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RMHP Physical Health Vagus Nerve Stimulation, Implantable

MCG Health
Ambulatory
Care
27th Edition

AUTH: RMHP-A-042427 (AC)

Link to Codes

Clinical Indications for Procedure

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NOTE: For **Behavioral Health** VNS addressing treatment resistant depression (TRD), use guideline RMHP-B-821-T, RMHP Vagus Nerve Stimulation, Implantable (VNS) in the MCG Behavioral Health Care (BHG section).

For **Medicare (CareAdvantage or DSNP Dual Special Needs Plan)** coverage **,** follow NCD 160.18 Vagus Nerve Stimulation (VNS), which states medical "VNS is reasonable and necessary for patients with medically refractory partial onset seizures for whom surgery is not recommended or for whom surgery has failed." See References.

- For **RMHP PRIME (Medicaid), CHP+ or Individual and Family Plan (IFP)** coverage, implantable vagus nerve stimulation may be indicated for **ALL** of the following(1)(2)(3)(4) :
  - Epilepsy that is refractory to anticonvulsant drug treatment [A] (6)(7)(8)
  - No history of left or bilateral vagotomy
  - Surgery considered or performed and **1 or more** of the following(9):
    - Epilepsy refractory to surgery(6)(10)
    - Patient not suitable candidate for epilepsy surgery
    - Patient refused epilepsy surgery.

Alternatives to Procedure

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- Alternatives for epilepsy include anticonvulsant drug therapy(11) and surgery.(12)(13)(14)

Evidence Summary

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Background

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For vagus nerve stimulation, a generator is implanted subcutaneously into the left chest wall and connected to bipolar electrodes that are attached to the left vagus nerve. The generator is programmed to deliver mild electric pulses in continuous cycles, each of which typically consists of 30 seconds of stimulation followed by 5 minutes of rest. The generator is programmed by a physician, and it can be turned off or on by holding a magnet over the generator. For patients who experience aura before a seizure, contemporaneous activation of the stimulator with the magnet may help stop the seizure.(15)(16)(17)(18)(13) **(EG 2)** The most frequent side effects of vagus nerve stimulation are voice alteration, cough, throat pain, and dyspnea.(12)(17)(19) **(EG 2)**

Criteria

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For epilepsy, Vagus nerve stimulation has been shown to be effective in reducing seizure frequency in adults and children, as well as epilepsy-related hospital admissions and emergency department visits.(17)(18)(20)(21)(22) **(EG 1)** A meta-analysis that included retrospective studies and over 3000 patients with medically intractable epilepsy concluded that vagus nerve stimulation was effective in reducing seizure frequency by 50% or more in approximately 50% of adults and children, with a delayed benefit more than 1 year after surgery; however, approximately 25% of patients did not receive any benefit from this therapy, and less than 5% achieved complete seizure freedom.(7) **(EG 2)** A systematic review and meta-analysis of 5 randomized controlled trials of vagus nerve stimulation for the treatment of drug-resistant partial epilepsy found that there was moderate-certainty to low-certainty evidence that high-frequency vagus nerve stimulation is significantly more effective than low-frequency vagus nerve stimulation in reducing seizure frequency.(23) **(EG 1)** An observational study of 66 patients with drug-resistant epilepsy who underwent vagus nerve stimulation found, at 10-year follow-up, that 64% of patients had a reduction in seizure frequency between 50% and 90%, and 15% of patients had a reduction in seizure frequency of 90% or greater. During the entire study period, 88% of patients had a change in antiepileptic medication.(24) **(EG 2)** A retrospective study of 146 patients younger than 18 years who were followed for a mean duration of 41 months following vagus nerve stimulator implantation reported similar efficacy (in terms of the outcomes of seizure frequency reduction, seizure duration, postictal period, medication use, and clinical or quality-of-life improvement), regardless of age (younger than 12 years vs 12 years or older) or epilepsy type (partial vs generalized).(25) **(EG 2)** A retrospective review of 56 children with drug-resistant epilepsy who underwent vagus nerve stimulation found, at 5-year follow-up, that 62.5% had greater than 50% reduction in seizure frequency, with 20% becoming seizure free.(26) **(EG 2)** A retrospective review that included 110 patients who had failed intracranial epilepsy surgery and underwent vagus nerve stimulation with at least 1 year of follow-up showed that failed intracranial epilepsy surgery did not affect the response to vagus nerve stimulation; more than 50% of patients experienced at least 50% reduction in seizure frequency.(10) **(EG 2)** A specialty society guideline supports the use of vagus nerve stimulation as adjunctive treatment for children with partial or generalized seizures that are medication resistant and who are poor surgical candidates or have had unsuccessful surgery.(27) **(EG 2)**

