Electrical Stimulators - Diaphragmatic/Phrenic Nerve, Functional and Neuromuscular

INDEPENDENT CARE HEALTH PLAN

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Medicare Advantage Medical Coverage Policy

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Related Medicare Advantage Medical/Pharmacy Coverage Policies

Obstructive Sleep Apnea and Other Sleep Related Breathing Disorders Surgical Treatments
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Related Documents

Please refer to CMS Medicare Coverage Database for the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA). Refer to CMS website for the most current applicable CMS Online Manual System (IOMs) and Transmittals.

Type	Title	Document ID Number	Jurisdiction Medicare Administrative	Applicable States/Territories

			Contractors (MACs)	
Internet-Only Manuals (IOMs)	Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15	§ 120 Prosthetic Devices (subsection - D. Supplies, Repairs, Adjustments, and Replacement)		
NCD	Neuromuscular Electrical Stimulation (NMES)	160.12		
NCD	Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES)	160.13		
NCD	Phrenic Nerve Stimulator	160.19		

Description

Partial or complete paralysis may occur when the brain and spinal cord are damaged by injury, stroke, or acute disease. Physical therapy (PT) treatment is a significant part of rehabilitation care for individuals with brain and spinal cord damage which can accelerate and improve function recovery. Commonly, PT uses active and passive techniques to retrain voluntary muscle control and preserve motion range.[7]

Neuromuscular Electrical Stimulation

Neuromuscular electrical stimulation (NMES), is a complementary approach to rehabilitation using electric pulses to elicit muscle contraction.[7] This PT modality consists of small electronic devices affixed externally to the individual's skin by way of electrodes to provide direct stimulation of affected muscles. The goal of NMES for an immobilized extremity, following a documented injury or surgical intervention, is to control edema, increase local blood circulation, maintain muscle tone, or delay the development of disuse atrophy. Additionally, NMES has also been proposed for other indications including treatment for muscle atrophy and neuromodulation of cranial nerves in conjunction with focused exercise therapy to improve neurological symptoms such as gait deficits with multiple sclerosis.

Functional Electrical Stimulation

Functional electrical stimulation (FES), is a specialized type of NMES, designed to enhance the ability to stand and/or walk for individuals with a spinal cord injury (SCI) by emitting electrical impulses to stimulate paralyzed or weak muscles in a specific order. FES devices may use surface electrodes or be an implanted system and has 2 primary clinical applications in individuals with SCI; functional and therapeutic. The goal of therapeutic FES is to encourage cardiovascular conditioning and prevent muscular atrophy through

resistance-based exercise. Functional FES enables or enhances functions such as: standing, ambulation, grasping, pinching, reaching, respiration, bowel or bladder voiding.[13]

Diaphragmatic/Phrenic Nerve Stimulation

Diaphragmatic/phrenic (D/P) nerve stimulation (also referred to as diaphragmatic/phrenic pacing) and diaphragm pacing may be an alternative to invasive, mechanical ventilation for individuals with ventilatory insufficiency or failure who have retained adequate function in the phrenic nerves and diaphragm.[12] This is most often accomplished by phrenic nerve pacing (electrodes are placed near the phrenic nerve), though direct pacing of the diaphragm muscle may be more helpful in some individuals (electrodes placed directly on or implanted into the diaphragm muscle).[12] Phrenic nerve pacing devices consist of both internal (electrodes and a receiving unit) and external components (transmitting box connected to an antenna taped to the surface of the skin, just over the implanted receiving unit). For implanted diaphragm pacing devices, after motor point mapping of the diaphragm muscle has been done, electrodes are implanted into the identified motor points and connected to an external stimulator.

Central sleep apnea (CSA) is a disorder characterized by repetitive cessation or decrease of both airflow and ventilatory effort during sleep. It can be primary (idiopathic CSA) or secondary. Examples of secondary CSA include CSA associated with Cheyne-Stokes breathing, a medical condition, a drug or substance or high-altitude periodic breathing. CSA associated with Cheyne-Stokes breathing is particularly common, especially among individuals who have heart failure or have had a stroke.[15] **Phrenic nerve stimulation (PNS)** for moderate to severe CSA uses an implantable device (eg, **remedē system)** that purportedly delivers unilateral transvenous stimulation to deliver diaphragmatic contraction that mimics normal breathing patterns. This approach is believed to help restore normal breathing patterns by stimulating the phrenic nerve, which innervates the diaphragm, allowing better oxygenation and improving sleep.[9]

Coverage Determination

ICare follows the Medicare requirements that only allow coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

Please refer to the above CMS guidance for **Neuromuscular electrical stimulation**

Please refer to the following CMS source for guidance regarding **NMES supplies**:

- CMS National Coverage Determination 160.13 – Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES)

Please refer to the following CMS source for guidance regarding **other device supplies, repairs, adjustments, and replacement**:

- Medicare Benefit Policy Manual, Chapter 15 Covered Medical and Other Health Services, 120 - Prosthetic Devices, subsection D - Supplies, Repairs, Adjustments, and Replacement

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, ICare may consider the criteria contained in the following:

Diaphragmatic/Phrenic Nerve Stimulation

While NCD 160.19– Phrenic Nerve Stimulator includes D/P nerve stimulation as nationally covered for individuals with partial or complete respiratory insufficiency it does not provide the additional information listed in the service description. ICare may consider the following to interpret or supplement such criteria in order to determine medical necessity consistently:

ICare members may be eligible under the Plan for **D/P nerve stimulation with partial or complete respiratory insufficiency** when the following criteria are met[3]:

