STATE OF IOWA DEPARTMENT OF
Health AND Human
SERVICES

# Vagus Nerve Stimulator
## SRG-018

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| **Iowa Medicaid Program:** | Prior Authorization | **Effective Date:** | 1/21/2011 |
| **Revision Number:** | 8 | **Last Rev Date:** | 4/19/2024 |
| **Reviewed By:** | Medicaid Medical Director | **Next Rev Date:** | 4/18/2025 |
| **Approved By:** | Medicaid Clinical Advisory Committee | **Approved Date:** | 6/4/2018 |

## Descriptive Narrative

Anticonvulsant medications are the frontline treatment for patients with seizures. However, in approximately one-third of people, medications alone do not achieve complete control. The seizures that occur in these patients are referred to as refractory or drug resistant. Nonpharmacologic options are an important component of the overall therapeutic approach to refractory seizures.

In general, vagus nerve stimulation (VNS) is considered a valid treatment option for children and adults with well-documented medically refractory seizures, including those with Lennox-Gastaut Syndrome (LGS), who are opposed to intracranial surgery, are not candidates, or whose medically refractory seizures were not substantially improved by prior intracranial epilepsy surgery.

The FDA has approved VNS therapy as adjunctive treatment for patients 4 years of age and older with focal seizures that are refractory to antiseizure medications.

Vagus nerve stimulator is a battery-powered device like a cardiac pacemaker. In most models, stimulating leads are surgically placed around the left vagus nerve in the carotid sheath and are connected to an infraclavicular subcutaneous programmable pacemaker. Impulses from the generator are transmitted up the vagus nerve to the brain. VNS is an established option for medication refractory seizures. Because the right vagus nerve provides more innervation to the cardiac atria than the left vagus nerve, electrical stimulation of the left vagus nerve is generally preferred in clinical practice to avoid adverse cardiac effects. The precise mechanisms by which VNS therapy achieves seizure reduction are not well established.

The acute efficacy of VNS for treatment-resistant major depression has not been demonstrated in rigorous studies.

## Criteria

Prior authorization is required.

Implantation of a VNS is considered medically necessary when **ALL** the following are met:

1. Diagnosis of drug resistant epilepsy defined as failure of adequate trials of two tolerated, appropriately chosen and used antiepileptic drug schedules (whether as monotherapies or in combination) to achieve sustained seizure freedom; **AND**
2. Surgery considered or performed and **ONE** of the following:
   a. Surgery failed to control seizures; **OR**
   b. Member is not a candidate for surgery; **OR**
   c. Member refuses surgery as a treatment.

Replacement or revision of an implanted neurostimulator pulse generator system (with or without lead changes) is considered medically necessary when the original criteria have been met and the current implanted device is no longer functioning appropriately.

## Contraindications

Baseline cardiac conduction disorders are generally considered a contraindication to VNS therapy, given the potential for efferent conduction through the vagus nerve, particularly on the right, to worsen cardiac conduction abnormalities.

Sleep apnea is a relative contraindication for VNS. Prior to VNS implantation, possible sleep apnea-related symptoms and physical signs should be sought on history and physical examination, and if found, should be pursued by testing to determine whether the patient does have clinically significant sleep apnea.

There are reports that programmable shunt valves can be affected by use of the VNS magnet. VNS using a magnet should probably be avoided in individuals with programmable shunts.

## Side Effects

The most common side effects of VNS include:

1. Voice alteration (such as hoarseness), throat pain, coughing shortness of breath, tingling or muscle pain;
2. Surgical site infection;
3. Bradycardia;
4. Vocal cord paralysis;
5. Aspiration;
6. Sleep apnea.

