on the data submitted in the HDE, that the NeuRx DPS, Diaphragm Pacing System will not expose patients to an unreasonable or significant risk or illness or injury, and the probable benefit to health from using the device outweighs the risks of illness or injury, and issued an approval order on September 28, 2011” (FDA, 2011).

The HDE post-approval study of NeuRx Diaphragm Pacing System (DPS) for Amyotrophic Lateral Sclerosis (ALS) can be found at [clinicaltrials.gov](http://clinicaltrials.gov) identifier NCT01605006 with estimated completion date of June 2017.

**Literature Review ALS:** The available studies in the peer-reviewed published scientific literature are primarily in the form of prospective reviews. The studies are limited by the small, heterogeneous patient populations (n=2-

38) and lack of a control or comparison group. The clinical effectiveness and long-term safety of diaphragm pacing in ALS needs to be assessed (FDA, 2011; Onders, et al., 2009a; 2009b).

Onders et al. (2009a) prospectively evaluated the complete worldwide multi-center experience with diaphragm pacing stimulation (DPS) to maintain and provide diaphragm function in ventilator-dependent spinal cord injury (SCI) patients and respiratory-compromised patients with amyotrophic lateral sclerosis (ALS). The study results for the SCI patients have been documented in the spinal cord injury literature review of the Coverage Policy. This study was undertaken under FDA Investigational Device Exemption (IDE). Each site's Institutional Review Board (IRB) approved the study. The studies were registered at clinicaltrials.gov with the specific identifiers NCT00010374 and NCT00420719. The ALS patients being reported were involved in three separate IRB trials under the same IDE with some overlap of the trials. After surgical implantation and diaphragm conditioning the patients were followed with the same tests every 4–12 weeks until the 1-year time period ended. The tests over the course of the trial for these patients included the Short Form 36 (SF-36), Revised Amyotrophic Lateral Sclerosis Functional Rating Scale (ALSFR-R) scoring, phrenic nerve studies, diaphragm ultrasound thickness, fluoroscopic sniff tests, pulmonary function tests, arterial blood gases, laboratory tests, and electrode characterizations including electromyographic assessments. Continuous positive airway pressure (CPAP) or noninvasive positive pressure ventilation (NIPPV) may still be needed to maintain an upper airway and was used in conjunction with DPS. From March of 2000 to September of 2007, a total of 38 ALS patients were implanted with DPS using the NeuRx device at five centers. The age of the patients at implantation ranged from 18-74 years. Patients with ALS had much weaker diaphragms identified surgically, requiring trains of stimulation during mapping to identify the motor point at times. There was no peri-operative mortality even in ALS patients with forced vital capacity (FVC) below 50% predicted. Five patients (13%) had capnothorax secondary to air tracking above the diaphragm. It was treated with either observation or simple aspiration. The capnothoraxes caused no hemodynamic or respiratory problems. There was no cardiac involvement from diaphragm pacing even when analyzed in 10 patients who had pre-existing cardiac pacemakers. No infections occurred even with simultaneous gastrostomy tube placements for ALS patients. The authors reported that after conditioning the diaphragm with the DPS, preliminary results show an average rate of decline in FVC of 0.9% per month from the pre-implantation decline of 2.4% a month, which extrapolates to an additional 24 months of ventilator-free survival. The authors reported that this multi-center experience has shown that laparoscopic diaphragm motor point mapping, electrode implantation, and pacing can be safely performed in ALS patients and delays the need for ventilators, increasing survival. The study is limited by the small, heterogeneous patient population and lack of a control or comparison group.

Onders et al. (2009b) prospectively evaluated perioperative management (i.e., preoperative planning, intraoperative management, and immediate postoperative management) to determine the safety and efficacy of laparoscopic implantation of the NeuRx system in ALS patients. The two-center study included a total of 51 patients in three subgroups, an initial pilot trial (n=16), two patients who were implanted for compassionate reasons, and 33 additional patients implanted at a later date. A predicted forced vital capacity (FVC) above 50% at enrollment and 45% at implantation was the primary inclusion criterion. There was a 19% increase of respiratory compliance when diaphragmatic pacing was synchronized with the anesthesiology ventilator. There were no perioperative respiratory infections, failures to extubate or 30-day mortalities. The study is limited by the small, heterogeneous patient population derived from three separate groups and lack of a control or comparison group.

