Geisinger

# Geisinger Health Plan Policies and Procedure Manual

**Policy: MP051**

**Section: Medical Benefit Policy**

**Subject: Vagus and Trigeminal Nerve Stimulation**

**Applicable Lines of Business**

| | | | |
|---|---|---|---|
| **Commercial** | **X** | **CHIP** | **X** |
| **Medicare** | **X** | **ACA** | **X** |
| **Medicaid** | **X** | | |

**I. Policy:** Vagus and Trigeminal Nerve Stimulation

**II. Purpose/Objective:**
To provide a policy of coverage regarding Vagus and Trigeminal Nerve Stimulation

**III. Responsibility:**
A. Medical Directors
B. Medical Management

**IV. Required Definitions**

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

**V. Additional Definitions**
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**Medicaid Business Segment**
Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

**DESCRIPTION:**

The vagus nerve (10th cranial nerve) is a mixed nerve carrying both somatic and visceral afferent and efferent signals. The basic premise of vagus nerve stimulation in the treatment of epilepsy is that the vagal visceral afferents have a diffuse central nervous system projection, and activation of these pathways has a widespread effect upon neuronal excitability and synchronization. Besides activation of well-defined reflexes, vagal stimulation produces evoked potentials recorded from the cerebral cortex, hippocampus, thalamus, and the cerebellum. Stimulation of the vagus nerve has been shown to decrease seizure frequency and severity.

Vagus nerve stimulation has also been recently purported to provide some degree of long-term adjunctive benefit in the treatment of chronic or recurrent depression refractory to multiple therapeutic antidepressant treatment modalities.

The vagus nerve stimulation system is comprised of an implantable pulse generator and lead, and an external programming system used to change stimulation settings.

The trigeminal nerve (5th cranial nerve) is responsible for sensation in the face and motor functions such as biting and chewing. It is the largest, and most complex of the cranial nerves. Electrical stimulation of the nerve branch has been used to treat trigeminal neuropathic pain, trigeminal neuralgia, supraorbital neuralgia, postherpetic neuralgia, and other facial pain syndromes. Investigators have also studied the potential of trigeminal nerve stimulation to reduce symptoms of treatment-resistant epilepsy, depression, post-traumatic stress disorder and attention-deficit hyperactivity disorder.

### INDICATIONS: <u>Requires Prior Authorization by a Plan Medical Director or Designee</u>

# For EPILEPSY:

Conventional implantable (open-loop) vagus nerve stimulator, may be considered medically necessary in members with a diagnosis of medically refractory partial-onset seizures*, for which surgery is not recommended or surgery has failed to control the events, and in which pharmacologic therapy has been maximized

*Partial onset seizures are divided into 3 subtypes:

a. <u>Simple partial seizures</u>: No alteration of consciousness, but may exhibit observable motor components, or may be solely a subjective sensory or emotional phenomenon.
b. <u>Complex partial seizures</u>: Involves an alteration of consciousness and may include automatisms, movements and staring, followed by a period of confusion, occasional amnesia and fatigue.
c. <u>Complex partial seizures, secondarily generalized</u>: Partial onset seizures that progress to involve both sides of the brain and result in complete loss of consciousness. These patients may continue on to experience a generalized tonic/clonic seizure. The presence of an aura prior to the generalized seizure, the observation of a focal symptom at the seizure onset, or a postictal focal deficit indicates the focal nature of the seizure.

# For DEPRESSION:

### FOR COMMERCIAL AND MEDICAID BUSINESS SEGMENT:

Consideration for coverage will default to the Behavioral Health department policies and/or applicable behavioral health vendor's policies.

### FOR MEDICARE BUSINESS SEGMENT:

On February 15, 2019 CMS issued an NCD that covers FDA approved vagus nerve stimulation (VNS) devices for treatment resistant depression (TRD) through Coverage with Evidence Development (CED) when offered in a CMS approved, double-blind, randomized, placebo-controlled trial with a follow-up duration of at least one year with the possibility of extending the study to a prospective longitudinal study when the CMS approved, double-blind, randomized placebo-controlled trial has completed enrollment, and there are positive interim findings.

**NOTE: Services related to component reimplantation or replacement in members previously approved for the implantation, or members having had the implantation prior to enrollment in the Plan, and who otherwise meet criteria for coverage, do not require prior authorization**.

