Keystone First
Family of Health Plans

Phrenic (diaphragmatic) nerve stimulation

Clinical Policy ID: CCP.1041

Recent review date:6/2026

Next review date: 10/2027

Policy contains: AeroPace; central sleep apnea; congenital central hypoventilation syndrome; diaphragm pacing; hypoventilation; NeuRx Diaphragm Pacing System; phrenic nerve stimulation; remedē System; spinal cord injury; transvenous phrenic nerve stimulation.

Keystone First VIP Choice has developed clinical policies to assist with making coverage determinations. Keystone First VIP Choice's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First VIP Choice, on a case by case basis, when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First VIP Choice's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First VIP Choice's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First VIP Choice will update its clinical policies as necessary. Keystone First VIP Choice's clinical policies are not guarantees of payment.

Coverage policy

Phrenic nerve (diaphragmatic) stimulation is clinically proven and, therefore, may be medically necessary for the treatment of chronic hypoventilation or chronic ventilatory insufficiency when implanted and managed by providers with expertise in phrenic nerve/diaphragm pacing and all of the following criteria are met (Perez, 2016; Trang, 2020; U.S. Food and Drug Administration, 1987, 2008, 2023a):

- Either of the following FDA-authorized systems is used for an FDA-authorized indication:
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    - The Avery Breathing Pacemaker System (Avery Biomedical Devices Inc., Commack, New York) for adult or pediatric members who require chronic ventilatory support because of upper motor neuron respiratory muscle paralysis, including high cervical spinal cord injury, or central alveolar/congenital central hypoventilation syndrome.
    - The NeuRx Diaphragm Pacing System (NeuRx DPS; Synapse Biomedical Inc., Oberlin, Ohio; formerly NeuRx DPS RA/4) for members age 18 years or older with stable high spinal cord injury, stimulatable diaphragms, and lack of diaphragm control, to allow breathing without mechanical ventilation for at least four continuous hours per day.
- The member meets all of the following criteria:
    - Requires chronic ventilatory support and cannot breathe spontaneously for more than four continuous hours without mechanical ventilation, or otherwise meets the FDA-authorized device indication for chronic ventilatory support.
    - The phrenic nerves and diaphragm have sufficient function to accommodate electrical stimulation.

- The member has relatively mild or no lung disease and no pulmonary or chest wall disease severe enough to prevent adequate ventilation with pacing.
- The member and caregiver have access to device-specific follow-up, conditioning, emergency planning, and backup ventilation when clinically required.

Transvenous phrenic nerve stimulation with an FDA-approved implantable system may be medically necessary for selected adults with moderate-to-severe central sleep apnea when all of the following criteria are met (Badr, 2025; U.S. Food and Drug Administration, 2017):

- The member is age 18 years or older.
- Central sleep apnea is moderate to severe and is primary central sleep apnea or central sleep apnea due to heart failure.
- Contributing conditions have been evaluated and optimized, and clinically appropriate noninvasive or less invasive therapies have been considered.
- The device is implanted and managed by clinicians with appropriate training and experience in transvenous phrenic nerve stimulation and sleep-disordered breathing.

Limitations

All other uses of phrenic nerve or diaphragmatic stimulation remain investigational/not clinically proven and, therefore, not medically necessary, except where separately addressed for FDA-approved transvenous phrenic nerve stimulation for moderate-to-severe central sleep apnea in adults. Diaphragm pacing for amyotrophic lateral sclerosis remains not medically necessary despite the NeuRx humanitarian device exemption for amyotrophic lateral sclerosis because randomized evidence showed decreased survival and no meaningful quality-of-life benefit (Miller, 2009; Woo, 2020; U.S. Food and Drug Administration, 2011a, 2011b).

