Clinical Policy: Diaphragmatic/Phrenic Nerve Stimulation

Reference Number: PA.CP.MP.203
Plan Effective Date: 05/2021
Date of Last Revision: 07/2025

Coding Implications
Revision Log

Description

Diaphragmatic/phrenic nerve stimulation, also referred to as diaphragm pacing, is a treatment option used to eliminate or reduce the need for ventilator support in those with chronic ventilatory insufficiency or failure due to bilateral paralysis or severe paresis of the diaphragm. Diaphragmatic/phrenic nerve stimulation uses the phrenic nerves to signal the diaphragm muscles to contract rhythmically and produce breathing through electrical stimulation.[8]

Policy/Criteria

I. It is the policy of PA Health & Wellness® (PHW) that diaphragmatic/phrenic nerve stimulation with the Mark IV™ Breathing Pacemaker System or the Spirit Diaphragm Pacing Transmitter is **medically necessary** when all of the following are met:

A. Stimulation is used as an alternative to mechanical ventilation for an individual with severe, chronic respiratory failure due to one of the following:
   1. Upper cervical spinal cord injury (at or above the C3 vertebral level);
   2. Central alveolar hypoventilation disorder;

B. Diaphragm movement with stimulation is visible under fluoroscopy;

C. Intact and sufficient function in the phrenic nerve, lungs, and diaphragm;

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;

E. Normal chest anatomy, a normal level of consciousness, and the ability to participate in and complete the training and rehabilitation associated with the use of the device.

II. It is the policy of PHW that diaphragmatic/phrenic nerve stimulation with the NeuRx RA/4 Diaphragm Pacing System® is **medically necessary** when provided in accordance with the Humanitarian Device Exemption (HDE) specifications of the U.S Food and Drug Administration when all of the following are met:

A. Stimulation is used as an alternative to mechanical ventilation for an individual with severe, chronic respiratory failure due to one of the following:
   1. Amyotrophic lateral sclerosis (ALS);
      a. Age 21 years or older;
      b. Experiencing chronic hypoventilation but not progressed to forced vital capacity (FVC) less than 45% predicted;
      c. Diaphragm movement with stimulation is visible under fluoroscopy or by other radiographic techniques such as ultrasound;
      d. Intact and sufficient function in the phrenic nerve, lungs, and diaphragm.
   2. Upper cervical spinal cord injury (at or above the C3 vertebral level);
      a. Age 18 years or older;
      b. Diaphragm movement with stimulation is visible under fluoroscopy or by other radiographic techniques such as ultrasound;
      c. Stimulation of the diaphragm will allow the individual to breathe without the assistance of a mechanical ventilator for at least four continuous hours a day;

d. Intact and sufficient function in the phrenic nerve, lungs, and diaphragm.

III. It is the policy of PHW that there is insufficient evidence to support the safety and efficacy of diaphragmatic/phrenic nerve stimulation for any other conditions, including but not limited to, central sleep apnea.

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.[8]

Avery Diaphragm Pacing System (Avery Biomedical Device, Inc.)

The Avery Diaphragm Pacing System includes receivers and electrodes that are surgically implanted. An electrode is placed under the phrenic nerve and is connected to a radiofrequency receiver, which is implanted under the skin.[3]

The different types of Avery systems include the Mark IV Breathing Pacemaker System and the Spirit Diaphragm Pacing System.[3] The Mark IV Breathing Pacemaker System is a diaphragmatic/phrenic stimulator system approved for use by the FDA in the United States. 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."[4] In 2019, the Spirit Diaphragm Pacing Transmitter received full FDA approval for the use of this system for patients who have functional lungs and diaphragm muscle and who have an intact phrenic nerve.[3,5,6]

NeuRx RA/4 Diaphragm Pacing System® (Synapse Biomedical, Inc.)

