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## Subject: Vagus Nerve Stimulation

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### DESCRIPTION:

Stimulation of the [vagus nerve](#) can be performed by means of an implantable stimulator within the carotid artery sheath. This technique has been proposed as a treatment for refractory seizures, depression, and other disorders.

Transcutaneous vagus nerve stimulation (tVNS) has been investigated as a non-invasive alternative to surgery for implantable vagus nerve stimulators. tVNS involves stimulation of superficial branches of the vagus nerve on the ear. Investigators have hypothesized that direct stimulation of the afferent nerve fibers on the ear area with afferent vagus nerve distribution may produce an effect similar to VNS with an implanted stimulator.

Vagus nerve blocking therapy for obesity consists of an implantable device that delivers electrical stimulation to branches of the vagus nerve on the anterior abdominal wall. The intent is to intermittently block signals to the intra-abdominal vagus nerve to disrupt hunger sensations and induce feelings of satiety.

**Summary and Analysis of Evidence:** An UpToDate review titled “Vagus nerve stimulation therapy for the treatment of epilepsy” (Schachter et al) states “In general, vagus nerve stimulation (VNS) therapy is considered a valid treatment option for children and adults with well-documented medically refractory seizures who are opposed to intracranial surgery, are not candidates, or whose medically refractory seizures were not substantially improved by prior intracranial epilepsy surgery. Although there are limited randomized studies in other age groups and seizure types, observational studies reviewed suggest that the benefits of VNS may extend to a broad range of seizure types. The effectiveness of VNS does not appear to vary significantly based on age, neurologic comorbidity, cause of epilepsy, location of the brain from which seizure arise, or epilepsy syndrome. Identification of factors that accurately predict a clinical response to VNS has been elusive. Although VNS is effective for seizures that originate from any lobe of the brain, one study found that seizures arising from the frontal lobes responded better than

seizures arising from the temporal region. Other studies have suggested that VNS may be more effective in patients who have had epilepsy for a shorter period of time and in patients with seizures beginning after one year of age. Earlier age of epilepsy onset is also a predictor of medical intractability. Further studies are needed to identify predictive factors associated with a response to VNS.” An UpToDate review titled “Bipolar disorder in adults: Overview of neuromodulation procedures” (Holtzheimer et al) states “It is not known if VNS is efficacious as adjunctive treatment for bipolar disorder due to the limited and low quality data that are available.” An UpToDate review titled “Cluster headache: Treatment and prognosis” (May et al)” states “Noninvasive vagus nerve stimulation (VNS) may reduce the frequency of cluster headache attacks, but evidence is inconsistent. In an open-label trial of 97 patients with chronic cluster headache, patients assigned to VNS had statistically significant reductions in the number of attacks per week compared with those assigned to medical treatment. However, a double-blind, randomized trial of 92 subjects with episodic or chronic cluster headache found no difference between noninvasive VNS and sham stimulation in the proportion of treated attacks achieving pain-free status within 15 minutes of treatment initiation.” Dawson et al (2021) reported on the Pivotal Study of VNS During Rehab After Stroke (VNS-REHAB) trial and stated “The results of this trial support the use of VNS paired with rehabilitation for the treatment of selected people with upper limb impairment at least 9 months after ischaemic stroke. Further research should explore how to implement this approach in clinical practice and whether VNS can be used to improve other impairments after stroke, including more severe degrees of arm impairment.”

## **POSITION STATEMENT:**

Vagus nerve stimulation **meets the definition of medical necessity** as a treatment of medically refractory seizures, defined as seizures that occur despite therapeutic levels of antiepileptic drugs or seizures that cannot be treated with therapeutic levels of antiepileptic drugs, because of intolerable adverse events of these drugs.

The available scientific evidence does not support conclusions regarding the effectiveness of vagus nerve stimulation for all other indications. Vagus nerve stimulation is considered **experimental or investigational** for all other conditions, including but not limited to the following:

- Depression
- Heart failure
- Upper limb impairment due to stroke
- Essential tremor
- Headache
- Fibromyalgia
- Tinnitus
- Traumatic brain injury

Intra-abdominal vagus nerve blocking therapy is considered **experimental or investigational** for all indications, including but not limited to the treatment of obesity. Data in published medical literature are inadequate to permit scientific conclusions on long-term and net health outcomes.

The use of **transcutaneous vagus nerve stimulation (tVNS)** (nonimplantable vagus nerve stimulation device) (e.g., Stivax, GammaCore, and Gammacore Sapphire stimulators) is considered **experimental or investigational** for the treatment of any condition, as there is insufficient clinical evidence to permit conclusions on net health outcomes.

