Vagus Nerve Stimulation
Medicare National Coverage Determination (NCD) 160.18 Checklist

NCD 160.18	
MM11461	**Patient Name:** **MR:**

Effective Date: For services performed on or after 2/15/2019

Vagus Nerve Stimuations (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. For treatment of TRD, it is subcutaneously connected to an electrode attached to the left vagus nerve in the neck.

GENERAL REQUIREMENTS

□	VNS device is FDA approved for treatment of refractory epilepsy or resistant depression.
□	VNS is an outpatient procedure.
□	Diagnoses (ICD-10) code reflecting qualifying condition (see coverage indications). Examples include: • G40.011 Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, with status epileptic • G40.019 Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, without status epilepticus

COVERAGE INDICATIONS

Vagus Nerve Stimulation IS considered medically reasonable and necessary for the following:

□	Patient with medically **refractory partial onset seizures** for whom surgery either has failed or is not recommended
□	1. Patient with **resistant depression under Coverage Evidence Development (CED)** in the CMS-approved, double-blind, randomized, placebo-controlled clinical trial * see below link *Note:Individuals who receive placebo VNS will be offered active VNS at the end of the trial.* *https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/VNS - trial details and enrollment info 2. Patient meets the following criteria: • must be in a major depressive disorder (MDD) episode for ≥ two years or have had at least four episodes of MDD, including the current episode. To confirm MDD, use accepted diagnostic criteria from the most current edition of the Diagnostic and Statistical Manual for Mental Disorder (DSM) and a structured clinical assessment; • depressive illness meets a minimum criterion of four prior failed treatments of adequate dose and duration as measured by a tool designed for this purpose; • with a major depressive episode (MDE) as measured by a guideline recommended depression scale assessment tool on two visits, within a 45-day span prior to implantation of the VNS device; • maintained a stable medication regimen for at least four weeks before device implantation; and • If with bipolar disorder, the condition is carefully characterized; 3. Patient does not have: • *current or lifetime history* of psychotic features in any MDE, schizophrenia or schizoaffective disorder, any other psychotic disorder, rapid cycling bipolar disorder; • *current* secondary diagnosis of delirium, dementia, amnesia, other cognitive disorder, suicidal intent; and • treatment with another investigational device or investigational drugs.
□	Patient requiring a **VNS device replacement** due to the end of battery life, or any other device-related malfunction; VNS device previously implanted for any approved treatment/clinical trial not required. • ICD-10 diagnosis codes or CED-related coding not required • KX modifier required, attesting to the reasonable and necessary need for the replacement device based off NCD160.18 criteria

NONCOVERED INDICATIONS

Vagus Nerve Stimulation is NOT covered for treatment of:
• All other types of seizure disorders which are medically refractory and for whom surgery is not recommended or for whom surgery has failed
• Resistant depression when furnished outside of a CMS-approved CED study
• Depression (all other indications)

Checklist completed by: **Date:**

Disclaimer: The content of the checklists were created as an educational tool. Use of these documents are not intended as a replacement for the documentation requirements published in National or Local Coverage Determinations, or the CMS's documentation guidelines, written law or regulations. Medicare policy changes frequently; Providers/Departments are reminded to review current National and Local Coverage Determination and Policy Articles for specific documentation and coding guidelines.