Inconclusive or Non-Supportive Evidence

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For chronic ischemic stroke, A randomized controlled trial including 108 chronic ischemic stroke patients with moderate to severe upper extremity impairment comparing rehabilitation paired with either active vagus nerve stimulation or sham stimulation found, after 6 weeks of in-clinic therapy and 90 days of a home exercise program, that rehabilitation paired with active vagus nerve stimulation was associated with a reduction in upper extremity motor deficits and improvement in motor function (measured by Fugl-Meyer Assessment-Upper Extremity and Wolf Motor Function Test scores) as compared with rehabilitation paired with sham stimulation. However, 42% and 20% of study participants experienced an adverse event potentially related to device implantation and device use, respectively, and the authors noted that longer-term efficacy of this treatment strategy is not certain; future research was recommended.(28) **(EG 1)**

For heart failure, A randomized open-label trial of 707 patients with New York Heart Association class III heart failure compared vagus nerve stimulation with continued medical therapy and found, at a mean follow-up of 16 months, no difference in the primary composite endpoint (death from any cause or first event attributed to worsening heart failure) between the intervention and control group; vagus nerve stimulation was associated with improved quality of life (as measured by the Kansas City Cardiomyopathy Questionnaire), New York Heart Association functional class, and 6-minute walk distance. However, the authors note that the lack of both blinding and a control group were study limitations that may have impacted the results.(29) **(EG 1)** A randomized sham-controlled trial of 87 New York Heart Association class II or III heart failure patients who underwent vagus nerve stimulation found, at 6-month follow-up, that although there were significant improvements in quality-of-life metrics, there was no significant change in left ventricular end diastolic diameter, end systolic volume, end diastolic volume, ejection fraction, peak oxygen uptake, and brain natriuretic peptide level. The authors concluded that vagus nerve stimulation was ineffective for the treatment of heart failure.(30) **(EG 1)** An observational study of 57 New York Heart Association class II or III heart failure patients found, at 6-month follow-up, that vagus nerve stimulation was associated with improved left ventricular ejection fraction, New York Heart Association classification, and 6-minute walk distance; however, there was no significant change in brain natriuretic peptide. A larger randomized controlled trial was recommended.(31) **(EG 2)** A follow-up study of 25 patients from the previous study (all of whom underwent ambulatory 24-hour electrocardiogram monitoring 24 months and 36 months after beginning the study) found, at 36-month follow-up, that chronic vagus stimulation therapy was associated with persistent improvements in heart rate and cardiac function (measured by left ventricular ejection fraction, New York Heart Association class, 6-minute walk test, and Minnesota Living with Heart Failure Questionnaire). However, the authors noted that the study was limited by the uncontrolled open-label design and the small sample size; a randomized controlled trial was recommended.(32) **(EG 2)**

Policy History

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History Summary: RMHP adopted MCG A-0424 with Medicare guidance added 7/17/2017. Annual reviews thereafter. Updates as needed.

11/13/2023 Annual review and upgrade to 27th edition MCG for non-Medicare plans and NCD 160.18 for Medicare plans.

References

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The Center for Medicare and Medicaid Services (CMS) National Coverage Determination (NCD) 160.18 Vagus Nerve Stimulation (VNS), Effective Date 2/15/2019, Implementation Date 7/22/2020, reviewed 11/13/2023.

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Footnotes

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[A] Intractable or medically refractory epilepsy is defined as seizures that are unresponsive to at least 2 different tolerated, appropriately chosen and used anticonvulsant medications.(5) [A in Context Link 1]

Codes

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CPT® : 61885, 61888, 64553, 64568, 64569, 64570, 95970, 95976, 95977
HCPCS: C1767, C1778, C1820, C1826, C1827, L8679, L8680, L8685, L8686, L8687, L8688