BLUE CROSS OF NORTHEASTERN PA "BCNEPA" MEDICAL POLICY BULLETIN	**MANUAL:** MEDICAL POLICY **REFERENCE NO.:** MPO-490-0018
EFFECTIVE DATE July 1, 2014	**SUBJECT:** Electrical/Neuromuscular Stimulator

Blue Cross of Northeastern Pennsylvania ("BCNEPA") Medical Policy

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical policy and claims payment policy are applied. Policies are provided for informational purposes only and are developed to assist in administering plan benefits and do not constitute medical advice. Treating providers are solely responsible for medical advice and treatment. Policies are based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and information are constantly changing and BCNEPA may review and revise its medical policies periodically. Also, due to the rapid pace of changing technology and the advent of new medical procedures, BCNEPA may not have a policy to address every procedure. In those cases, BCNEPA may review other sources of information including, but not limited to, current medical literature and other medical resources, such as Technology Evaluation Center Assessments (TEC) published by the Blue Cross Blue Shield Association. BCNEPA may also consult with health care providers possessing particular expertise in the services at issue.

I. DESCRIPTION:

Electrical Stimulation is the use of electric current to stimulate a tissue, such as muscle or bone.

Neuromuscular Stimulation involves both nerves and muscles.

II. BENEFIT POLICY STATEMENT:

BCNEPA makes decisions on coverage based on Policy Bulletins, benefit plan documents, and the member's medical history and condition. Benefits may vary based on product line, group or contract, therefore, Member benefits must be verified. In the event of a conflict between the Member's benefit plan document and topics addressed in Medical Policy Bulletins (i.e., specific contract exclusions), the Member's benefit plan document always supersedes the information in the Medical Policy Bulletins. BCNEPA determines medical necessity only if the benefit exists and no contract exclusions are applicable.

Benefits are determined by the terms of the Member's specific benefit plan document [i.e., the Fully Insured policy, the Administrative Services Only (ASO) agreement applicable to the Self-Funded Plan Participant, or the Individual Policy] that is in effect at the time services are rendered.

III. MEDICAL POLICY STATEMENT:

Coverage is subject to the terms, conditions, and limitations of the member's contract.

Autonomic Nerve Stimulator

A. BCNEPA will not provide coverage for autonomic nerve stimulators to treat other than partial or complete respiratory insufficiency as this is considered investigational.

Cranial Electrotherapy Stimulation (CES) and Auricular Electrostimulation

B. BCNEPA will not provide coverage for cranial electrotherapy stimulation (also known as cranial electrostimulation therapy or CES e.g. Alpha-Stim) as this is considered investigational.

C. BCNEPA will not provide coverage for electrical stimulation of auricular acupuncture points as this is considered investigational.

Deep Brain Stimulation

D. BCNEPA will provide coverage for deep brain stimulation when medically necessary.

1. Unilateral deep brain stimulation of the thalamus may be considered medically necessary in patients with disabling, medically unresponsive tremor due to essential tremor or Parkinson's disease.

    a) Disabling, medically unresponsive tremor is defined as all of the following:

        - Tremor causes significant limitation in daily activities; and
        - Inadequate control by maximal dosage of medication for at least 3 months before implant.

2. Unilateral or bilateral deep brain stimulation of the globus pallidus or subthalmic nucleus may be considered medically necessary in the following patients:

    a) Those with Parkinson's disease with all of the following:

        - A good response to levodopa; and
        - A minimal score of 30 points on the motor portion of the Unified Parkinson's Disease Rating Scale when the patient has been without medication for approximately 12 hours; and
        - Motor complications not controlled by pharmacologic therapy.

    b) Patients aged greater than 7 years with chronic, intractable (drug refractory) primary dystonia, including generalized and/or segmental dystonia, hemidystonia and cervical dystonia (torticollis).

3. Contraindications to deep brain stimulation include:

    a) Patients who are not good surgical risks because of unstable medical problems or because of the presence of a cardiac pacemaker;

    b) Patients who have medical conditions that require repeated magnetic resonance imaging;

    c) Patients who have dementia that may interfere with the ability to corporate; and

    d) Patients who have had botulinum toxin injections within the last 6 months.

E. BCNEPA will not provide coverage for deep brain stimulation for the following indications as they are considered investigational and, therefore, not covered because the safety and effectiveness of these services cannot be established by review of the available published peer-reviewed literature:

1. Movement disorders including, but not limited to multiple sclerosis, posttraumatic dyskinesia, and tardive dyskinesia.

2. Treatment of chronic cluster headaches.

3. Treatment of other psychiatric or neurologic disorders including, but not limited to Tourette's syndrome, depression, obsessive compulsive disorders, and epilepsy.

