

## Clinical Policy: Vagus Nerve Stimulation

Reference Number: CP.MP.12

Last Review Date: 08/20

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### Description

Vagus nerve stimulation (VNS) has been used in the treatment of epilepsy and has been studied for the treatment of refractory depression and other indications. Electrical pulses are delivered to the cervical portion of the vagus nerve by an implantable device called a neurocybernetic prosthesis. Chronic intermittent electrical stimulation of the left vagus nerve is designed to treat medically refractory epilepsy. It has recently been introduced and approved by the FDA as an adjunctive therapy for treatment-resistant major depression.

### Policy/Criteria

- I. It is the policy of health plans affiliated with Centene Corporation® that VNS is **medically necessary** in patients with medically refractory seizures who meet all of the following:
  - A. Diagnosis of focal onset (formerly partial onset) seizures or generalized onset seizures;
  - B. Intractable epilepsy (both):
    1. Failure of at least 1 year of adherent therapy of at least two anti-seizure drugs, *and*
    2. Continued seizures which have a major impact on activities of daily living; *and*
  - C. Not a suitable candidate for or has failed resective epilepsy surgery;
  - D. Request is for an FDA-approved device.
  
- II. It is the policy of health Plans affiliated with Centene Corporation that VNS therapy is considered **investigational** for any other conditions, including but not limited to the following, because the evidence is limited supporting its safety and efficacy:
  - A. Refractory (treatment resistant) major depression or bipolar disorder;
  - B. Obesity;
  - C. Headaches;
  - D. Cognitive impairment associated with Alzheimer's disease;
  - E. Addiction;
  - F. Anxiety Disorders;
  - G. Autism;
  - H. Eating Disorders;
  - I. Cancer;
  - J. Crohn's Disease;
  - K. Essential trauma;
  - L. Fibromyalgia;
  - M. Heart failure;
  - N. Impaired glucose tolerance/pre-diabetes;
  - O. Inflammation;
  - P. Overweight and obesity;
  - Q. Obsessive-compulsive disorder;
  - R. Panic disorder;
  - S. Post-traumatic stress disorder;

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- T. Prader-Willi Syndrome;
- U. Sjogren's Syndrome;
- V. Rheumatoid arthritis;
- W. Schizophrenia;
- X. Sleep disorders;
- Y. Stroke;
- Z. Tinnitus;
- AA. Tourette's syndrome;
- BB. Traumatic brain injury.

**III.** It is the policy of health plans affiliated with Centene Corporation that the following types of VNS therapy are considered **investigational** due to the lack of large, high-quality studies supporting their use:

- A. Aspire SR Model 106 (Cyberonics) for vagus nerve stimulation;
- B. Transcutaneous VNS or active auricular transcutaneous electrical nerve stimulation.

#### *Removal of Implant*

Less than 0.5 percent of all patients have had the device removed. It can be turned off in the physician's office if the patient feels it is not helping or if the patient cannot tolerate the stimulation. If the device needs to be removed, only the pulse generator is removed, as attempting to remove the electrodes from around the nerve can cause damage and is not recommended.

#### **Background**

The vagus nerve stimulator is a pacemaker-like device implanted under the skin in the left side of the chest through a small incision, with a second small incision made at the base of the neck. The surgery is performed under local, regional, or general anesthesia and lasts 45 minutes to two hours. Most often, it is performed as an outpatient surgery but some patients need to stay in the hospital overnight following surgery.

#### *Focal (partial) seizures*

Several studies have been done evaluating the safety and effectiveness of vagus nerve stimulation for treatment of epilepsy. A randomized active-control trial known as the E05 study found that 94 patients (of the total 254 patients in the study) receiving high stimulation showed an average reduction in seizure frequency, compared to baseline, of 28% versus 15% reduction in the 102 patients receiving low stimulation. A total of 310 patients completed the E03 and E05 double-blinded trials. Mean decline of seizure frequency overall was about 25-30% compared to baseline. Clinical experience has shown that improvement in seizures is maintained, or may even increase over time, but these data are based on uncontrolled observations. Side effects in both studies were similar and included hoarseness and occasional shortness of breath.

Although questions regarding patient selection criteria, optimal stimulation parameters, and cost-effectiveness in the United States remain under investigation, there is sufficient evidence regarding the benefit and safety of VNS to conclude that VNS may improve health outcomes in

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patients with medically refractory focal-onset seizures who are not suitable candidates for surgery or in whom surgical treatment has failed.

#### *Generalized seizures*

Study results suggest VNS may be effective for generalized epilepsy (Karceski & Schachter, 2015). However, case series and observational studies constitute the majority of available evidence. Although VNS is not currently FDA approved for the treatment of generalized seizures, it is often used in children and other patients, and in Europe is approved as adjunct therapy for epileptic disorders predominantly characterized by generalized or focal seizures that are refractory to antiseizure medications. In addition, the National Institute for Health and Care Excellence (NICE) recommends VNS for focal and generalized seizures, and the Scottish Intercollegiate Guidelines Network (SIGN) guidelines recommend VNS for epilepsy in patients unsuitable for respective surgery without stipulating seizure type.

