JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Medical Policy Manual** **Medical Policy**	*Policy Number*	CMS22.06
		Effective Date	02/01/2024
		Approval Date	11/21/2023
	Subject **Vagus Nerve Stimulation for Depression**	*Supersedes Date*	02/01/2023
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This document applies to the following Participating Organizations:

Advantage MD	EHP	Johns Hopkins Health Plan of Virginia Inc. (JHHPVA)	Priority Partners
US Family Health Plan			

Keywords: Vagus Nerve Stimulation, Vagus Nerve Stimulation for Depression

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I. ACTION

	New Policy	
X	Revising Policy Number	CMS22.06
	Superseding Policy Number	
	Retiring Policy Number	

II. POLICY DISCLAIMER

Johns Hopkins Health Plans (JHHP) provides a full spectrum of health care products and services for Advantage MD, Employer Health Programs, Johns Hopkins Health Plan of Virginia Inc., Priority Partners, and US Family Health Plan. Each line of business possesses its own unique contract, benefits, regulations, and regulators' clinical guidelines that supersede the information outlined in this policy.

III. POLICY

For Advantage MD refer to: Medicare Coverage Database

- No Local Coverage Determinations (LCDs) identified (Accessed 10/11/2023)
- National Coverage Determination (NCD) 160.18 Vagus Nerve Stimulation (VNS)

For Employer Health Programs (EHP) refer to:

- Plan specific Summary Plan Descriptions (SPD's)

For Johns Hopkins Health Plan of Virginia LLC (JHHPVA) refer to: Medicare Coverage Database

- No Local Coverage Determinations (LCD) identified (Accessed 10/11/2023)
- National Coverage Determination (NCD) 160.18 Vagus Nerve Stimulation (VNS)

For Priority Partners (PPMCO) refer to: Code of Maryland Regulations

- No specific information located in COMAR 10.67.06.01 – 10.67.06.31 (Accessed 10/11/2023)

For US Family Health Plan refer to: Tricare Policy Manuals

- TRICARE Policy Manual 6010.63-M, April 1, 2021, Chapter 4, Section 20.1 Nervous System

IV. POLICY CRITERIA

A. Unless specific benefits are provided under the member's contract, JHHP considers implantable Vagus Nerve Stimulation (VNS) experimental and investigational for the adjunctive long-term treatment of chronic or recurrent depression, as it does not meet the Technology Evaluation Criteria (TEC).

B. Unless specific benefits are provided under the member's contract, JHHP considers transcutaneous Vagus Nerve Stimulation (tVNS) (auricular vagus nerve stimulation (taVNS) or cervical branch vagus nerve stimulation in the neck (tcVNS)), experimental and investigational for the treatment of acute, chronic or recurrent depression, as it does not meet Technology Evaluation Criteria (TEC).

V. DEFINITIONS

Technology Assessment: The systematic evaluation of the properties, effects and/or impacts of health technologies and interventions. It covers both the direct, intended consequences of technologies and interventions and their indirect, unintended consequences (World Health Organization, 2023).

Technology Evaluation Criteria (TEC): A service, device or supply must meet all the following criteria:

1. The technology must have final approval from the appropriate government regulatory bodies for intended use.
2. There must be sufficient scientific evidence-based studies to permit conclusions concerning the effect of technology on health outcomes.
3. The technology must improve the member's net health outcome.
4. The technology must be as beneficial as any established alternatives.
5. The improvement must be attainable outside the investigational setting.

Transcutaneous Vagus Nerve Stimulation (tVNS): A noninvasive method of electrical stimulation which is usually carried out through auricular vagus nerve stimulation (taVNS) in the ear or transcutaneous cervical branch vagus nerve stimulation in the neck (tcVNS), which enables stimulation of the vagus nerve non-invasively by the use of electrodes (Baig et al., 2022).

Vagus Nerve Stimulator (VNS): VNS is a pulse generator, similar to a pacemaker, that is surgically implanted under the skin of the left chest and an electrical lead (wire) is connected from the generator to the left vagus nerve. Electrical signals are sent from the battery-powered generator to the vagus nerve via the lead. These signals are in turn sent to the brain (CMS, 2017). After a postoperative recovery period, the stimulation is initiated and delivered intermittently. Treatment parameters of current, pulse width, and frequency are set using a hand held transmitter (Holtzheimer, 2022).