Contraindications, relative contraindications, and precautions are device-specific and include (Avery Biomedical Devices Inc., 2026; Perez, 2016; Trang, 2020; U.S. Food and Drug Administration, 2023a):

- Presence of active infection or inability to tolerate the surgical procedure.
- Insufficient phrenic nerve, diaphragm, or lung function to accommodate electrical stimulation.
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- Obstructive sleep apnea or upper airway obstruction that has not been adequately evaluated or managed.
- Magnetic resonance imaging, shock-wave lithotripsy, or therapeutic diathermy when contraindicated by the specific device labeling. Avery labeling lists magnetic resonance imaging as contraindicated; remedē has MR Conditional labeling under specified conditions (U.S. Food and Drug Administration, 2023c, 2025).
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- Ability to breathe spontaneously for four continuous hours or more without a mechanical ventilator, unless the member otherwise meets FDA-approved transvenous phrenic nerve stimulation criteria for central sleep apnea.
- Temporary respiratory insufficiency or temporary ventilator-weaning neurostimulation, including the AeroPace System, which is outside the scope of this chronic hypoventilation policy and should be reviewed separately (U.S. Food and Drug Administration, 2024a).
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- Severe behavioral disorders or inability to comply with device management and follow-up.

- Obesity with excess fat tissue that can impair electrical signal transfer.

Use with cardiac pacemakers or other active implanted electrical devices requires device-specific assessment. Avery labeling specifies bipolar cardiac pacemaker leads and at least 10 cm separation between the cardiac pacemaker and breathing pacemaker receiver. NeuRx labeling states that there is insufficient information to know whether NeuRx can be used safely with active implanted devices and advises specialist assessment and device-to-device interaction testing; its procedure-risk section states patients with cardiac pacemakers or other implanted electrical devices should not be implanted (Avery Biomedical Devices Inc., 2026; U.S. Food and Drug Administration, 2023a).

Alternative covered services

- Guideline-directed medical therapy for the underlying condition contributing to hypoventilation or central sleep apnea.
- Positive airway pressure or ventilatory support, including mechanical ventilation, noninvasive respiratory assist devices, continuous positive airway pressure, bilevel positive airway pressure with a backup rate when appropriate, and adaptive servo-ventilation when clinically appropriate and not contraindicated.
- Oxygen therapy or pharmacologic therapy such as acetazolamide when supported by the member's central sleep apnea etiology and clinical circumstances.
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Background

Hypoventilation (a.k.a. respiratory depression or hypoventilation syndrome) is the inadequate exchange of carbon dioxide and oxygen within the lungs, creating abnormal retention of carbon dioxide in the blood. It is usually secondary to other medical problems and, if left untreated, can cause significant morbidity and become life threatening. A variety of conditions can cause hypoventilation, including conditions causing diaphragmatic dysfunction (Perez, 2016; Vashisht, 2022).

Both invasive and noninvasive mechanical ventilation can assist patients with diaphragmatic dysfunction to maintain adequate ventilation. Invasive ventilation requires a tracheostomy, and both ventilator types can restrict activity participation and speech. Diaphragmatic stimulation, also known as pacing, is an alternative to mechanical ventilation for improving hypoventilation and potentially quality of life (Perez, 2016).

Diaphragmatic pacing stimulates the diaphragm to contract and relax enabling the patient to breathe without mechanical ventilation. There are two types of diaphragmatic pacers (Vashisht, 2022):

- Diaphragmatic/phrenic nerve pacing systems involve electrodes surgically attached to the phrenic nerves at the cervical, thoracic, or diaphragmatic level. Pacing wires connect the electrodes to a receiver placed under the skin. An external transmitter, serving as the main control unit, is placed above the receiver on the surface of the skin and emits radiofrequency signals.
- Diaphragmatic pacing systems provide direct stimulation to the diaphragm through four electrodes laparoscopically implanted in the diaphragm (intramuscularly) and a fifth grounding electrode implanted under the skin. An electrode connector groups the five electrodes that exit the skin into a socket called an external pulse generator.

Respiratory rates are set in the transmitter. Surgical implantation is done under general anesthesia usually in an outpatient setting, and the equipment is tested during surgery. Approximately six to eight weeks after the procedure, when surgical incisions heal, diaphragm pacing starts. Initial pacing lasts 60 to 90 minutes per night,

as diaphragms tire. By three months after surgery, as the diaphragm strengthens, patients achieve the maximum of about eight to 12 hours each day. As 24-hour pacing is not recommended due to diaphragm fatigue, some may require another method of support such as home mechanical ventilation by tracheostomy or noninvasive positive pressure ventilation (Perez, 2016).