ECRI conducted a systematic review of the literature on NeuRx DPS. ECRI reported that the ideal study of intramuscular diaphragm stimulation would be prospective, provide data on quality of life and adverse events (AE), and report a mean follow-up of at least six months. Patients could serve as their own controls. ECRI identified two comprehensive reports of the same prospective, observational study (FDA SBSS, 2008; Onders, et al., 2009a). The prospective, observational study (n=50) had a mean 1.7 years follow-up. The study did not include a quality of life assessment measuring the impact of NeuRx on mobility, speech, comfort level and sense of taste and smell. No comparative studies were found and outcome consistency could not be assessed. Gonzalez-Bermejo et al. (2012) conducted an ancillary single-center study of 18 patients with ALS from the aforementioned multi-center trial that assessed sleep and function before and up to seven months after intramuscular diaphragm stimulator implantation. The authors reported that intramuscular diaphragm stimulation improved sleep efficiency by decreasing the time spent awake after sleep onset and decreasing the number of awakenings; however, patients still spent hours awake and had numerous awakenings during the night, so the clinical significance of these results is unclear (ECRI, 2013).

## Other Indications

D/P pacing has been proposed for respiratory support in other diagnostic conditions to delay the need for mechanical ventilation. The NeuRx has been proposed for patients with muscular dystrophies, polio and hypoventilation syndromes tetraplegia. However, the evidence in the published peer-reviewed scientific literature does not support the NeuRx or the Mark IV stimulation systems for any other indications.

## Professional Societies/Organizations

**American Academy of Neurology (AAN):** The 2009 Practice Parameter update: The care of the patient with amyotrophic lateral sclerosis: drug, nutritional, and respiratory therapies (an evidence-based review): report of the Quality Standards Subcommittee of the American Academy of Neurology does not mention diaphragmatic/phrenic (D/P) nerve pacing as a treatment (Miller et al., 2009). There has been no update to this Practice Parameter since 2009.

**American Thoracic Society (ATS):** In their discussion of the diagnosis and management of children with congenital central hypoventilation syndrome (CCHS), ATS stated that D/P pacing is one form of chronic ventilation at home that is an option for children with CCHS. D/P pacing allows for increased mobility and improved quality of life (Weese-Mayer et al., 2010).

## Use Outside of the US

Phrenic nerve stimulation devices available outside of the United States that do not have FDA approval include the Atrostim<sup>®</sup> Phrenic Nerve Stimulator (Atrotech Ltd, Tampere, Finland) and the Vienna phrenic pacemaker (Medimplant, Vienna, Austria).

**National Institute for Health and Clinical Excellence (NICE):** In a guidance document on intramuscular diaphragm stimulation as an alternative for phrenic nerve stimulation using implanted electrodes in the neck or chest for ventilator-dependent patients with chronic respiratory failure, NICE (2009) (United Kingdom), stated that although the evidence “raises no major safety concerns”, “current evidence on its efficacy is inadequate to quantify”. Studies included patients with spinal cord injury and ALS.

In an Issues in Emerging Health Technologies report regarding laparoscopic diaphragm pacing for tetraplegia (i.e., NeuRx), the Canadian Agency for Drugs and Technologies in Health (2009) reported that there were “no evidence-based recommendations regarding appropriate strategies for ventilator support” for this patient population. The published data is comprised of ongoing prospective studies with a mean follow-up of 1.7 years. Long-term effects are unknown, and data comparing the NeuRx to existing pacing systems are lacking.

## Summary

The Mark IV device is a safe and effective alternative to invasive mechanical ventilation and is considered an established alternative therapy in appropriate candidates. The evidence in the published peer-reviewed scientific literature and professional societies support diaphragmatic/phrenic (D/P) nerve stimulation with the Mark IV<sup>™</sup> Breathing Pacemaker for a subgroup of individuals with chronic respiratory failure requiring mechanical ventilation.

Under the Humanitarian Device Exemption (HDE) specifications of the U.S. Food and Drug Administration (FDA) the NeuRx DPS<sup>™</sup> RA/4 Respiratory Stimulation System is indicated for a subgroup of individuals with stable, high spinal cord injuries or in individuals with amyotrophic lateral sclerosis (ALS). There is insufficient evidence to support D/P nerve stimulation by either device for the treatment of all other indications.

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## Coding/Billing Information

**Note:** 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

**Covered when medically necessary:**

CPT <sup>®</sup> *	Description
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<b>Codes</b>	
64575	Incision for implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64580	Incision for implantation of neurostimulator electrode array; any peripheral nerve (excludes sacral nerve), neuromuscular
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling

<b>HCPCS Codes</b>	<b>Description</b>
C1767	Generator, neurostimulator (implantable), nonrechargeable
C1778	Lead, neurostimulator (implantable)
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
C1883	Adaptor/extension, pacing lead or neurostimulator lead (implantable)
C1897	Lead, neurostimulator test kit (implantable)
L8680	Implantable neurostimulator electrode, each
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency received
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

**\*Current Procedural Terminology (CPT®) ©2013 American Medical Association: Chicago, IL.**

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