4. All other indications not identified above as medically necessary.

Electrical Stimulation for the Treatment of Arthritis

F. BCNEPA will not provide coverage for electrical stimulation for the treatment of osteoarthritis or rheumatoid arthritis, as this is considered investigational.

Form-fitting Conductive Garment

G. BCNEPA will provide coverage for a form-fitting conductive garment for the delivery of TENS or NMES when medically necessary.

1. A form-fitting conductive garment may be considered medically necessary only when:

a) It has received permission or approval for marketing by the FDA; and

b) It has been prescribed by a physician for use in delivering covered TENS or NMES treatment; and

c) One of the medical indications outlined below is met:

- The patient cannot manage without the conductive garment because there is such a large area or so many sites to be stimulated and the stimulation would have to be delivered so frequently that it is not feasible to use conventional electrodes, adhesive tapes and lead wires;

- The patient cannot manage without the conductive garment for the treatment of chronic intractable pain because the areas or sites to be stimulated are inaccessible with the use of conventional electrodes, adhesive tapes and lead wires;

- The patient has a documented medical condition such as skin problems that preclude the application of conventional electrodes, adhesive tapes and lead wires;

- The patient requires electrical stimulation beneath a cast either to treat disuse atrophy, where the nerve supply to the muscle is intact, or to treat chronic intractable pain; or

- The patient has a medical need for rehabilitation strengthening (pursuant to a written plan of rehabilitation) following an injury where the nerve supply to the muscle is intact.

2. BCNEPA will not provide coverage for a form-fitting conductive garment when the above criteria have not been met, as this is considered not medically necessary.

Functional Neuromuscular Electrical Stimulation

H. BCNEPA will not provide coverage for neuromuscular stimulation as a technique to restore function following nerve damage or nerve injury, as this is considered investigational. This includes its use in the following situations:

1. As a technique to provide ambulation in patients with spinal cord injury; or

2. To provide upper extremity function in patients with nerve damage (e.g., spinal cord injury or post-stroke); or

3. To improve ambulation in patients with foot drop caused by congenital disorders (e.g., cerebral palsy) or nerve damage (e.g., post-stroke or in those with multiple sclerosis).

Gastric Electrical Stimulation

I. BCNEPA will not provide coverage of gastric electrical stimulation for the following indications as they are considered investigational:

1. The treatment of gastroparesis of diabetic, idiopathic or post-surgical etiology.

2. The treatment of obesity.

Interferential Current Stimulation

J. BCNEPA will not provide coverage for interferential current stimulation as this is considered investigational.

Occipital Nerve Stimulation

K. BCNEPA will not provide coverage for occipital nerve stimulation for all applications as this is considered investigational.

Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence

L. BCNEPA will not provide coverage for electrical or magnetic stimulation of the pelvic floor muscles (pelvic floor stimulation) as a treatment of urinary incontinence as this is considered investigational.

M. BCNEPA will not provide coverage for electrical or magnetic stimulation of the pelvic floor muscles (pelvic floor stimulation) as a treatment for fecal incontinence as this is considered investigational.

Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy

N. BCNEPA will not provide coverage for percutaneous electrical neurostimulation or neuromodulation as this is considered investigational.

Peripheral Subcutaneous Field Stimulation

O. BCNEPA will not provide coverage for peripheral subcutaneous field stimulation as this is considered investigational.

Posterior Tibial Nerve Stimulation for Voiding Dysfunction

P. BCNEPA will not provide coverage for posterior tibial nerve stimulation for urinary dysfunction, including, but not limited to overactive bladder syndrome, neurogenic bladder, urinary frequency, urgency, incontinence, and retention as this is considered investigational.

Sacral Nerve Neuromodulation/Stimulation

Q. BCNEPA will provide coverage for sacral nerve neuromodulation when medically necessary.

1. For urinary incontinence and non-obstructive retention, a trial period of sacral nerve neuromodulation with either percutaneous nerve stimulation or a temporarily implanted lead may be considered medically necessary in patients who meet all of the following criteria:

   a) There is a diagnosis of at least one of the following:

      - Urge incontinence
      - Urgency-frequency syndrome
      - Non-obstructive urinary retention
      - Overactive bladder (see Definitions)

   b) There is documented failure or intolerance to at least two conventional conservative therapies (e.g., behavioral training such as bladder training, prompted voiding, or pelvic muscle exercise training, pharmacologic treatment for at least a sufficient duration to fully assess its efficacy, and/or surgical corrective therapy);

   c) The patient is an appropriate surgical candidate;

   d) Incontinence is not related to a neurologic condition.

2. Permanent implantation of a sacral nerve neuromodulation device may be considered medically necessary in patients who meet all of the following criteria:

   a) All of the above criteria in 1. a) - d) are met, and

   b) A trial stimulation period demonstrates at least 50% improvement in symptoms over a period of at least 1 week.