FDA lists original PMA P860026 for Avery's diaphragmatic/phrenic nerve stimulator with a January 5, 1987 decision date. Later FDA supplements include the Mark IV transmitter and a 2019 supplement replacing the Mark IV transmitter with the digital Spirit transmitter. The Avery system is indicated for persons requiring chronic ventilatory support because of upper motor neuron respiratory muscle paralysis or central alveolar hypoventilation when phrenic nerve, lung, and diaphragm function are sufficient to accommodate electrical stimulation (U.S. Food and Drug Administration, 1987, 2019).

The NeuRx Diaphragm Pacing System received FDA PMA P200018 on March 31, 2023 for patients age 18 years or older with stable high spinal cord injuries, stimulatable diaphragms, and lack of diaphragm control, to allow breathing without the assistance of mechanical ventilation for at least four continuous hours per day. FDA previously granted a humanitarian device exemption in 2008 for spinal cord injury and expanded a humanitarian device exemption in 2011 to selected patients age 21 years or older with amyotrophic lateral sclerosis, but randomized amyotrophic lateral sclerosis evidence supports noncoverage (U.S. Food and Drug Administration, 2008, 2011a, 2011b, 2023a).

In October 2017, FDA approved the remedē System as an implantable phrenic nerve stimulator for treatment of moderate-to-severe central sleep apnea in adults. remedē consists of an implantable pulse generator and transvenous leads that monitor respiratory signals and provide unilateral electrical stimulation to the left or right phrenic nerve. In 2023, the remedē System received MR Conditional labeling for 1.5T and 3T magnetic resonance imaging, and in 2025 FDA approved revised labeling removing the requirement to program the implantable pulse generator to off mode before magnetic resonance imaging because the device automatically enters Therapy Disabled Magnet Mode during magnetic resonance imaging exposure (U.S. Food and Drug Administration, 2017, 2023c, 2025).
In December 2024, FDA approved the AeroPace System for temporary transvenous diaphragm neurostimulation to improve weaning success in adults on mechanical ventilation for at least 96 hours who have not weaned. This temporary ventilator-weaning technology is related to diaphragm neurostimulation but distinct from chronic hypoventilation pacing and should be reviewed separately (U.S. Food and Drug Administration, 2024a).

Findings

Clinical Guidelines

Clinical guidelines offer conditional support for phrenic nerve or diaphragmatic stimulation, primarily for patients with congenital central hypoventilation syndrome or high cervical spinal cord injury. The American Thoracic Society recommends this approach for carefully selected individuals to enhance ventilation, decrease reliance on mechanical ventilators, and potentially eliminate the need for a tracheostomy, thereby improving quality of life. Potential complications, including surgical challenges, device malfunctions, and airway muscle desynchronization, require meticulous patient selection and ongoing management (Perez, 2016). Similarly, the European Congenital Central Hypoventilation Syndrome Consortium supports diaphragmatic pacing for patients over one year old who need extensive ventilatory support, noting better outcomes with tracheostomy-assisted pacing in younger children (Trang, 2020).

patients with congenital central hypoventilation syndrome who need substantial ventilatory support, particularly when managed by experienced multidisciplinary teams (Trang, 2020).

NICE HealthTech Guidance 725, which replaced IPG790, recommends phrenic nerve pacing as an option for congenital central hypoventilation syndrome with standard governance, consent, and audit arrangements. NICE states patient selection should be performed by a multidisciplinary team experienced in managing the condition, the procedure should be performed in specialist centers by clinicians with specific training, and follow-up should be conducted by clinicians experienced in the condition. NICE found limited evidence because congenital central hypoventilation syndrome is rare, but noted benefits such as increased ventilator-free time and tracheostomy tube removal without major safety concerns (National Institute for Health and Care Excellence, 2024).