#### *Depression*

VNS was FDA-approved for treatment resistant depression in 2005. However, VNS has no rigorous research data proving it is efficacious for treatment-resistant, unipolar major depression. Open-label studies suggest VNS may be effective; however, these are at risk for bias due to placebo effects. The one randomized trial of VNS for depression found no benefit, with outcomes comparable for active and sham treatment (response rates of 15 vs. 10 percent). In addition, there is a lack of thorough safety data for the use of VNS in depression.

#### *Other Investigational Indications*

Ongoing research efforts continue to investigate the role of vagus nerve stimulation (VNS) for a the treatment of a variety of indications, including but not limited to cognitive deficits in Alzheimer's disease, resistant obesity, and headaches. Data supporting the long-term safety and efficacy from large clinical trials of VNS for the treatment of these indications, however, continue to be lacking.

#### *AspireSR Model 106 (Cyberonics) for Vagus Nerve Stimulation*

The AspireSR Model 106 (Cyberonics Inc.) received FDA Premarket Approval (PMA) in February 2014. The newest modification to the implantable VNS device detects tachycardia heart rates, which may be associated with an impending seizure, and automatically delivers stimulation to the vagus nerve. Like its predecessors, the AspireSR can also deliver stimulation in the normal and magnet modes. However, when programmed for AutoStim mode, the AspireSR requires no patient interaction to trigger the delivery of electrical stimulation. The AutoStim mode should not be used in patients with significant arrhythmias being treated with pacemakers and/or an implantable defibrillator, beta-blockers, or any other treatment that may impact the intrinsic heart rate.

A few small, preliminary studies and case reports have evaluated the AspireSR Model 106, and have shown positive results (Boon et al., 2015; Fisher et al., 2015; Schneider et al., 2015; Hampel et al, 2015). However, there is insufficient evidence to establish the safety and efficacy of the AspireSR Model 106 in reducing seizures until further, high quality trials establish its clinical value.

*Transcutaneous (non-implantable) Vagus Nerve Stimulation*

Transcutaneous vagus nerve stimulation (tVNS) has been proposed as a noninvasive alternative to implantable VNS for a variety of indications, including, but not limited to epilepsy, major depression, chronic tinnitus and headaches. Currently, there are two main ways to apply tVNS. One is to apply stimulation on the ear and the other is cervical noninvasive VNS, superficially applying stimulation in the vicinity of the vagus nerve using a specially designed device, (e.g. gammaCore). Noninvasive auricular tVNS stimulates the afferent auricular branch of the vagus nerve located medial of the tragus at the entry of the acoustic meatus. Given that the right vagal nerve has efferent fibers to the heart, tVNS is safe to be performed only in the left ear. tVNS has been proposed to study cognitive functioning in patients with epilepsy and major depression. The rationale is that direct stimulation of the afferent nerve fibers on the ear area with afferent vagus nerve distribution should produce a similar effect as classic VNS in reducing depressive symptoms without the burden of surgical intervention. A noninvasive, transcutaneous vagal nerve stimulator has been in use in Europe. Although no randomized studies have been done in patients with epilepsy, it appears promising in one pilot study.<sup>18</sup> Small studies have shown positive results with tVNS for the treatment of depression (Hein et al, 2013; Fang et al, 2016). Additional, larger, peer-reviewed studies, with longer follow-up are necessary to determine the long-term safety and efficacy of transcutaneous VNS for depression.

gammaCore Sapphire™ (ElectroCore, LLC), is a hand-held prescription device that is placed externally on the side of the neck in the vicinity of the vagus nerve to deliver a low voltage electric signal to the nerve's afferent fibers. gammaCore has received FDA approval for the treatment of both episodic cluster and migraine headaches and more recently for the prevention of cluster headaches (CH). gammaCore delivers up to 30 stimulations in a 24-hour period, each lasting 2 minutes. The patient controls the intensity level. Once the maximum daily number of treatments has been reached, the device will not deliver any more treatments until the following 24-hour period. gammaCore is rechargeable and includes a charging case to charge the device. A gammaCore refill card is used to load the device with days of therapy based on a healthcare provider's prescription.

In the randomized PRESTO study, noninvasive vagus nerve stimulation (nVNS.) was superior to sham in the treatment of episodic migraine for pain freedom at 30 minutes and 60 minutes after the first treated attack.<sup>29</sup> In both the ACT1 and ACT2 trials, nVNS was superior to sham therapy in episodic CH but not in chronic CH.<sup>31,32</sup> Preliminary clinical trials of nVNS in various primary headache disorders are encouraging, however, well-designed randomized controlled trials with larger sample size and long-term follow-up regarding safety and benefit is warranted. In addition, patient selection criteria needs to be defined.