VI. BACKGROUND

Major depression is one of the most common mental disorders in the United States. In 2020, the National Survey on Drug Use and Health (NSDUH) shows that 14.8 million adults (6.0% of all adults) in the U.S. aged 18 years or older had at least one major depressive episode with a severe impairment (SAMHSA, 2021). Major depression is also highly recurrent with an estimated rate of recurrence of greater than 40% in the two years following an episode. The risk of recurrence increases to approximately 75% within five years (Rush, 2023). When standard treatments of psychotherapy and pharmacotherapy are ineffective, neuromodulation with electroconvulsive therapy (ECT) is a treatment option with established safety and efficacy. However, there remains a stigma and concern about cognitive effects on its use and alternate treatment options for treatment resistant depression have been proposed. Another form of neuromodulation, Vagus Nerve Stimulation (VNS) therapy, was FDA approved in July of 2005. The pre-market approval was granted to Cyberonics, Inc. (now LivaNova PLC) for the adjunctive long-term treatment of chronic or recurrent depression in patients 18 years or older experiencing a major depressive episode with inadequate response to four or more antidepressant treatments (FDA, 2005). Vagus nerve stimulation is delivered through an implanted device consisting of a pulse generator and therapy lead and an external programming system used to adjust stimulation parameters.

Vagus nerve stimulation is not universally recommended and based on the Hayes report from 2019 with an annual review in 2022, the vast majority of available evidence on safety and efficacy comes from studies funded or performed in collaboration with LivaNova (former Cyberonics). Overall, the quality of the evidence was considered to be low. Of the 16 studies reviewed, only one was rated a good quality study, the remaining ranged from very-poor to fair-quality and showed inconsistency in findings with regard to the effect of VNS on depression outcomes. Furthermore, Hayes reports that although much of the evidence comprising nonrandomized comparative studies found significant improvement with VNS, the randomized controlled trials did not demonstrate these improvements without changing statistical approaches or combining patient groups. Complications of VNS related to the surgical procedure and post-surgical stimulation include: delayed wound healing, infection, pain, headache, dizziness, hoarseness and dysphagia. Some complications were serious, requiring hospitalization, including suicide, attempted suicide, and suicide ideation; worsening of depression; manic episodes, agitation, hypomania, central nervous system toxicity, and asystole (Hayes, 2022; O'Reardon, 2006).

According to the *UpToDate* report on surgical treatments for depression, Holtzheimer concurs there is no rigorous data that indicates vagus nerve stimulation is efficacious for treatment resistant unipolar major depression. Referring to a 10-week, acute, randomized, controlled, masked trial adjunctive (Rush et al.). VNS was compared with sham treatment in 235 outpatients with non-psychotic major depressive disorder (n= 210) or non-psychotic, depressed phase, bipolar disorder (n = 25) and the reduction of baseline symptoms ≥ 50% was similar for the treatment and sham groups. Holtzheimer notes evidence that VNS may lead to improvements over time: a five-year observational study (Aaronson et al., 2017) (n= 765) of patients with treatment-resistant depression who received VNS vs. patients receiving treatment as usual did show that adjunctive VNS had enhanced antidepressant effects compared with treatment as usual in this severely depressed patient population.

The Center for Medicare & Medicaid Services (CMS), currently excludes coverage for vagus nerve stimulation as not reasonable and necessary in the treatment of resistant depression. However, CMS has proposed to cover FDA approved VNS for this indication through Coverage with Evidence Development (CED) when offered in a CMS approved, double-blind, randomized, placebo-controlled trial with a follow-up duration of at least one year (CMS, 2019). Similarly, the National Institute for Health and Care Excellence (NICE) guideline cautions that vagus nerve stimulation for treatment-resistant depression should only be performed with special arrangements for clinical governance, consent or audit and research due to inadequate evidence on safety and efficacy. The Veterans Affairs (VA) Department of Defense (DoD) clinical practice guideline strongly opposes VNS for treatment-resistant depression outside of the research setting (Hayes, 2022).

The RECOVER study, *A Prospective, Multi-center, Randomized Controlled Blinded Trial Demonstrating the Safety and Effectiveness of VNS Therapy® System as Adjunctive Therapy Versus a No Stimulation Control in Subjects With Treatment-*

Resistant Depression, is a prospective, multi-site, randomized, delayed activation-controlled, blinded trial with two parallel cohort subpopulations of patients with unipolar and bipolar difficult to treat depression (DTD). In this study, all trial participants will be implanted with VNS devices: half receive active stimulation during year one, and half receive delayed stimulation after year one. Participants will be followed for 5 years. This RCT is unique for DTD studies: 1) large sample size and long study duration (one year of controlled comparison); 2) use of a percent time in response as the primary outcome measure, given the chronic illness and its fluctuating course; 3) inclusion of diverse measures of VNS impact on function, including quality of life, degree of disability, health status, and suicidality. The study began in 2019 and the estimated completion date is 2030. https://clinicaltrials.gov/RECOVER NCT03887715