3. A trial period of sacral nerve neuromodulation with either percutaneous nerve stimulation or a temporarily implanted lead may be considered medically necessary for the treatment of fecal incontinence in patients who meet all of the following criteria:

    a) There is a diagnosis of chronic fecal incontinence of greater than 2 incontinent episodes on average per week with duration greater than 6 months or for more than 12 months after vaginal childbirth; and

    b) There is documented failure or intolerance to conventional conservative therapy (e.g., dietary modification, the addition of bulking and pharmacologic treatment for at least a sufficient duration to fully assess its efficacy, performed more than 12 months [or 24 months in case of cancer] previously); and

    c) The patient is an appropriate surgical candidate; and

    d) The condition is not related to an anorectal malformation (e.g., congenital anorectal malformation; defects of the external anal sphincter over 60 degrees; visible sequelae of pelvic radiation; active anal abscesses and fistulae) or chronic inflammatory bowel disease; and

    e) Incontinence is not related to neurologic condition.

4. Permanent implantation of a sacral nerve neuromodulation device may be considered medically necessary in patients who meet all of the following criteria:

    a) All of the criteria in 3. a) - e) above are met.

    b) A trial stimulation period demonstrates at least 50% improvement in symptoms over a period of at least 1 week.

R. BCNEPA will not provide coverage for sacral nerve neuromodulation for the following indications as they are considered investigational and, therefore, not covered because the safety and effectiveness of these services cannot be established by review of the available published peer-reviewed literature:

1. Other urinary/voiding applications of sacral nerve neuromodulation, including but not limited to treatment of stress incontinence or urge incontinence due to a neurologic condition, e.g., detrusor hyperreflexia, multiple sclerosis, spinal cord injury, or other types of chronic voiding dysfunction.

2. Other fecal incontinence applications of sacral nerve neuromodulation, including but not limited to the treatment of chronic constipation or chronic pelvic pain.

3. All other indications not identified above as medically necessary.

Threshold Electrical Stimulation as a Treatment of Motor Disorders

S. BCNEPA will not provide coverage for threshold electrical stimulation as a treatment of motor disorders, including, but not limited to cerebral palsy as this is considered not medically necessary.

Transcranial Magnetic Stimulation as a Treatment of Depression and Other Psychiatric/Neurologic Disorders

T. BCNEPA will not provide coverage for transcranial magnetic stimulation of the brain as a treatment of depression and other psychiatric/neurologic disorders such as schizophrenia or migraine headaches as this is considered investigational.

Treatment of Tinnitus

U. BCNEPA will not provide coverage for treatment of tinnitus with electrical stimulation, transcutaneous electrical stimulation, or transcranial magnetic stimulation as this is considered investigational.

Vagus Nerve Stimulation

V. BCNEPA will provide coverage for vagus nerve stimulation when medically necessary.

1. Vagus nerve stimulation may be considered medically necessary as a treatment of medically refractory seizures.

a) Medical refractory seizures are defined as seizures that occur in spite of therapeutic levels of antiepileptic drugs or seizures that cannot be treated with therapeutic levels of antiepileptic drugs because of intolerable adverse effects of these drugs.

W. BCNEPA will not provide coverage for vagus nerve stimulation for the following indications as they are considered investigational and, therefore, not covered because the safety and effectiveness of these services cannot be established by review of the available published peer-reviewed literature:

1. Treatment of other conditions, including but not limited to heart failure, fibromyalgia, depression, essential tremor, headaches, obesity, tinnitus and traumatic brain injury.

2. Non-implantable vagus nerve stimulation devices for all indications.

3. All other indications not identified above as medically necessary.

Spinal Cord Stimulation

X. BCNEPA will provide coverage for spinal cord stimulation when medically necessary.

1. Spinal cord stimulation may be considered medically necessary for the treatment of patients with severe and chronic pain of the trunk or limbs that is refractory to all other pain therapies and all of the following guidelines have been met:

a) The treatment is used only as a last resort; other treatment modalities (pharmacological, surgical, psychological, or physical, if applicable) have been tried and failed or are judged to be unsuitable or contraindicated;

b) Pain is neuropathic in nature, i.e., resulting from actual damage to the peripheral nerves. Common indications include, but are not limited to failed back syndrome, complex regional pain syndrome (i.e., reflex

sympathetic dystrophy), arachnoiditis, radiculopathies, phantom limb/stump pain, peripheral neuropathy. Spinal cord stimulation is generally not effective in treating nociceptive pain (resulting from irritation, not damage to the nerves) and central deafferentation pain (related to CNS damage from a stroke or spinal cord injury);

c) No serious untreated drug habituation exists;

d) Demonstration of at least 50% pain relief with a temporarily implanted electrode precedes permanent implantation; and

e) All the facilities, equipment, and professional and support personnel required for the proper diagnosis, treatment, and follow-up of the patient are available.