For central sleep apnea, the 2025 American Academy of Sleep Medicine guideline changed the evidence context. The guideline conditionally suggests transvenous phrenic nerve stimulation over no transvenous phrenic nerve stimulation for adults with primary central sleep apnea or central sleep apnea due to heart failure, based on very low-certainty evidence. The guideline also notes that transvenous phrenic nerve stimulation is invasive, costly, not universally accessible, and may be more appropriate after other therapies have been considered (Badr, 2025). This supports separating FDA-approved transvenous phrenic nerve stimulation for central sleep apnea from chronic hypoventilation pacing rather than continuing to describe all central sleep apnea use as investigational.

Regulatory and Device Evidence

The Avery Diaphragm Pacing System has FDA premarket approval for persons requiring chronic ventilatory support because of upper motor neuron respiratory muscle paralysis or central alveolar hypoventilation when phrenic nerve, lung, and diaphragm function are sufficient for electrical stimulation. FDA records list original PMA P860026 with a January 5, 1987 decision date, with later supplements including the Mark IV transmitter and the 2019 digital Spirit transmitter supplement (U.S. Food and Drug Administration, 1987, 2019).

The NeuRx Diaphragm Pacing System received FDA PMA P200018 on March 31, 2023 for adults age 18 years or older with stable high spinal cord injuries, stimulatable diaphragms, and lack of diaphragm control. FDA states the device is intended to allow breathing without mechanical ventilation for at least four continuous hours per day. In FDA's 92-patient study summary, 88% achieved at least four consecutive hours of pacing, 76% received stimulation for at least 12 hours per day, and 60.8% used stimulation for 24 hours per day. These data support updating the policy's prior statement that 24-hour pacing is not recommended (U.S. Food and Drug Administration, 2023a).

The remedē System received FDA PMA approval in 2017 as an implantable phrenic nerve stimulator for moderate-to-severe central sleep apnea in adults. FDA's summary reports that in the pivotal trial, 51% of treated patients had at least a 50% reduction in apnea-hypopnea index at six months, compared with 11% of control patients. Current evidence supports narrow, device-specific discussion of transvenous phrenic nerve stimulation for central sleep apnea, but does not support broad coverage for all phrenic or diaphragm stimulation uses (U.S. Food and Drug Administration, 2017).

AeroPace received FDA PMA approval in December 2024 for temporary transvenous diaphragm neurostimulation to improve weaning success in adults on mechanical ventilation for at least 96 hours who have not weaned. This is a related but distinct temporary ventilator-weaning technology and should be reviewed separately from this chronic hypoventilation policy (U.S. Food and Drug Administration, 2024a).

Systematic Reviews and Meta-Analyses

Systematic reviews generally support a disease-specific interpretation of diaphragm pacing. Earlier reviews found that diaphragm stimulation can help selected ventilator-dependent patients with high cervical spinal cord injury achieve partial or complete ventilator independence, but study quality was limited and complications were common but often manageable (Garara, 2016; Sieg, 2016). Evidence is weaker and less consistent outside spinal cord injury and congenital central hypoventilation syndrome.

A 2024 systematic review and meta-analysis comparing diaphragm pacing with mechanical ventilation in chronic respiratory failure due to diaphragmatic dysfunction found disease-specific outcomes. In spinal cord injury, diaphragm electrical stimulation was associated with reduced hospital stays and respiratory infections while maintaining comparable quality of life. In amyotrophic lateral sclerosis, diaphragm pacing was associated with higher mortality and no quality-of-life benefit, supporting continued noncoverage for amyotrophic lateral sclerosis despite historical FDA humanitarian device exemption status (Arango-Cortes, 2024).

A 2025 systematic review of 10 case reports in Japan further supports diaphragmatic pacing for ventilator-dependent patients with spinal cord injury or congenital central hypoventilation syndrome (Yamauchi, 2025). All patients achieved partial or complete ventilator weaning, with 27% attaining full independence, alongside enhanced qualityoflife, mobility, and social reintegration. Reported complications included respiratory muscle fatigue (54%), ventilatory challenges in seated positions (18%), and stimulation-related pain (9%). The review identified barriers to adoption in Japan, such as delayed initiation (median 24 months post-injury), limited interdisciplinary collaboration, and inadequate home care support. Recommendations included early intervention, structured follow-up, and telemedicine to improve outcomes, though the small sample size and reliance on case reports limit generalizability. These reviews collectively underscore the potential of diaphragmatic pacing but call for higher-quality studies and standardized guidelines to optimize its clinical use.

