Electrical Nerve Stimulation

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Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under medical surgical benefits of the Company's Medicaid products for medically necessary electrical nerve stimulation.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Highmark Health Options (HHO) – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children Program (DHCP) and Diamond State Health Plan Plus members.

Electrical Nerve Stimulation – The use of electric current produced by a device to stimulate the nerves for therapeutic purposes.

PROCEDURES

A prior authorization is required for implantable electrical stimulation devices, external devices, and associated accessories exceeding the $500 DME limitation.

Electrical nerve stimulation, (Transcutaneous electrical nerve stimulation (TENS) and Percutaneous electrical nerve stimulation) (PENS) may be considered medically necessary when used for the treatment

of acute or chronic pain and as a means of assessing the need for continued treatment with an implanted electrical nerve stimulator.

Electrical nerve stimulation for pain control may be considered medically necessary when the following criteria have been met:

- For acute pain including post-operative pain the first thirty (30) days from the day of surgery; or
- For chronic pain, an individual is unresponsive to at least three (3) months of conservative therapy (e.g., nonsteroidal anti-inflammatory medications, ice, rest and/or physical therapy); and
  - The individual is responsive to a trial of electrical stimulation for chronic pain control for at least two (2) weeks performed under medical supervision (e.g., physical therapy). For example, a demonstration of a reduction in pain that is clinically significant as defined by accepted documented outcome measures (e.g., pain scale); and
  - The trial period is monitored and documented by a licensed professional that is qualified to provide treatment (e.g., physical therapist).

The use of PENS and TENS not meeting the criteria as indicated in this policy is considered experimental/investigational and therefore, noncovered because the safety and/or effectiveness of this service cannot be established by the available published peer reviewed literature.

Supplies for electrical stimulation device may be considered medically necessary when annual documentation is noted in the individual's medical record.

Normal utilization with a covered electrical stimulation device is:

- For two (2) lead device, four (4) electrodes per month; or
- For four (4) lead device, eight (8) electrodes per month.

Procedure code A4595 is allowed 12 every one (1) floating month.

Quantity of supplies that exceed the frequency guidelines listed on this policy are considered not medically necessary.

PHRENIC NERVE STIMULATOR

The implantation of a United States Food and Drug Administration (U.S. FDA) approved phrenic nerve stimulator may be considered medically necessary:

- The phrenic nerve is viable and intact; and
- Diaphragmatic function is sufficient to accommodate chronic stimulation; and
- For treatment of chronic ventilator or respiratory insufficiency requiring mechanical ventilation due to ONE (1) of the following conditions:
  - Lesions/injury of the spinal cord at or above the C-3 vertebral level; or
  - Central alveolar hypoventilation, either primary or secondary to a brain stem disorder, or
  - Central sleep apnea (e.g., the Remede System) and central sleep related hypoventilation/hypoxemic syndromes.

Phrenic nerve stimulation not meeting the criteria as indicated in this policy is considered experimental/investigational and therefore, noncovered because the safety and/or effectiveness of this service cannot be established by the available published peer reviewed literature.

VAGUS NERVE STIMULATOR

The implantation of a vagus (vagal) nerve stimulator for seizure control may be considered medically necessary only when used as a last resort for individuals with epilepsy with partial onset seizures.

A U.S. FDA approved vagus nerve stimulator for the management of epilepsy with partial onset seizures may be considered medically necessary for individuals when seizures cannot be controlled by any other method such as:

- Drug-resistant epilepsy ("failure to control seizures with two (2) or more appropriately chosen drugs in adequate doses"); or
- When surgery cannot be performed.

Vagus (vagal) nerve stimulation not meeting the criteria as indicated in this policy is considered not medically necessary.

NON-IMPLANTABLE VAGUS STIMULATOR

U.S. FDA approved nonimplantable vagus nerve stimulation devices (i.e., gammaCore) may be considered medically necessary for the abortive treatment of migraine or cluster headache under ALL the following circumstances:

- The individual is aged eighteen (18) years or older; and
- The individual has a diagnosis of migraine or cluster headache; and
- The individual has failed or has contraindication or has intolerance to at least two medications from each of the following categories: NSAIDS, Triptans, and Ergotamines; and
- The individual must be re-evaluated in 30 days. To obtain renewal of the device, there must be documentation of significant efficacy in the medical record.

To maintain coverage for gammaCore, the following efficacy must be documented:

- Reduction of pain from moderate or severe to mild or pain free within 60 minutes, without the use of rescue medicine, for at least 50% of attacks.

U.S. FDA approved non-implantable vagus nerve stimulation devices (e.g., gammaCore) may be considered medically necessary for the preventive treatment of migraine headache or for the acute treatment of pain associated with migraine headache under ALL the following circumstances:

- The individual is age 12 to 17; and
- The individual has a diagnosis of migraine; and
- The individual has failed or has contraindication or has intolerance to at least two (2) medications from each of the following categories: NSAIDS, Triptans, and Ergotamines; and
- The individual must be re-evaluated in 30 days. To obtain renewal of the device, there must be documentation of significant efficacy in the medical record.

To maintain coverage for gammaCore, the following efficacy must be documented:

- Reduction of pain from moderate or severe to mild or pain free within 60 minutes, without the use of rescue medicine, for at least 50% of attacks.