Y. BCNEPA will not provide coverage for the use of spinal cord stimulation for the following conditions as they are considered investigational and, therefore, not covered because the safety and effectiveness of these services cannot be established by review of the available published peer-reviewed literature:

1. Treatment of critical limb ischemia as a technique to forestall amputation.

2. Treatment of refractory angina pectoris.

3. All other indications not identified above as medically necessary.

IV. DEFINITIONS:

Electrical Stimulation: The use of electric current to stimulate a tissue, such as muscle or bone.

Peripheral Nervous System Stimulators:

a) Transcutaneous Electrical Nerve Stimulation (TENS): a technique that involves the attachment of a transcutaneous nerve stimulator to the surface of the patient's skin over the peripheral nerve to be stimulated. It is undertaken to relieve pain, which is unresponsive to other standard therapies.

b) Percutaneous Electrical Nerve Stimulators (PENS): a procedure involving stimulation of the peripheral nerves by a needle electrode inserted through the skin.

Occipital nerve stimulation (ONS): delivers a small electrical charge to the occipital nerve in an attempt to prevent migraines and other headaches in patients who have not responded to medications. The device consists of a subcutaneously implanted pulse generator (in the chest wall or abdomen) attached to extension leads that are tunneled to join electrodes placed across one or both occipital nerves at the base of the skull. Continuous or intermittent stimulation may be used.

Peripheral Percutaneous Electrical Nerve Stimulation: (peripheral PENS) is a diagnostic procedure, which is used to test effectiveness of nerve stimulation prior to implanting a permanent nerve stimulator. The procedure involves insertion of Neurostimulator electrodes through the skin without making an incision as is performed when the electrodes are being placed for a long time.

Implanted Peripheral Nerve Stimulators: involves the implantation of electrodes around a

selected peripheral nerve.

Vagus Nerve Stimulator: consists of a generator which is implanted under the collar bone and connected by wire to the vagus nerve in the neck, where it delivers electrical signals to the brain. The procedure is performed in the hospital and usually requires an overnight stay.

Central Nervous System Stimulators:

a) Dorsal Column (Spinal Cord Neurostimulation): is the surgical implantation of neurostimulator electrodes within the dura mater (endodural) or the percutaneous insertion of electrodes in the epidural space).

b) Depth Brain Neurostimulation: is the stereotactic implantation of electrodes in the deep brain (e.g., thalamus and periaqueductal gray matter).

Simple Neurostimulators: Defined as those affecting 3 or fewer neurostimulatory parameters (e.g., pulse amplitude, duration, frequency, number of electrode contacts, etc.) while a complex device affects more than three parameters.

Spinal Cord and Deep Brain Stimulation: Electrical stimulation of the dorsal columns (by implantation of electrodes in the epidural space) or specific regions of the brain (e.g., thalamus and periaquaductal gray matter) is a treatment for chronic pain.

Sacral Nerve Stimulation (SNS), or Sacral Nerve Neuromodulation: Defined as the implantation of a permanent device that modulates the neural pathways controlling bladder function.

Interstim Sacral Nerve Stimulation (SNS) System: FDA approved for the indication of urinary urge incontinence in patients who have failed or could not tolerate more conservative treatments. No other implantable SNS device currently has FDA approval, and this device has not yet been approved for other indications.

Overactive Bladder: The International Continence Society states that Overactive Bladder Syndrome (OAB) “is defined as urinary urgency, usually with urinary frequency and nocturia, with or without urgency urinary incontinence.” http://wiki.ics.org/Overactive+Bladder

CODING:

- **The identification of a code in this section does not denote coverage or separate reimbursement.**
- Covered procedure codes are dependent upon meeting criteria of the policy and appropriate diagnosis code.
- The following list of codes may not be all-inclusive, and are subject to change at any time.
- Benefits are determined by the terms of the Member's specific benefit plan document [i.e., the Fully Insured policy, the Administrative Services Only (ASO) agreement applicable to the Self-Funded Plan Participant, or the Individual Policy] that is in effect at the time services are rendered.

PROCEDURE CODES

0282T	61860	63663	64590	95981
0283T	61863	63664	64595	95982
0284T	61864	63685	64999	E0731
0285T	61867	63688	90867	E0740
0312T	61868	64550	90868	E0744
0313T	61870	64553	90869	E0745
0314T	61875	64555	95970	E0762
0315T	61880	64561	95971	E0764
0316T	61885	64565	95972	E0769
0317T	61886	64566	95973	E0770
43647	61888	64568	95974	E0935
43648	63650	64569	95975	E0936
43881	63655	64570	95978	L8679
43882	63661	64581	95979	L8680
61850	63662	64585	95980	L8681

L8682	L8685	L8688	S8130
L8683	L8686	L8689	S8131
L8684	L8687	L8695	S8930