A 2025 systematic review and meta-analysis of diaphragmatic stimulation techniques in critically ill patients with prolonged mechanical ventilation found possible reductions in ventilator duration and intensive care unit length of stay, and a higher proportion of successful weaning. However, the population, stimulation approaches, and protocols were heterogeneous, and certainty was low or very low. These findings support separate review of temporary ventilator-weaning neurostimulation technologies rather than expansion of this chronic hypoventilation policy (Tong, 2025).

Other Evidence and Safety Considerations

Observational and pivotal studies of transvenous phrenic nerve stimulation for central sleep apnea show improvements in apnea-hypopnea index, central apnea burden, sleep quality, and quality-of-life measures, but evidence for mortality, hospitalization, and long-term comparative outcomes remains limited. The AASM guideline therefore characterizes the certainty of evidence as very low and recommends individualized treatment selection (Badr, 2025; Costanzo, 2018; Iftikhar, 2022; Luni, 2020; Sagalow, 2022; Wang, 2023).

Safety language should be device-specific. Avery labeling warns that device failure can cause respiratory arrest, hypoventilation, or death, and that backup ventilation and an apnea alarm should be available for patients dependent on pacing. Avery labeling also lists magnetic resonance imaging, shock-wave lithotripsy, and therapeutic diathermy as contraindicated, and states radiofrequency energy may interfere with demand-type cardiac pacemakers unless precautions such as bipolar pacemaker leads and adequate separation are met. NeuRx labeling and FDA safety history support careful device-to-device assessment, attention to implanted electrical devices, and review of recall history. FDA posted a Class I NeuRx external pulse generator recall for a printed-circuit-board defect with potential for impaired ventilation and serious cardiopulmonary adverse events; the recall was terminated in 2023. FDA also lists a Class III NeuRx DPS recall related to labeling and storage conditions that was terminated in 2024. The remedē System has device-specific MR Conditional labeling,

including later FDA-approved magnetic resonance imaging labeling updates, so magnetic resonance imaging should no longer be listed as a blanket contraindication for all phrenic nerve stimulation devices (Avery Biomedical Devices Inc., 2026; U.S. Food and Drug Administration, 2023b, 2023c, 2024b, 2025).

In 2026, we revised

the findings section to incorporate FDA NeuRx PMA P200018, the 2025 AASM central sleep apnea guideline, NICE HTG725, updated device-specific magnetic resonance imaging and cardiac-device precautions, FDA NeuRx recall history, AeroPace scope considerations, and recent systematic reviews.

References

On May 5, 2026, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “phrenic nerve” (MeSH), “diaphragm” (MeSH), “electrical stimulation” (MeSH), “sleep apnea, central/therapy” (MeSH), “phrenic nerve stimulation,” “transvenous phrenic nerve stimulation,” “diaphragm pacing,” “NeuRx,” “remedē,” and “AeroPace.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

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6/2014: Policy references updated.

6/2015: Policy references updated.

6/2016: Policy references updated.

6/2017: Policy references updated.

6/2018: Policy references updated.

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6/2020: Policy references updated.

6/2021: Policy references updated.

6/2022: Policy references updated. Coverage modified.

6/2023: Policy references updated.

6/2024: Policy references updated.

6/2025: Policy references updated.

6/2026: Policy references updated.

Related codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy CCP.1041. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

Code	Code description
33276-33288	Phrenic nerve stimulation system implantation, replacement, revision, repositioning, or removal services, typically for transvenous central sleep apnea systems; consult current coding manuals.
93150-93153	Therapy activation, interrogation, and programming of an implanted phrenic nerve stimulator system.
64575	Open implantation of neurostimulator electrode array; peripheral nerve, when specified as phrenic nerve stimulator.
64590	Insertion or replacement of peripheral neurostimulator pulse generator or receiver, when specified as phrenic nerve stimulator.