The NeuRx RA/4 Diaphragm Pacing System® includes implanted intramuscular diaphragm electrodes, which are connected to an external stimulator.[2]

The United States Food and Drug Administration (FDA) approval for distribution of the NeuRx DPS® (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 four 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.[1]

In 2011, the FDA approved the NeuRx RA/4 Diaphragm Pacing System® as a humanitarian-use device (HUD) in amyotrophic lateral sclerosis (ALS) following the submission of a humanitarian device exemption (HDE) application. The FDA approved indications are: "For use in amyotrophic lateral sclerosis (ALS) patients with a stimulatable 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 less than 45% predicted. For use only in patients 21 years of age or older."[2(p.1)]

In 2023, NeuRx RA/4 Diaphragm Pacing System received full FDA approval for use in "patients with stable, high spinal cord injuries with stimulatable diaphragms, but who lack control of their diaphragms."[14]

Remedé System (ZOLL® Medical Corporation)
Although the Remedé System was approved as a treatment option for moderate to severe central sleep apnea in adults by the FDA in 2017, there is insufficient evidence to determine the safety and effectiveness of this system.[9,15] Additional high-quality studies are recommended to evaluate the clinical significance and long-term safety and efficacy of the Remedé System for central sleep apnea.[9]

Coding Implications
This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2024, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT®* Codes	Description
64575	Open implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64580	Open implantation of neurostimulator electrode array; neuromuscular
64590	Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver
64595	Revision or removal of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array
HCPCS ®* Codes	**Description**
C1778	Lead, neurostimulator (implantable)
C1816	Receiver and/or transmitter, neurostimulator (implantable)
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
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, nonrechargeable, includes extension

CPT®* Codes	Description
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension
L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only
L8695	External recharging system for battery (external) for use with implantable neurostimulator, replacement only
L8696	Antenna (external) for use with implantable diaphragmatic/phrenic nerve stimulation device, replacement, each

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Approved by MPC. No changes. (Original approval date 08/11)	04/16	04/16
Approved by MPC. No changes.	04/17	04/17
Approved by MPC. No changes.	03/18	03/18
Approved by MPC. No changes.	03/19	03/19
Approved by MPC. No changes.	04/20	04/20
Integrated diaphragmatic pacing criteria from PA.CP.MP.107 DME and Legacy WellCare Diaphragmatic Phrenic Nerve Stimulation HS-185 policy. Removed ICD-10-PCS codes and replaced with ICD-10-CM codes. Seperated criteria by FDA approved device. Added medical necessity criteria for amyotrophic lateral sclerosis (ALS), additional verbiage changes made with no clinical significance. Specialist reviewed. Background and references reviewed and updated. Replaced "member" with "member/enrollee" in all instances.	11/20	12/20
New Policy to PHW	4/2021	
Annual review. References reviewed, updated, and reformatted. Changed "review date" in the header to "date of last revision" and "date" in the revision log header to "revision date." In section III, replaced investigational verbiage with "evidence is limited in supporting safety and efficacy." Added CPT 64580 and 64590 and HCPCS L8680, L8682, L8683, L8695, and L8696.	7/29/2022	
Annual review. Updated code G83.89 to G83.9. Criteria II.A.1.c. and Criteria II.A.2.b. updated to include "or by other radiographic techniques such as ultrasound" in addition to fluoroscopy. Background updated to include U.S. Food and Drug Administration premarket approval information regarding the Avery Spirit Diaphragm Pacing Transmitter. ICD-10 codes removed. Product name updates in criteria II. and in background with no clinical significance. References reviewed and updated. Reviewed by external specialist.	10/2023	1/17/2024

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Annual review. Criteria I. updated to include the Spirit Diaphragm Pacing Transmitter. Background updated to include information regarding full FDA approval of the Spirit Diaphragm Pacing Transmitter. References reviewed and updated. Reviewed by external specialist.	07/2024	09/2024
Annual review. Description updated with no clinical significance. Background updated to include information regarding full FDA approval of NeuRx RA/4 Diaphragm Pacing System and added section regarding the Remedé System. Added codes L8685, L8686, L8687, L8688 to HCPCs Codes table. Coding reviewed. References reviewed and updated.	07/2025	

References

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