Transcutaneous vagus nerve stimulation (tVNS) is a relatively newer, noninvasive VNS method based on the rationale that there is afferent/efferent vagus nerve distribution on the surface of the ear. It is proposed as a safe and low-cost modality with the potential to expand the clinical application of VNS. A small study evaluating the effects of transcutaneous VNS vs. sham treatment on patients with major depressive disorder (MDD) with mild to moderate symptoms concluded the results provide insights into the brain mechanism of transcutaneous VNS treatment for MDD patients (Fang, 2016). A meta-analysis to evaluate the effectiveness and safety of transcutaneous VNS in treating major depressive disorder was conducted (Wu et al., 2018). The authors conclude that analysis of the four studies included (222 patients) preliminarily demonstrated that transcutaneous VNS therapy can effectively decrease symptoms of major depressive disorder. However, advice on more well-designed RCT's with larger sample sizes and follow-ups are needed in future studies to confirm the findings (Wu et al., 2018). In an *UpToDate* report, transcutaneous VNS is described as one of several investigational noninvasive neuromodulation procedures (Thase, 2023). A small 4-week single-arm feasibility trial (n 20) of tVNS for treatment resistant depression, assessing compliance, usability, side effects, cognitive speed, and depression showed acceptable usability, few side effects, and a significant improvement in depressive symptoms and cognitive speed, though no change in sleep or suicidal ideation. Some participants found it difficult to use. The authors recommend larger, long-term randomized studies of tVNS to assess antidepressant effect (Evensen et al., 2022).

VII. CODING DISCLAIMER

Note: The following CPT/HCPCS codes are included below for informational purposes and may not be all-inclusive. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member's specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee of payment. Other policies and coverage determination guidelines may apply.

Note: All inpatient admissions require pre-authorization.

Adherence to the provision in this policy may be monitored and addressed through post payment data analysis and/or medical review audits
Advantage MD: Regulatory guidance supersedes JHHP Medical Policies. If there are no statutes, regulations, NCDs, LCDs, or LCAs, or other CMS guidelines, apply the Medical Policy criteria.
Employer Health Programs (EHP): Specific Summary Plan Descriptions (SPDs) supersedes JHHP Medical Policy. If there are no criteria in the SPD, apply the Medical Policy criteria.

Johns Hopkins Health Plan of Virginia Inc. (JHHPVA): Regulatory guidance supersedes JHHP Medical Policies. If there are no statutes, regulations, NCDs, LCDs, or LCAs, or other CMS guidelines, apply the Medical Policy criteria.
Priority Partners (PPMCO): Regulatory guidance supersedes JHHP Medical Policy. If there are no criteria in COMAR regulations, or other State guidelines, apply the Medical Policy criteria.
US Family Health Plan (USFHP): Regulatory guidance supersedes JHHP Medical Policy. If there are no TRICARE policies, or other regulatory guidelines, apply the Medical Policy criteria.

VIII. CODING INFORMATION

CPT® CODES ARE FOR INFORMATIONAL PURPOSES ONLY	
CPT® CODES	**DESCRIPTION**
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array
61888	Revision or removal of cranial neurostimulator pulse generator or receiver
64568	Open 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
95976	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, 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 simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
95977	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, 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 complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional

HCPCS CODES ARE FOR INFORMATIONAL PURPOSES ONLY	
HCPCS CODES	**DESCRIPTION**
C1767	Generator, neurostimulator (implantable), nonrechargeable
C1778	Lead, neurostimulator (implantable)
L8680	Implantable neurostimulator electrode, each
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension

ICD-10 CODES ARE FOR INFORMATIONAL PURPOSES ONLY	
ICD10 CODES	**DESCRIPTION**
F32.0 - F32.3	Major depressive disorder, single episode
F32.9	Major depressive disorder, single episode, unspecified
F33.0 - F33.3	Major depressive disorder, recurrent
F33.9	Major depressive disorder, recurrent, unspecified

IX. REFERENCE STATEMENT

Analyses of the scientific and clinical references cited below were conducted and utilized by the Johns Hopkins Health Plans (JHHP) Medical Policy Team during the development and implementation of this medical policy. The Medical Policy Team will continue to monitor and review any newly published clinical evidence and revise the policy and adjust the references below accordingly if deemed necessary.

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XI. APPROVALS

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