## Investigational

Use of VNS as treatment for the following conditions is considered investigational/not proven:

1. Behavioral health disorders, including refractory/treatment resistant depression, bipolar disorder, schizophrenia, OCD, addiction, or eating disorders;
2. Inflammatory conditions such as Crohn's disease, Sjogren's syndrome, or rheumatoid arthritis;
3. Genetic disorders such as Prader-Willi syndrome;
4. Neurologic disorders such as tremors, headaches, Tourette's syndrome, or cognitive impairment due to Alzheimer's dementia;
5. Brain injuries such as cerebral palsy, TBI, or stroke rehabilitation;
6. Autism;
7. Cancer;
8. Fibromyalgia;
9. Heart failure;
10. Obesity.

## Coding

The following list(s) of codes are provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS/CPT code is inappropriate.

| HCPCS | Description |
|---|---|
| 61885 | Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array. |
| 64568 | Open implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator. |

## Compliance

1. Should conflict exist between this policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual and as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

## References

EncoderPro.

Milliman Care Guidelines 27th Edition.

Holtzheimer P. Unipolar depression in adults: Overview of neuromodulation procedures. UpToDate. Topic last updated: August 23, 2023.

Schachter C. Sirven JI. Vagus nerve stimulation therapy for the treatment of epilepsy. UpToDate. Topic last updated: January 30, 2024.

American Academy of Neurology: Evidence-based guideline on vagus nerve stimulation for the treatment of epilepsy, update (2013, reaffirmed 2022).
National Institute for Health and Care Excellence (NICE): Quality standard on epilepsies in children, young people, and adults (2023).

Epilepsy and Seizures. National Institute of Neurological Disorders and Stroke. Last reviewed November 28, 2023.

Health Technology Assessment. Vagus nerve stimulation for treatment-resistant depression. Hayes. Published February 21, 2019 (annual review January 26, 2022).

Vagus Nerve Stimulation. CMS. National Coverage Determination 160.18. Implementation date July 22, 2020.

Kwan P, et al. Definition of drug resistant epilepsy: consensus proposal by the ad hoc Task Force of the ILAE Commission on Therapeutic Strategies. Epilepsia 2010;51(6):1069-1077. DOI: 10.1111/j.1528-1167.2009.02397.x (reaffirmed 2022 July).

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

## Criteria Change History

| Change Date | Changed By | Description of Change | Version |
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**Signature**

| Change Date | Changed By | Description of Change | Version |
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| Change Date | Changed By | Description of Change | Version |
|---|---|---|---|
| 4/19/2024 | CAC | Annual review. Rewritten Descriptive Narrative and Criteria. Added Contraindications and Side Effects sections. Updated References. | 8 |

**Signature**
William (Bill) Jagiello, DO 

| Change Date | Changed By | Description of Change | Version |
|---|---|---|---|
| 4/21/2023 | CAC | Annual review. | 7 |

**Signature**
William (Bill) Jagiello, DO 

| Change Date | Changed By | Description of Change | Version |
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| 4/15/2022 | CAC | Annual review. | 6 |

**Signature**
William (Bill) Jagiello, DO 

| Change Date | Changed By | Description of Change | Version |
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| 4/16/2021 | CAC | Annual review. Minor formatting changes. | 5 |

**Signature**
William (Bill) Jagiello, DO 

| Change Date | Changed By | Description of Change | Version |
|---|---|---|---|
| 4/20/2018 | CAC | Deleted criteria #2 and #3. Added new criterion #2. Added picture diagram. Added References. | 4 |

**Signature**
C. David Smith, MD 

| Change Date | Changed By | Description of Change | Version |
|---|---|---|---|
| 4/21/2017 | CAC | Criterion #1 removed "surgical". Added criteria # 2, #3, and #4. | 3 |

**Signature**

| Change Date | Changed By | Description of Change | Version |
|---|---|---|---|
| 4/17/2015 | CAC | Criterion #1 removed "all" from intolerance to approved surgical and pharmaceutical management. Added paragraph in References. | 2 |

**Signature**

| Change Date | Changed By | Description of Change | Version |
|---|---|---|---|
| 10/19/2012 | CAC | Criterion #1 removed "to all suitable medical" and changed to "to all approved surgical …". | 1 |

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