Clinical Policy: Diaphragmatic/Phrenic Nerve Stimulation

Reference Number: CP.MP.203
Date of Last Revision: 07/25
Effective Date: 10/01/2025

Coding Implications
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 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 health plans affiliated with Centene Corporation® 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 health plans affiliated with Centene Corporation 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 health plans affiliated with Centene Corporation 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

HCPCS ®* Codes	Description
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension
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
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." 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.	12/21	12/21
Updated code G83.89 to G83.9.	09/22	
Annual review. 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. References reviewed and updated. Reviewed by external specialist.	12/22	12/22
Annual review. Product name updates in criteria II. and in background with no clinical significance. References reviewed and updated.	08/23	08/23
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.	07/24	07/24
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.	07/25	07/25

References

1. U.S. Food and Drug Administration. Premarket Notification Database: NeuRx DPS™ RA/4 Respiratory Stimulation System. Summary of Safety and Probable Benefit. U.S. Food and Drug Administration Center for Devices and Radiological Health Web site. https://www.accessdata.fda.gov/cdrh_docs/pdf7/H070003B.pdf. Published June 17, 2008. Accessed June 17, 2025.
2. U.S. Food and Drug Administration. Premarket Approvals for the NeuRx DPS™ Diaphragm Pacing System. Summary of Safety and Probable Benefit. U.S. Food and Drug Administration Center for Devices and Radiological Health Website. https://www.accessdata.fda.gov/cdrh_docs/pdf10/H100006b.pdf. Published September 28, 2011. Accessed June 17, 2025.
3. Avery Biomedical Devices. System Information. https://averybiomedical.com/systems-information/. Accessed June 17, 2025.
4. U.S. Food and Drug Administration. Diaphragmatic Pacemaker Phrenic Nerve Stimulator - P860026. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_template.cfm?id=p860026. Published February 25, 1987. Accessed June 17, 2025.
5. U.S. Food and Drug Administration. Avery Diaphragm Pacing System - P860026. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P860026S009. Published November 04, 2019. Accessed June 17, 2025.
6. Avery Biomedical Devices. https://averybiomedical.com/spirit-earns-fda-approval/. Published November 18, 2019. Accessed June 17, 2025.
7. National coverage determination: phrenic nerve stimulator (160.19). Centers for Medicare and Medicaid Services Web site. http://www.cms.hhs.gov/mcd/search.asp. Accessed June 13, 2025.
8. Marion DW. Pacing the diaphragm: Patient selection, evaluation, implantation and complications. UpToDate. www.uptodate.com. Published November 07, 2023. Updated April 29, 2025. Accessed June 13, 2025.
9. Health Technology Assessment. Phrenic nerve stimulation (remedē System) for central sleep apnea. Hayes. www.hayesinc.com. Published April 22, 2022. Updated April 22, 2022. Accessed June 23, 2025.
10. Le Pimpec-Barthes F, Legras A, Arame A, et al. Diaphragm pacing: the state of the art. *J Thorac Dis.* 2016;8(Suppl 4):S376 to S386. doi:10.21037/jtd.2016.03.97
11. Onders RP, Elmo M, Khansarinia S, et al. Complete worldwide operative experience in laparoscopic diaphragm pacing: results and differences in spinal cord injured patients and amyotrophic lateral sclerosis patients. *Surg Endosc*. 2009;23(7):1433 to 1440. doi:10.1007/s00464-008-0223-3
12. U.S. Food and Drug Administration. Approval for NeuRx Diaphragm Pacing System – P200018. https://www.fda.gov/medical-devices/recently-approved-devices/neurx-diaphragm-pacing-system-p200018. Published March 31, 2023. Accessed June 13, 2025.
13. McDermott CJ, Bradburn MJ, Maguire C, et al. DiPALS: Diaphragm Pacing in patients with Amyotrophic Lateral Sclerosis - a randomised controlled trial. *Health Technol Assess*. 2016;20(45):1 to 186. doi:10.3310/hta20450

14. U.S. Food and Drug Administration. NeuRX Diaphragm Pacing System (DPS) - P200018. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P200018. Published March 31, 2023. Accessed June 17, 2025.
15. U.S. Food and Drug Administration. remede® System - P160039. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160039. Published October 23, 2017. Accessed June 23, 2025.

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. The Health Plan 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. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

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 Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. 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. The Health Plan 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 the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, member/enrollees and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, member/enrollees and their representatives agree to be bound by such terms and conditions by providing services to member/enrollees and/or submitting claims for payment for such services.

Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.