## EXCLUSIONS:

At this time, published, peer-reviewed, medical literature to support the long-term efficacy of this treatment for Depression is limited. With the exception of Medicare CED program coverage, the Plan currently considers the use of vagus nerve stimulation in the treatment of recurrent or chronic major depression refractory to multiple maximized antidepressant therapeutic antidepressant treatment modalities to be **experimental, investigational or unproven** and **NOT COVERED.**

The Plan considers the use of Vagus Nerve Stimulation for the treatment of all other conditions, including but not limited to treatment of obesity, heart failure, seizure types other than partial onset, etc. to be **experimental, investigational or unproven and NOT COVERED.**

The Plan considers the use of responsive or "closed-loop" vagus nerve electrical stimulators that utilize the detection and stimulation of heart rate including but not limited to the AspireSR and SenTiva Model 1000 for the treatment of epilepsy to be **experimental, investigational or unproven** and **NOT COVERED**.

The Plan considers the use of vagus nerve electrical stimulators and transcutaneous vagus nerve stimulation (e.g., gammaCore-S®) for the prevention of chronic migraine and/or cluster headache to be **experimental, investigational or unproven** and **NOT COVERED.**

The Plan considers the use of external or transcutaneous (non-implantable) trigeminal nerve stimulation devices (e.g., Monarch® eTNS System, Cefaly®) for the treatment of epilepsy and headache to be **experimental, investigational or unproven** and **NOT COVERED.**

The Plan considers the use of distal transcutaneous electrical peripheral nerve stimulation (e.g., Nerivo), for the treatment of episodic and chronic migraine headache to be **experimental, investigational or unproven** and **NOT COVERED.**

The Plan considers the use of vagus nerve electrical stimulators and transcutaneous vagus nerve stimulation for the treatment of tinnitus to be **experimental, investigational or unproven** and **NOT COVERED.**

## Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in **MP 15 - Experimental Investigational or Unproven Services or Treatment.**

**CODING ASSOCIATED WITH:** Vagus Nerve Stimulation

***The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at*** www.cms.gov ***or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.***

| | |
|---|---|
| 61885 | Incision and subcutaneous placement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array |
| 61886 | with connection to two or more electrode arrays |
| 64553 | percutaneous implantation of neurostimulator electrode array; cranial nerve |
| 64568 | Open implantation of cranial nerve (e.g. vagus nerve) neurostimulator electrode array and pulse generator |
| 64569 | Revision or replacement of cranial nerve (eg. vagus nerve) neurostimulator electrode array, including connection o exsisting pulse generator |
| 64570 | removal of cranial nerve (eg. vagus nerve) neurostimulator electrode array and pulse generator |
| 95970 | Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (i.e., cranial nerve, peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming |
| 95974 | complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or |

subsequent programming, with or without nerve interface testing, first hour
95975 complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour (List separately in addition to code for primary procedure)
C1767 generator neurostimulator (implantable) non-rechargeable
C1778 lead, neurostimulator (implantable)
C1787 patient programmer, neurostimulator
C1816 receiver and/or transmitter, neurostimulator (implantable)
C1820 generator, neurostimulator (implantable), non high-frequency with rechargeable battery and charging system
C1822 generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system
C1897 lead, neurostimulator test kit (implantable)
L8679 implantable neurostimulator, pulse generator any type
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
L8689 external recharging system for battery (internal) for use with implantable neurostimulator, replacement only
K1020 Non-invasive vagus nerve stimulator
K1016 – Transcutaneous electrical nerve stimulator for electrical stimulation of the trigeminal nerve
K1017 – Monthly supplies for use of device coded at K1016
K1023 Distal transcutaneous electrical nerve stimulator, stimulates peripheral nerves of the upper arm (Nerivio)



**LINE OF BUSINESS:**
**Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.**

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This policy will be revised as necessary and reviewed no less than annually**.**

**Devised:** 7/99

**Revised:** 12/01, 02/02 (expanded coverage to members < 12 yrs old); 02/04; 10/05 (added information related to depression); 5/06 (add definition); 11/09; 11/10 (coding); 11/16; 10/17 (added headache exclusion); 10/18; 10/19 (add Medicare CED coverage for depression); 10/21 (Title, add exclusions), 10/22 (add tinnitus exclusion)

**Reviewed:** 02/03; 2/05, 10/07, 10/08, 11/11, 11/12, 11/13, 11/14, 11/15, 10/20, 10/23