## BILLING/CODING INFORMATION:

### CPT Coding:

|       |   |
|-------|---|
| 61885 | Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct <b>OR</b> inductive coupling; with connection to a single electrode array   |
| 61886 | Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct <b>OR</b> inductive coupling; with connection to 2 or more electrode arrays |
| 64553 | Percutaneous implantation of neurostimulator electrode array; cranial nerve   |
| 64568 | Open implantation of cranial nerve (eg, 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  |

### HCPCS Coding:

|       |  |
|-------|--|
| E0735 | Non-invasive vagus nerve stimulator ( <b>investigational</b> ) |
|-------|--|

## REIMBURSEMENT INFORMATION:

Refer to sections entitled [POSITION STATEMENT](#) and [PROGRAM EXCEPTIONS](#).

### PROGRAM EXCEPTIONS:

**Federal Employee Program (FEP):** Follow FEP guidelines.

**State Account Organization (SAO):** Follow SAO guidelines.

**Medicare Advantage Products:** The following National Coverage Determination (NCD) was reviewed on the last guideline reviewed date: VAGUS Nerve Stimulation (VNS) (160.18) located at cms.gov.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at [Coverage Protocol Exemption Request](#).

### DEFINITIONS:

**Epilepsy:** recurrent, unprovoked paroxysmal transient disturbances of brain function that may be manifested as episodic impairment or loss of consciousness, abnormal motor phenomena, psychic or sensory disturbances, or perturbation of the autonomic nervous system.

**Seizure:** a transient disturbance of cerebral function due to an abnormal paroxysmal neuronal discharge in the brain.

**Vagus nerve (nervus vagus):** tenth cranial nerve; supplies sensory fibers to the ear, tongue, pharynx, and larynx, motor fibers to the pharynx, larynx, and esophagus, and parasympathetic and visceral afferent fibers to thoracic and abdominal viscera.

## RELATED GUIDELINES:

[Gastric Electrical Stimulation, 01-91000-04](#)

## OTHER:

None applicable.

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## COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 01/25/24.

## GUIDELINE UPDATE INFORMATION:

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| 06/15/00 | New Medical Coverage Guideline.  |
| 08/23/01 | Review of guideline with no revisions.   |
| 06/15/02 | Revised to delete age limitation.  |
| 06/15/03 | Review of guideline with no changes in coverage.   |
| 06/15/04 | Review and revision of guideline; consisting of updated references.                          |
| 01/01/05 | Annual HCPCS update; consisting of the revision of 61885, 61886 and 64590.                   |
| 04/15/05 | Review and revision of guideline; consisting of updated references.                          |
| 04/15/06 | Review and revision of guideline consisting of updated references.                           |
| 01/01/07 | HCPCS coding update consisting of the revision of 64590 and 64595.                           |
| 06/15/07 | Review and revision of guideline consisting of updated references and reformatted guideline. |
| 04/15/08 | Review and revision of guideline consisting of updated references.                           |
| 06/15/09 | Scheduled review; no change to position statement. Update references.                        |
| 01/01/10 | Annual HCPCS coding review: revise descriptor for CPT code 61886.                            |
| 06/15/10 | Biennial review; no change in position statement. References updated.                        |

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| 01/01/11 | Annual HCPCS coding update. Added codes 64568, 64569 and 64570; deleted code 64573.   |
| 01/01/12 | Annual HCPCS coding update. Revised 64553, 95974 and 95975 descriptors.   |
| 06/15/12 | Scheduled review. Revised description section and position statement (added additional indications which are considered experimental/investigational); revised Medicare Advantage program exception and updated references. |
| 01/01/13 | Annual CPT coding update. Added codes 0312T, 0313T, 0314T, 0315T, 0316T and 0317T.  |
| 06/15/13 | Scheduled review. Revised description, position statement and program exceptions section. Updated references and reformatted guideline.   |
| 11/15/17 | Unscheduled review. Maintained position statement. Revised CPT coding and program exceptions section. Updated references and reformatted guideline.   |
| 01/01/18 | Annual CPT/HCPCS coding update: revised 64550.  |
| 01/01/19 | Annual CPT/HCPCS coding update. Deleted 64550, 95974, 95975.  |
| 03/15/20 | Scheduled review. Revised description and position statement. Updated references.   |
| 04/01/21 | Quarterly CPT/HCPCS coding update. Added code K1020.  |
| 01/01/21 | Annual CPT/HCPCS coding update. Revised descriptor 64568.   |
| 02/15/22 | Scheduled review. Maintained position statement and updated references.   |
| 01/01/23 | Annual CPT/HCPCS coding update. Deleted 0312T, 0313T, 0314T, 0315T, 0316T, 0317T.   |
| 02/15/23 | Revision. Updated references and maintained position statement.   |
| 05/25/23 | Update to Program Exceptions section.   |
| 01/01/24 | Annual CPT/HCPCS coding update. Added E0735; deleted K1020.   |
| 02/15/24 | Scheduled review. Revised description, maintain position statements, and updated references.  |