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Developed By: Medical Criteria Committee	

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Approved:

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Date:

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**Description:**

A vagus nerve stimulator (VNS) is an implantable device that is used as an adjunctive treatment for medical refractory partial onset seizures as well as for the treatment of severe or chronic depression. Similar to a pacemaker, the VNS pulse generator is surgically implanted under the skin near the collar bone. A lead wire connects the pulse generator to the left vagus nerve in the neck. The VNS is then programmed to produce weak electrical signals that travel along the vagus nerve to the brain at regular intervals. These signals help prevent the electrical bursts in the brain that cause seizures. The signals can also affect mood centers of the brain, possibly improving depressive symptoms.

**Criteria:**

- I. ODS will cover vagus nerve stimulators to plan limitations when **all** of the following criteria are met:
  - A. The member is 12 years of age or older;
  - B. The member has medically refractory partial onset seizures:
    1. Medically refractory means seizures that occur in spite of therapeutic levels of anti-epileptic medications; or
    2. Seizures that cannot be treated with therapeutic levels of anti-epileptic drugs because of intolerable side effects;
  - C. The member has failed or is not a candidate for surgery
- II. ODS considers vagus nerve stimulation experimental and investigational for use in treatment-resistant depression due to the lack of well-designed controlled clinical trials. Only one randomized control trial evaluating the effectiveness of VNS for treatment-resistant depression has been identified. This study did not find statistically significant improvement on most measures of depression. Therefore, the available evidence is not sufficient to permit conclusions on the effect of VNS therapy on health outcomes or its effects compared with alternative therapies for depression treatment.
- III. ODS considers vagus nerve stimulation experimental and investigational for the treatment of all other indications, including but not limited to, refractory depression, cognitive impairment associated with Alzheimer's disease, anxiety disorders, autism, obesity, headaches, addictions, Tourette's syndrome and obsessive compulsive disorder. The effectiveness of vagus nerve stimulation for the treatment of these, or other conditions, has not been established.

**Information to be Submitted with Pre-Authorization Request:**

- Medical records from the treating neurologist documenting a diagnosis of partial onset seizures as well as medical and surgical treatment tried and failed.

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