buckeye health plan

# Clinical Policy: Diaphragmatic/Phrenic Nerve Stimulation

Reference Number: OH.CP.MP.203 Coding Implications

Date of Last Revision: 07/23 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 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 DPS™ 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:

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 DPS RA/4 Respiratory Stimulation System (Synapse Biomedical, Inc.)*
United States Food and Drug Administration (FDA) approval for distribution of the NeuRx DPS™ RA/4 Respiratory Stimulation System (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 4 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.[6]

In 2011 the FDA approved the NeuRx DPS™ RA/4 Respiratory Stimulation 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."[7(p.1)]

*Mark IV™ Breathing Pacemaker System (Avery Biomedical Device, Inc.)*
The Avery Breathing Pacemaker System (i.e., the Mark IV™ Avery Biomedical Device, Inc., Commack, NY) is the only other 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."[8] In 2019, the Spirit Diaphragm Pacing Transmitter received FDA premarket approval for the use of this system for patients who have functional luncgs and diaphragm muscle and who have an intact phrenic nerve.[10,11]

**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 |

| 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] |
| 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 |

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| 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 |

**References**


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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
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15. Avery Biomedical Devices. https://averybiomedical.com/spirit-earns-fda-approval/. Accessed November 23, 2022.

**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 are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/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 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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