Electrical Stimulators - Diaphragmatic/Phrenic Nerve, Functional and Neuromuscular

INDEPENDENT CARE HEALTH PLAN

Effective Date: 01/01/2024
Revision Date: Click or tap to enter a date.
Review Date: Click or tap to enter a date.
Policy Number: WI.PA-1076
Line of Business: Medicare

Medicare Advantage Medical Coverage Policy

Table of Contents

Related Medicare Advantage Medical/Pharmacy Coverage Policies

Obstructive Sleep Apnea and Other Sleep Related Breathing Disorders Surgical Treatments
Peripheral Nerve Stimulators

Related Documents

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

Type	Title	ID Number	Jurisdiction Medicare Administrative	Applicable States/Territories

			Contractors (MACs)	
NCD	Neuromuscular Electrical Stimulation (NMES)	160.12		
NCD	Phrenic Nerve Stimulator	160.19		
NCD	Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES)	160.13		

Description

Functional Electrical Stimulators

A functional electrical stimulator (FES), a specialized type of neuromuscular stimulator, is 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.

Functional electrical stimulation attempts to prevent or reverse muscle atrophy and bone demineralization by stimulating paralyzed lower limbs (legs) to perform stationary exercise or assist with standing and walking. Additionally, functional electrical stimulation has been investigated as a way to improve gait disorders of individuals with hemiplegia. An FES device may use surface electrodes or be an implanted system.

Examples of FES devices to assist with ambulation in individuals with an SCI include, but may not be limited to, the **Parastep I System**. Currently, the **Parastep I** is the only device with US Food & Drug Administration (FDA) approval for restoring ambulation for individuals with an SCI.

Examples of FES devices for the lower extremities include, but may not be limited to, **Cionic Neural Sleeve NS-100**, **ERGYS systems, MyoCycle, NESS L300 systems, ODFS Dropped Foot Stimulator, RT300 systems, RT600 FES Step and Stand Rehabilitation Therapy system** and the **WalkAide stimulator**.

FES has also been proposed for individuals with upper extremity paralysis due to injury or disease of the central nervous system such as cervical spinal cord injuries or stroke. It is suggested as a treatment option for exercising the hand and/or conditioning selected muscles of the forearm and hand.

Examples of FES devices for paralyzed upper extremities include, but may not be limited to, the **MyndMove systems**, **NESS H200 Hand Rehabilitation System,** and **RT300 systems**.

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 a C3 level or above spinal cord injury or for some motor neuron diseases such as amyotrophic lateral sclerosis (ALS). 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). 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.

Examples of these devices include, but may not be limited to, **Avery Diaphragm Pacing System** (also known as Breathing Pacemaker System), **Mark IV Breathing Pacemaker System, NeuRx DPS Diaphragm Pacing System**, and **NeuRx DPS RA/4 Respiratory Stimulation System**.

Neuromuscular Electrical Stimulators

Neuromuscular electrical stimulators (NMES) are small electronic devices that are affixed externally to the individual's skin by way of electrodes to provide direct stimulation of affected muscles. NMES stimulates muscle to maintain its tone during temporary extremity immobilization. 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. NMES has also been proposed for other indications including treatment for muscle atrophy characteristic in conditions such as cerebral palsy, congestive heart failure and upper extremity hemiplegia (eg, stroke). NMES may also be used for neuromodulation of cranial nerves in conjunction with focused exercise therapy to improve neurological symptoms such as gait deficits with multiple sclerosis.

Examples of a NMES include, but may not be limited to:

- **Biomove systems are** devices where electromyography (EMG) is triggered by NMES. These devices are designed to detect any EMG signals (nerve impulses from the brain to the muscles) that are supposed to stimulate a muscle contraction but are too weak to do so. When the device detects these signals, it applies stimulation to the muscle and induces a contraction, to purportedly retrain the brain and muscle to properly coordinate contractions and movement. This device is also proposed for relaxation of muscle spasms and prevention or retardation of disuse atrophy

- **Empi Phoenix**, **Flex-MT Plus**, **Kneehab XP**, **NexWave and QB1** are combination NMES and transcutaneous electrical nerve stimulation (TENS) devices.

- **geko W-2** device delivers neuromuscular electro-stimulation via the common peroneal nerve to activate the calf and foot muscle pumps of the lower leg to increase blood circulation.

- **Guardian dysphagia therapy systems** and **VitalStim Therapy** devices are proposed for muscle re-education by application of external stimulation for pharyngeal contraction.

- **Portable Neuromodulation Stimulator (PoNS)** is a nonimplantable device, proposed for the use in individuals with multiple sclerosis, which delivers mild neuromuscular stimulation to the tongue stimulating the facial and trigeminal nerves sending impulses to the brain to purportedly provide treatment of short- term gait deficits. The device consists of a controller and mouthpiece that are connected to each other by a cable.

- **RS-2m** muscle stimulator

- **RS-4i Plus** sequential stimulator (also referred to as a combination unit) initially provides an interferential treatment followed by the muscle stimulation.

- **RS-4m** muscle stimulator

Coverage Determination

iCare follows the CMS requirements that only allows 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 (NMES) and Phrenic Nerve Stimulator**

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

Electrical Stimulators – Diaphragmatic/Phrenic Nerve, Functional and Neuromuscular

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. 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

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.

CPT® Code(s)	Description	Comments
64575	Incision for implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)	
64580	Incision for implantation of neurostimulator electrode array; neuromuscular	
93152	Interrogation and programming of implanted phrenic nerve stimulator system during polysomnography	
93153	Interrogation without programming of implanted phrenic nerve stimulator system	
CPT® Category III Code(s)	**Description**	**Comments**
No code(s) identified		
HCPCS Code(s)	**Description**	**Comments**
A4556	Electrodes (e.g., apnea monitor), per pair	
A4558	Conductive gel or paste, for use with electrical device (e.g., TENS, NMES), per oz	
A4560	Neuromuscular electrical stimulator (nmes), disposable, replacement only	
A4595	Electrical stimulator supplies, 2 lead, per month, (e.g., TENS, NMES)	
E0731	Form-fitting conductive garment for delivery of TENS or NMES (with conductive fibers separated from the patient's skin by layers of fabric)	
E0744	Neuromuscular stimulator for scoliosis	
E0745	Neuromuscular stimulator, electronic shock unit	
E0764	Functional neuromuscular stimulation, transcutaneous stimulation of sequential muscle groups of ambulation with computer control, used for walking by spinal cord injured, entire system, after completion of training program	
E0770	Functional electrical stimulator, transcutaneous stimulation of nerve and/or muscle groups, any type, complete system, not otherwise specified	
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	
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	
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	

References

1. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD). Neuromuscular electrical stimulation (NMES) (160.12). https://www.cms.gov. Published October 1, 2006. Accessed November 7, 2023.

2. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD). Phrenic nerve stimulator (160.19). https://www.cms.gov. Published January 1, 1966. Accessed November 7, 2023.

3. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD). Supplies used in the delivery of transcutaneous electrical nerve stimulation (TENS) and neuromuscular electrical stimulation (NMES) (160.13). https://www.cms.gov. Published July 14, 1988. Accessed November 7, 2023.

Change Summary

- 01/01/2024 New Policy.
-