

Clinical Policy: Diaphragmatic/Phrenic Nerve Stimulation

Reference Number: [OH.CP.MP.203](#)

[Coding Implications](#)

Date of Last Revision: 10/25

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Policy Statement

In compliance with Ohio Medicaid, Buckeye Health Plan must ensure coverage of medically necessary procedures. The plan covers all the services in the amount, duration, and scope that is no less than that covered by FFS Ohio Medicaid and in accordance with 42 CFR 438.210, with limitations, exclusions, and clarifications provided in the Ohio Medicaid Managed Care Provider Agreement and the Ohio Administrative Code.

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 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 DPSTM RA/4 Respiratory Stimulation 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:

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- 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.

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 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 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 stimlatable 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

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

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	Incision for implantation of neurostimulator electrode array; peripheral nerve, (excludes sacral nerve)
64580	Incision for implantation of neurostimulator electrode array; neuromuscular
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling

64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver
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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 [for phrenic nerve stimulator]
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver [for phrenic nerve stimulator]
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
Policy created and approved.	08/11	08/11
Centene Policy CP.MP . updated with OH Addendum	11/22	12/22
Policy moved to Ohio Specific template and Addendum language integrated into policy template as Policy Statement and Procedure. Annual Review. No material changes in review criteria.	07/23	07/23
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.	10/25	10/25
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References

1. Ohio Administrative Code 5160-1-14 EPSDT. <https://codes.ohio.gov/ohio-administrative-code/rule-5160-1-14>
2. Ohio Administrative Code 5160-26-03 Managed healthcare programs-covered services. <https://codes.ohio.gov/ohio-administrative-code/rule-5160-26-03>
3. Ohio Administrative Code 5160-26-03.1 Managed healthcare programs-primary care and utilization management. <https://codes.ohio.gov/ohio-administrative-code/rule-5160-26-03.1>
4. Ohio Department of Medicaid Fee Schedule: <https://medicaid.ohio.gov/resources-for-providers/billing/fee-schedule-and-rates/fee-schedule-and-rates>
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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. Buckeye 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 Buckeye Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by Buckeye 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 referred to in this clinical policy are independent contractors who exercise independent judgment and over whom Buckeye Health Plan has no control or right of control. Providers are not agents or employees of Buckeye Health Plan.

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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.

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