Clinical Policy: Diaphragmatic/Phrenic Nerve Stimulation

Reference Number: LA.CP.MP.203 Coding Implications
Date of Last Revision: 08/24 Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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 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 and produce breathing through electrical stimulation.

Policy/Criteria

I. It is the policy of Louisiana Healthcare Connections 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 Louisiana Healthcare Connections 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 Louisiana Healthcare Connections 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.

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

Avery Diaphragm Pacing System (Avery Biomedical Device, Inc.)
The Avery Diaphragm Pacing System includes receivers and electrodes that are surgically implanted and includes an external transmitter worn over the implanted receivers.[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]

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

NOTE: Coverage is subject to each requested code's inclusion on the corresponding LDH fee schedule. Non-covered codes are denoted (*) and are reviewed for Medical Necessity for members under 21 years of age on a per case basis.

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
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	Effective Date
Converted Corporate policy to local policy	2/22	4/14/22	
Annual review. Criteria II.A.1.c. and Criteria II.A.2.b. updated to include "or by other radiographic techniques such as	01/23	4/10/23	

Reviews, Revisions, and Approvals	Revision Date	Approval Date	Effective Date
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. Removed codes not on LDH fee schedule: CPT 64575, 64580, 64595 and HCPCS C1816, L8680, L8681, L8682, L8683, L8689. References reviewed and updated.			
Annual review. Product name updates in criteria II. and in background with no clinical significance. References reviewed and updated. Note for non-covered codes added.	09/23	11/27/23	
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.	8/24	10/23/24	11/22/24

References

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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise

professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of member/enrollees. This clinical policy is not intended to recommend treatment for member/enrollees. Member/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.