

## OHCA Guideline

<b>Medical Procedure Class:</b>	<b>Vagal Nerve Stimulator</b>
Initial Implementation Date:	September 6, 2006
Last Review Date:	May 2021
Effective Date:	September 2021
Next Review/Revision Date:	September 2024
* This document is not a contract, and these guidelines do not reflect or represent every conceivable situation. Although all items contained in these guidelines may be met, this does not reflect, or imply, any responsibility of this agency or department to change the plan provision to include the stated service as an eligible benefit.	
<input type="checkbox"/> New Criteria <span style="float: right;"><input checked="" type="checkbox"/> Revision of Existing Criteria</span>	
<b>Summary</b>	
<b>Purpose:</b>	To provide guidelines to assure medical necessity and consistency in the prior authorization process.
<b>Definitions</b>	
<p><b>Seizures:</b> paroxysmal disorders of the central nervous system characterized by abnormal cerebral neuronal discharge, with or without a loss of consciousness. Seizures have been further sub classified as generalized onset, beginning throughout the brain, and focal onset, can start in one area or group of cells in one side of the brain.</p> <p><b>Focal (formerly known as Partial) Onset Seizures:</b> can start in one area or group of cells in one side of the brain. These seizures fall into two categories: Focal Onset Aware Seizures and Focal Onset Impaired Awareness.</p> <p><b>Generalized Onset Seizures:</b> often occur in all parts of the brain simultaneously and have no identifiable focus. The source of a generalized seizure can be difficult to detect as many of them start and spread quickly. With the often unidentifiable source, surgery is not an option for treatment. Some examples of generalized seizures are absence seizures, myoclonic, clonic, tonic, tonic-clonic, and atonic.</p>	
<b>Description</b>	
<p><b>Vagal Nerve Stimulator (VNS)</b> is an implantable pacemaker type device designed to prevent seizures by sending regular mild pulses of electrical energy to the brain via the vagus nerve. The device is placed under the skin on the chest wall and a wire runs from the device to the vagus nerve in the neck.</p>	
<b>CPT Codes Covered Requiring Prior Authorization (PA)</b>	
<p><b>64568</b> – Incision for implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator</p> <p><b>64585</b> – Revision or removal of peripheral neurostimulator electrode array</p> <p><b>95970</b> – 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 brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming</p>	

**95971** – with simple spinal cord or peripheral nerve (e.g., sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional

**95972** – with complex spinal cord or peripheral nerve (e.g., sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional

**95976** – with simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional

**95977** – with complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional.

### Approval Criteria

#### INDICATIONS

Vagal Nerve Stimulator is considered medically necessary for shortening the duration or reducing the severity of seizures in members with Focal (partial) onset seizures or Generalized seizures that remain refractory to optimal AED's and/or surgical intervention (secondary generalization is not a contraindication of coverage).

1. Objective documentation supports the diagnosis of medically refractory Focal (partial) onset seizures or medically refractory Generalized seizures.
2. An attempt of three or more antiepileptic drugs (AEDs) must be documented as unresponsive or intolerant.
3. Member must have documentation of three to four identifiable Focal (partial) onset or seizures each month and be diagnosed with intractable epilepsy for a period of at least 6 months **or**:
4. Member must have documentation of greater than three per week identifiable generalized seizures and be diagnosed with intractable epilepsy for a period of at least 6 months.
5. VNS recipients must not be candidates for epilepsy surgery. If both VNS and epilepsy surgery are concurrent options, documentation from the treating physician must detail why VNS is the preferred mode of therapy.
6. The implantation of a VNS must improve the quality of life and there must be a recommendation from the treating physician indicating this expectation.
7. Mental impairment is not a contraindication however, intellectual disabilities may obscure recognition of seizure phenomena. Intellectual disabilities may detract from the ability to recognize any potential benefits resulting from VNS. Therefore, when a diagnosis of Intellectual Disability exists and VNS is being considered, the treating physician must specify how VNS will benefit the recipient.

Removal and replacement of the Vagal Nerve Stimulator is considered medically necessary when the following criteria are met:

1. If the device malfunctions, breaks, or becomes infected; **AND**
2. If the medical necessity criteria continue to be met; **AND**
3. If replacement is not part of the manufacturer warranty.

#### DOCUMENTATION REQUIREMENTS

Required documents with the Prior Authorization request are:

1. Letter of Medical Necessity (LMN) completed by requesting physician (contracted with OHCA). The LMN must provide objective data indicating a diagnosis of medically

refractory Focal (partial) onset or Generalized seizures including a monthly log of the frequency and type of identifiable seizures. Anticipated benefits and goals of the implantation of the VNS should be detailed in the LMN.

2. History and Physical documenting a neurological history, recent examination and supportive documentation of neurological symptoms. History should also include any failed surgical procedure for the diagnosis of epilepsy or any evidence contraindicating surgical intervention (e.g. multi-focal seizures, non-resectable foci or no identified structural abnormality).
3. Documentation of having a body mass that is supportive of VNS implantation.
4. EEG and any other study reports should be submitted to clearly support the request including video EEG or seizure activity when manifestation can be otherwise considered non-epileptic in origin.
5. Documentation of all AEDs attempted (three or more) and failed; including duration, dosage/any adjustments and the response to all AEDs prescribed.
6. A listing of the current medication regimen.
7. Documentation of failed epilepsy surgical procedures or evidence contraindicating surgical intervention. If both VNS and surgical intervention are recommended a letter from the physician must be submitted detailing why VNS is the preferred mode of therapy.
8. Statement of the absence of disorders that would render the use of this therapy as contraindicated.
9. Members aged 3-12 years must have a written recommendation from a Board of Certified Pediatric Neurologist skilled in VNS implantation prior to being considered for the procedure.
10. Documentation indicating parent/caretaker/guardian understands the follow-up requirements and all potential side effects and/or complications of the procedure, and is committed to the long range treatment plan.
11. A detailed listing of all anticipated billing codes that will be associated with the procedure.

#### References

1. Oklahoma Health Care Authority; Policies & Rules, OAC 317: 30-3-1; 317:30-3-65.5; 317:30-5, Part 17.
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3. Neurology Journal of the American Academy of Neurology: Evidence Based GL update: VN stimulation for the treatment of epilepsy: Report of the Guideline Development Subcommittee of the American Academy of Neurology. (2013). Retrieved from [https://www.aesnet.org/docs/default-source/pdfs-clinical/neurology-2013-morris-1453-9.pdf?sfvrsn=aaaad07\\_2](https://www.aesnet.org/docs/default-source/pdfs-clinical/neurology-2013-morris-1453-9.pdf?sfvrsn=aaaad07_2)
4. Aetna. (2021). *Vagus Nerve Stimulation Policy #0191*. Retrieved from [http://www.aetna.com/cpb/medical/data/100\\_199/0191.html](http://www.aetna.com/cpb/medical/data/100_199/0191.html)
5. BCBS NC. (2020). *Vagus Nerve Stimulation Policy*. Retrieved from <https://www.bluecrossnc.com/providers/medical-policies-and-coverage/search-medical-policy/medical-guidelines-alphabetical-index>
6. John Hopkins Medicine. (2021). *Epilepsy*. Retrieved from <https://www.hopkinsmedicine.org/health/conditions-and-diseases/epilepsy>
7. International League Against Epilepsy. (2017). *New ILAE Seizure Classification*. Retrieved from <https://www.ilae.org/news-and-media/news-about-ilae/new-ilae-seizure-classification>
8. American Medical Association. (2020). *CPT 2021 Professional Edition*. Chicago, IL