IEHP UM Subcommittee Approved Authorization Guidelines

_Vagus Nerve Stimulation_

**Policy:**
IEHP has determined that vagus nerve stimulators (VNS) are a covered benefit for the treatment of refractory partial onset seizures. The use of vagus nerve stimulators for all other indications is considered to be experimental as there is a lack of data to support the use of the device in all other circumstances.

A partial onset seizure has a focal onset in one area of the brain and may or may not involve a loss of motor control or alteration of consciousness. Partial onset seizures may be simple, complex, or complex partial seizures, secondarily generalized.

Refractory seizures are classified as at least one seizure per month and results in an intolerable interruption of the Member’s capability to function regardless of the prescribed intake of anti-seizure medication.

**CMS National Coverage Determination Manual Section 160.18 (2007):**
CMS states VNS is reasonable and necessary for patients with refractory partial onset seizures for who surgery is not recommended or for whom surgery has failed. In addition, VNS is not considered reasonable or necessary for all other types of seizure disorders. VNS is not reasonable and necessary for drug resistant depression.

**Medi-Cal (2007):**
The Medi-Cal guideline states for Medi-Cal Members all the following criteria must be met for authorization of a VNS procedure:

- A Member has a documented intractable seizure disorder and has an appropriate trial period taking anticonvulsant medications.
- If the Member is not a good candidate for other more effective anti-seizure surgical therapy, or if the Member refuses anti-seizure surgical therapy, or previous surgical therapy has been unsuccessful.
- Implantation of the VNS device must be requested by the Member’s epileptologist/neurologist.
- The surgeon implanting the VNS device must have surgical privileges that allow insertion of this device.
• The surgeon requesting authorization to implant the device must indicate on the referral the name of the neurologist who will follow-up with the Member post-implantation. For children under 12 years of age with a medical condition related to the seizure disorder, there must be a recommendation for implantation from a Board Certified Pediatric Neurologist. In addition, children under 6 years of age will need a recommendation from two Board Certified Pediatric Neurologists, and their notes must coincide with one another regarding the Member’s seizure disorder.

**Apollo (2013):**

Apollo states that electrical stimulation of the vagus nerve in patients over the age of 12 years with partial onset seizures that are refractory or intolerant of anti-epileptic medication therapy and/or post-surgery (or when surgery is inappropriate), may be beneficial in patients.

**Aetna (2013):**

Aetna considers vagus nerve electrical stimulators medically necessary durable medical equipment (DME) for shortening the duration or reducing the severity of seizures in Members with partial onset seizures who remain refractory to optimal anti-epileptic medications and/or surgical intervention, or who have debilitation side effects from anti-epileptic medications when criteria is met. Aetna considers vagus nerve electrical stimulators and transcutaneous vagus nerve stimulation experimental and investigational for the treatment of all other indications because its effectiveness for these indications has not been established.

**Anthem (2013):**

Anthem considers implantation of a vagus nerve stimulation device medically necessary in an individual with medically or surgically refractory seizures when criteria are met. Implantation of a vagus nerve stimulation device is considered investigational and not medically necessary as a treatment for all other conditions.

**Background:**

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.
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