VAGUS NERVE STIMULATION FOR INTRACTABLE EPILEPSY CRITERIA

The following provides established criteria for the Vagus Nerve Stimulator (VNS). VNS may be considered medically necessary as an adjunctive therapy in reducing the frequency of refractory or intractable partial-onset seizures (seizures that begin in a particular focus in the brain) in patients over 12 years of age. Refractory epilepsy will be determined by seizure frequency, seizure type, severity of attacks, response to antiepileptic (AED) drugs, drug toxicity, and overall impact on quality of life (QOL).

All requests for the VNS will be considered by Total Health Care and are subject to review by the Medical Director in conjunction with the UM Committee. THC reserves the right to refer the member for an independent second medical opinion to assist in the decision-making process.

The member must meet all of the following conditions to qualify for the VNS:

1. Diagnosis of refractory epilepsy for at least 2 consecutive years.
2. Seizures are only partial complex in nature.
3. Experiencing a minimum of 8 identifiable debilitating seizures each month for a minimum of 24 consecutive months.
4. Seizures have been treated with, and have failed, medical therapy with at least 5 different AEDs either separately and/or in combination, including both conventional and newer FDA approved medications given as add-on treatment, for at least 24 consecutive months.
5. Unable to tolerate medication.
7. Documented evidence of continued compliance with the epileptic treatment plan, including AED therapy measured by peak and trough blood levels, follow-up doctor appointments, etc. for a minimum of 24 consecutive months.
8. Documentation to support diagnostic work-up and/or follow-up care to evaluate response to treatment regimen.
9. Evidence of test results to determine structural abnormality, abnormal excitability, and interictal non-epileptic dysfunction. (i.e., CT, EEG, video EEG, MRI, PET, etc.).
10. Is not a candidate for curative epilepsy surgery or prior curative epilepsy surgery has failed.
11. Demonstrate failed epilepsy control under the supervision of a specialized epilepsy center.
12. Completion and scoring of Quality of Life in Epilepsy-31 for patients over the age of 20 years or Quality of Life in Epilepsy-AD-48 for adolescent patients over 12 years of age up to 20 years of age. Assessment must be completed and scored by a qualified expert.
13. Completion of the Seizure Activity Questionnaire.
14. Completion of a 30 consecutive day diary of seizure activity.
15. Evidence of psychiatric evaluation to rule out non-epileptic seizures and behavioral aberrations, including self-injurious behavior (SIB).
16. When diagnoses of mental retardation (MR), mental illness such as psychosis, bipolar, etc. and epilepsy co-exist, the treating physician must document how VNS will benefit the patient in spite of the co-existing diagnosis.
17. Focus is to help restore the ability to function in society.
18. Used as a last resort measure.
19. Must not have a progressive disorder.

**CONTRAINDICATIONS:**

VNS will not be considered for authorization if any of the following condition(s) exist:

1. Any other types of seizure disorders.
2. Manifestations are not recognized as a seizure or seizure equivalent (i.e., convulsive syncope, psychogenic seizures, etc.).
3. VNS will likely not affect quality of life.
4. Patient and/or caregiver demonstrate evidence of noncompliance in epilepsy management.
5. Implantation is considered elsewhere other than the left vagus nerve.
6. Those who may benefit from available AED’s and epilepsy surgery.
7. Patient does not any of the following conditions:
   - Previous bilateral or left cervical vagotomy
   - Cardiac arrhythmias or other cardiac abnormalities
   - Circulatory disorders
   - History of or active peptic ulcer disease
   - Respiratory diseases or disorder
   - Unstable medical conditions
   - Previous therapeutic brain surgery
   - Pre-existing hoarseness
   - Pregnancy or nursing
   - Other concurrent forms of brain stimulation
   - Severe neurological disease
   - Degenerative diseases of the nervous system
   - Genetic neurological diseases
   - Tumors and/or neoplasms of the nervous system
   - Other neurological conditions including, but not limited to, stroke, infections, poisoning, etc.

**DOCUMENTATION REQUIREMENTS:**

The treating physician must provide documentation to establish diagnosis of partial onset epilepsy, the intractability to medical treatment, and all other conditions as outlined in this Criteria. Clinical documentation must be submitted with the request for prior authorization.