The American Headache Society position statement on integrating new migraine treatments into clinical practice note that empirically validated behavioral treatments with Grade A evidence for the prevention of migraine, including cognitive behavioral therapy, biofeedback, and relaxation therapies, should be considered in the management of migraine. These modalities may also be used alone or in addition to pharmacologic treatment. They note further that several noninvasive devices have been developed and approved by the FDA for the treatment of patients with migraine.(i.e., single-pulse transcranial magnetic stimulation, electrical trigeminal nerve stimulation and nVNS.) Patients who prefer nondrug therapies and those who have failed to

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respond to, have contraindications to, or poor tolerability with pharmacotherapy may be candidates for neuromodulation.<sup>33</sup>

Per UpToDate, “There are several promising but unproven methods using neurostimulation to treat medically refractory cluster headache, including sphenopalatine ganglion stimulation, occipital nerve stimulation, noninvasive VNS, and deep brain stimulation. All are investigational and require further study to confirm long-term benefit and safety.”

**Coding Implications**

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| <b>CPT® Codes</b> | <b>Description</b>   |
|-------------------|--|
| 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 |
| 61888             | Revision or removal of cranial neurostimulator pulse generator or receiver   |
| 64553             | Percutaneous implantation of neurostimulator electrodes; cranial nerve   |
| 64568             | Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator   |
| 64569             | Revision or replacement of cranial nerve (eg, vagus nerve) neurostimulator electrode array, including connection to existing pulse generator                   |
| 64570             | Removal of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator   |

| <b>HCPCS Codes</b> | <b>Description</b>  |
|--------------------|---|
| C1767              | Generator, neurostimulator (implantable), nonrechargeable   |
| C1778              | Lead, neurostimulator (implantable)   |
| C1816              | Receiver and/or transmitter, neurostimulator (implantable)  |
| C1883              | Adaptor/extension, pacing lead or neurostimulator lead (implantable)  |
| 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                |

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| HCPCS Codes | Description  |
|-------------|--|
| 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 implanted neurostimulator, replacement only |

**ICD-10-CM Diagnosis Codes that Support Coverage Criteria**

| ICD-10-CM Code | Description  |
|----------------|--|
| G40.011        | Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, with status epilepticus    |
| G40.019        | Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, without status epilepticus |
| G40.111        | Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, with status epilepticus       |
| G40.119        | Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, without status epilepticus    |
| G40.211        | Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, with status epilepticus      |
| G40.219        | Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, without status epilepticus   |
| G40.311        | Generalized idiopathic epilepsy and epileptic syndromes, intractable, with status epilepticus  |
| G40.319        | Generalized idiopathic epilepsy and epileptic syndromes, intractable, without status epilepticus   |
| G40.A11        | Absence epileptic syndrome, intractable, with status epilepticus   |
| G40.A19        | Absence epileptic syndrome, intractable, without status epilepticus  |
| G40.411        | Other generalized epilepsy and epileptic syndromes, intractable, with status epilepticus   |
| G40.419        | Other generalized epilepsy and epileptic syndromes, intractable, without status epilepticus  |
| G40.803        | Other epilepsy, intractable, with status epilepticus   |
| G40.804        | Other epilepsy, intractable, without status epilepticus  |

| ICD-10-CM Code | Description  |
|----------------|--|
| G40.813        | Lennox-Gastaut syndrome, intractable, with status epilepticus    |
| G40.814        | Lennox-Gastaut syndrome, intractable, without status epilepticus |

| Reviews, Revisions, and Approvals  | Date  | Approval Date |
|--|-------|---------------|
| Deleted age criteria; background updated   | 09/13 | 10/13         |
| Reviewed and references and coding updated   | 09/14 | 10/14         |
| Combined with VNS for depression policy<br>Added bipolar disorder to not medically necessary list<br>Converted into new template, added ICD-10 codes   | 10/15 | 10/15         |
| Added generalized seizures as medically necessary. Removed requirement for 4-6 seizures per month. Added requirement that VNS be performed with a FDA approved device. Changed depression and bipolar disorder to investigational, and also added obesity, headaches, cognitive impairment due to Alzheimer's, transcutaneous VNS/auricular transcutaneous electrical nerve stimulation, and AspireSR Model 106 as investigational. Added supporting background information. | 09/16 | 10/16         |
| Changed II. to apply to the listed conditions as well as others that were not mentioned. Coding updates. References reviewed and updated.  | 10/17 | 10/17         |
| Changed "partial onset" to "focal onset" throughout to reflect seizure classification changes made by the International League Against Epilepsy in 2017. References reviewed and updated.  | 08/18 | 08/18         |
| Updated background with additional information on non-implantable VNS  | 01/19 |               |
| References reviewed and updated. Added CPT code-61888. Added ICD-10 code, G40.311 Specialist review.   | 07/19 | 08/19         |
| Added additional investigational indications for VNS to section II. References reviewed and updated. Removed ICD-10 Codes: G40.001, G40.009, G40.201, G40.209, G40.309, G40.A09, G40.409, G40.509, G40.802, G40.909, G40.911 and G40.919. Added ICD-10: G40.813, G40.814.  | 07/20 | 08/20         |

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### **Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

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**Note: For Medicaid members,** when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

**Note: For Medicare members,** to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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