- Individual has intact phrenic nerve and diaphragm; **AND**
- Individuals with respiratory insufficiency who are dependent upon the usual therapy of intermittent or permanent use of a mechanical ventilator as well as maintenance of a permanent tracheotomy stoma

The use of the criteria above provides clinical benefits highly likely to outweigh any clinical harms (eg, adverse effects including, but not limited to, dehiscence or cellulitis at the site of the receiver implantation, postoperative infections and mechanical failures).[15] Services that do not meet the criteria above are not medically reasonable and necessary and may result in unnecessary exposure to potential complications. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage

The following **NMES/FES for walking in SCI individuals** will **not** be considered medically reasonable and necessary[2]:

- Autonomic dysflexia; **OR**
- Individuals with cardiac pacemakers; **OR**
- Irreversible contracture; **OR**
- Severe scoliosis or severe osteoporosis; **OR**
- Skin disease or cancer at area of stimulation

A review of the current medical literature shows that the **evidence is insufficient** to determine that this service is standard medical treatment for these indications. There is an absence of current, widely-used treatment guidelines or acceptable clinical literature (as defined by CMS) examining benefit and long-term clinical outcomes establishing the value of this service in clinical management for these indications.

The following **diaphragmatic/phrenic nerve stimulation** will not be considered medically reasonable and necessary[16]:

- Individuals with amyotrophic lateral sclerosis (ALS); **OR**
- Individuals with denervated diaphragm

A review of the current medical literature shows that the **evidence is insufficient** to determine that this service is standard medical treatment for these indications. There is an absence of current, widely-used treatment guidelines or acceptable clinical literature (as defined by CMS) examining benefit and long-term clinical outcomes establishing the value of this service in clinical management for these indications.

CSA surgical treatments including, but may not be limited to, **phrenic nerve stimulation,** will not be considered medically reasonable and necessary. A review of the current medical literature shows that the **evidence is insufficient** to determine that this service is standard medical treatment. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

Summary of Evidence

ALS

Direct diaphragmatic pacing stimulation in individuals with ALS remains a topic of debate. D/P stimulation may not be effective if there are not enough innervated muscle fibers to facilitate diaphragm contraction. Furthermore, findings from two randomized trials have indicated possible adverse effects linked to the utilization of DPS. The reasons for conflicting data are unclear but may include the degree of diaphragm thickness or atrophy, diaphragmatic denervation, and/or upper relative to lower motor neuron disease.[1615]

Autonomic dysflexia (AD)

Published evidence discusses there are contraindications and precautions that should be recognized in electrical stimulation, especially with NMES and individuals with uncontrolled autonomic dysreflexia have been identified as a contraindication.[6] Applications of FES may lead to episodes of AD, which has been attributed to increased electrical charges that commonly developed underneath the stimulated electrodes and serve as a source of noxious stimuli. These noxious stimuli can generate sympathetic reflex at or below the level of injury, which can lead to an increase in blood pressure and the development of AD. As a result, these individuals are less likely to be considered for this important form of physical activity and exercise, which puts them at risk for the manifold side effects of immobility and inactivity.[13] In addition, caution should be used in patients with history of autonomic dysreflexia.[13]**Error! Reference source not found.**

Denervated diaphragm

Published evidence states that diaphragmatic pacing should be avoided in individuals with evidence of a denervated diaphragm. When the phrenic nerve function is not intact, the diaphragm is denervated, and D/P stimulation is not feasible.[13]

Individuals with cardiac pacemakers

Published evidence discusses there are contraindications and precautions that should be recognized in electrical stimulation, especially with NMES, where individuals with pacemakers have been identified as a contraindication.[6] Additional evidence reported contraindications to FES which include cardiac pacemakers and that caution should be used in patients with any implanted medical device, suspected or diagnosed heart problems.[13]**Error! Reference source not found.**

Individuals with irreversible contractures, severe scoliosis or severe osteoporosis
Published evidence states FES seems to be ineffective in treatment of scoliosis. Some studies have shown that FES may be more effective if it's combined with other exercises or a brace.[14] Furthermore, the lack of data concerning electrical stimulation activities on older adults with SCI and osteoporosis raises the question of safety. Additionally, the number of individuals with SCI and osteoporosis who have safely used FES leg cycling ergometry cannot be quantified.[5] Additional evidence reported contraindications to FES include severe osteoporosis and limited range of motion and caution should be used in patients with any severe spasticity.[13]

Phrenic nerve stimulation for CSA
Studies demonstrate Remedē is safe and report consistent findings that Remedē improves outcomes from baseline in individuals with moderate to severe CSA and that those benefits are sustained long term. However, some study limitations restrict findings generalizability. Some studies included in the systematic review (SR) are at elevated risk of bias; individuals in the RCT's inactive stimulation arm received active stimulation after 6 months; therefore, the study was no longer an RCT, and the risk of bias for outcomes after 6 months increased. Controlled trials that compare Remedē with alternative treatment options for patients with moderate to severe CSA and report on long-term (greater than 5 years) outcomes are needed to assess Remedē's comparative safety and effectiveness.[9,11,15]

Skin disease or cancer at area of stimulation
Despite the evidence for effectiveness of NMES in other patient populations, relatively few studies have been performed to test the potential usefulness of NMES in patients with cancer.[13] Published evidence reported contraindications to FES include malignancy and skin rash or disease at areas of stimulation.[13]

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

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Change Summary

01/01/2024 New Policy.
03/26/2024 Provider Claims Codes Update, No Coverage Change.
07/01/2024 Update, Coverage Change.
09/10/2024 Update, Coverage Change.
09/26/2024 Annual Review, No Coverage Change.