Nonimplantable stimulation devices not meeting the criteria as indicated in this policy are considered experimental/investigational and therefore, noncovered because the safety and/or effectiveness of this service cannot be established by the available published peer reviewed literature.

PERCUTANEOUS NERVE FIELD STIMULATOR

The use of a Percutaneous nerve field stimulator in opioid withdrawal treatment is considered experimental/investigational and therefore noncovered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

PERCUTANEOUS NEUROMODULATION THERAPY

The use of Percutaneous neuromodulation therapy is considered experimental/investigational and therefore noncovered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

PERCUTANEOUS OR OPEN IMPLANTATION OF NEUROMUSCULAR NEUROSTIMULATOR

The percutaneous or open (via incision) implantation of neuromuscular neurostimulator electrodes for chronic pain relief is considered experimental/investigational and therefore noncovered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

OCCIPITAL NERVE STIMULATION (ONS)

ONS is considered experimental/investigational and therefore noncovered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

REMOTE ELECTRICAL NEUROMODULATION

The use of a Remote Electrical Neuromodulation (REN) device (i.e., Nerivio) is considered experimental/investigational and therefore noncovered, because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

PERCUTANEOUS ELECTRICAL NERVE FIELD STIMULATOR

The use of a Percutaneous Electrical Nerve Field Stimulator (PENFS) device is considered experimental/investigational and therefore noncovered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

EXTERNAL TRIGEMINAL NERVE STIMULATION SYSTEM

An external trigeminal nerve stimulation (eTNS) system is considered experimental/investigational and therefore noncovered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

EXTERNAL UPPER LIMB TREMOR STIMULATOR

An external upper limb tremor stimulator is considered experimental/investigational and therefore noncovered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

TRANSCUTANEOUS ELECTRICAL MODULATION PAIN REPROCESSING THERAPY

Transcutaneous electrical modulation pain reprocessing therapy (TEMPR) (i.e., scrambler therapy) is considered experimental/investigational and therefore noncovered, because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature. Replacement batteries are not eligible for payment and therefore noncovered.

POST-PAYMENT AUDIT STATEMENT

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

PLACE OF SERVICE: INPATIENT/OUTPATIENT

Experimental/investigational (E/I) services are not covered regardless of place of service.

Electrical Nerve Stimulation is typically an outpatient procedure which is only eligible for coverage as an inpatient procedure in special circumstances, including, but not limited to, the presence of a co-morbid condition that would require monitoring in a more controlled environment such as the inpatient setting.

CODING REQUIREMENTS

CPT code	Description
A4595	Electrical stimulator supplies, two lead, per month (e.g., TENS, NMES).
E0720	Transcutaneous electrical nerve stimulation (TENS) device, two lead, localized stimulation.
E0730	Transcutaneous electrical nerve stimulation (TENS) device, four or more leads, for multiple nerve stimulation.
64575	Incision for implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve).
64580	Incision for implantation of neurostimulator electrodes; neuromuscular.
64585	Revision or removal of peripheral neurostimulator electrodes.
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.
95970	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) simple or complex brain, spinal cord, or peripheral (i.e., cranial nerve, peripheral nerve, autonomic nerve, neuromuscular), neurostimulator pulse generator/transmitter, without reprogramming.
95976	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, with or without nerve interface testing, first hour.
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver.
L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only.

L8696	Antenna (external) for use with implantable diaphragmatic/phrenic nerve stimulation device, replacement, each.
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array.
61886	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to two or more electrode arrays.
64553	Percutaneous implantation of neurostimulator electrodes; cranial nerve.
64568	Incision for implantation of cranial nerve (e.g., Vagus nerve) Neurostimulator electrode array and pulse generator.
64569	Revision or replacement of cranial nerve (e.g., Vagus nerve) neurostimulator electrode array, including connection to existing pulse generator.
64570	Removal of cranial nerve (e.g., Vagus Nerve) neurostimulator electrode array and pulse generator.
95976	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group(s), interleaving, amplitude, pulse width, frequency(hz), on/of cycling, burse, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple cranial nerve neurostimulator pulse generator/ transmitter programming by physician or other qualified health care professional.
95977	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group(s), Interleaving, amplitude, pulse width, frequency (hz), on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only.
A4630	Replacement batteries, medically necessary, transcutaneous electrical stimulator, owned by patient.

COVERED DIAGNOSIS CODES FOR VAGUS NERVE STIMULATION (61885, 61886, 64553, 64568, 64569, AND 64570)

Codes						
G40.001	G40.009	G40.011	G40.019	G40.101	G40.109	G40.111
G40.119	G40.201	G40.209	G40.211	G40.219	Z45.42	

COVERED DIAGNOSIS CODES FOR PHRENIC NERVE STIMULATION (64575, 64580, 64585, 64590, 64595, L8683, L8689, AND L8696

Codes						
G47.31	G47.34	G47.35	G47.36	G47.37		

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

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POLICY UPDATE HISTORY

12/22/2021	Approved in Medical Policy Committee
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12/28/2022	Annual review; approved in Medical Policy Committee
01/03/2023	Approved in QI/UM