

# RMHP Behavioral Health Vagus Nerve Stimulation, Implantable

ORG\_OTG: RMHP-B-821-T-27 (BHG)

**MCG Health**  
Behavioral  
Health  
Guidelines  
27th Edition

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## Clinical Indications for Procedure

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For Members with **Medicare (CareAdvantage or DSNP Dual Special Needs Plan)** coverage, the case will be pended. RMHP follows CMS National Coverage Determination (NCD) limited coverage for Vagus Nerve Stimulation (VNS) (160.18), which allows VNS for treatment resistant depression (TRD) ONLY within a specific CMS approved clinical trial. The requester will be notified of the decision per protocol. See References.

For all **RMHP non-Medicare plans, including PRIME (Medicaid), CHP+, and Individual and Family Plan (IFP)**

**Commercial** coverage, the current role remains uncertain per MCG. The case will be denied as experimental. See paragraph below.

- Current role remains uncertain. Based on review of existing evidence, there are currently no clinical indications for this technology. See Inappropriate Uses for more detailed analysis of the evidence base. [\(1\)](#)[\(2\)](#)[\(3\)](#)

## Alternatives to Procedure

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- Alternatives include:
  - For major depressive disorder[\(4\)](#)[\(5\)](#)[\(6\)](#):
    - Bright light therapy, for patient with depression and seasonal component.

See [Bright Light Therapy](#) <sup>BHG</sup> for more information.

- Electroconvulsive therapy. See [Electroconvulsive Therapy \(ECT\)](#) <sup>BHG</sup> for more information.
- Pharmacotherapy
- Psychotherapy
- Transcranial magnetic stimulation. See [Transcranial Magnetic Stimulation](#) <sup>BHG</sup> for more information.

## 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.(2)(7)(8)(9)(10) (EG 2) The most frequent side effects of vagus nerve stimulation are voice alteration, cough, throat pain, and dyspnea.(2)(7)(8)(9)(11) (EG 2) Unlike electroconvulsive therapy, vagus nerve stimulation does not require anesthesia and has no cognitive side effects.(12) (EG 2)

### Inconclusive or Non-Supportive Evidence

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For Alzheimer disease, Small uncontrolled observational studies have been performed to investigate the effects of vagus nerve stimulation, but no clear evidence of efficacy has been found.(13)(14) (EG 2)

For eating disorders, Small uncontrolled studies have been performed to investigate the effects of vagus nerve stimulation, but no conclusive evidence of efficacy has been found.(14) (EG 2)

For major depressive disorder, A meta-analysis and systematic review of vagus nerve stimulation in the treatment of depression concluded that there was insufficient evidence available to support the effectiveness of vagus nerve stimulation; specifically, only unblinded nonrandomized trials showed any benefit.(15)(16) (EG 1) An industry-funded systematic review and meta-analysis (22 studies, 2136 patients) of vagus nerve stimulation for treatment-resistant depression in adults found statistically significant heterogeneity between studies, leading authors to recommend further comparative studies evaluating outcomes and safety.(17) (EG 1) A comparative effectiveness review described the evidence for vagus nerve stimulation in patients with treatment-resistant major depression to be of poor quality; one high-quality trial comparing vagus nerve stimulation to sham (the sample included patients with both major depressive disorder and bipolar disorder) reported no difference in depression severity, response, or remission rates between the active therapy and sham groups.(18) (EG 1) A prospective, open-label, nonrandomized, industry-sponsored disease registry study of 795 patients with treatment-resistant depression found that vagus nerve stimulation combined with treatment as usual was superior to treatment as usual alone for improving 5-year cumulative response rates (67.6% vs 40.9%, respectively) and remission rates (43.3% vs 25.7%, respectively).(19) (EG 2) A national guideline notes that the evidence for the safety and efficacy of vagus nerve stimulation for treatment-resistant depression is inadequate in quantity and quality.(20) (EG 2) A specialty society guideline states that there is limited evidence supporting vagus nerve stimulation for depression; however, it could be considered in patients with chronic or recurrent depression who have not responded to 4 or more antidepressant treatments.(21) (EG 2)

## Policy History

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Policy History: Created in 2020 using the current MCG edition for non-Medicare and NCD 160.18 for Medicare. Annual reviews thereafter with updates as needed.

11/13/2023 Annual review with upgrade to MCG 27th edition.

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The Center for Medicare and Medicaid Services (CMS) National Coverage Determination (NCD) for Vagus Nerve Stimulation (VNS) 160.18, Version Number 3, Effective date 2/15/2019, Implementation Date 7/22/2020, reviewed 11/13/2023.

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## Codes

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