VAGUS NERVE STIMULATION

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member’s specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms “experimental” and “investigational” are considered to be interchangeable.

Description:

Vagus nerve stimulation (VNS) is the delivery of intermittent electrical impulses to the brain via the vagus nerve. A generator is surgically implanted in the upper chest and a wire is threaded under the skin to the left vagus nerve where two electrodes are attached. The stimulator can be programmed to deliver electrical impulses at regular intervals or on demand by passing a magnet over the generator.

VNS is a treatment alternative for individuals with medically refractory seizures. VNS has also been investigated as a treatment for depression, essential tremor, headaches, obesity, heart failure, and fibromyalgia.
VAGUS NERVE STIMULATION (cont.)

Criteria:

- Vagus nerve stimulation for the treatment of medically refractory seizures is considered *medically necessary*.

- Vagus nerve stimulation for the treatment of depression is considered *experimental or investigational* based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

- Vagus nerve stimulation for the treatment of obesity is considered *experimental or investigational* based upon:
  1. Lack of final approval from the Food and Drug Administration,
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes,
  3. Insufficient evidence to support improvement of the net health outcome,
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  5. Insufficient evidence to support improvement outside the investigational setting.

- Vagus nerve stimulation for all other indications not previously listed is considered *experimental or investigational* based upon:
  1. Lack of final approval from the Food and Drug Administration, and
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  3. Insufficient evidence to support improvement of the net health outcome.

Examples include, *but are not limited to*:

- Essential tremor
- Headaches
- Heart failure
- Fibromyalgia
VAGUS NERVE STIMULATION (cont.)

Resources:

Resources prior to 03/20/2013 may be requested from the BCBSAZ Medical Policy and Technology Research Department.


FDA Premarket Approval Database for NeuroCybernetic Prosthesis®:

- FDA-approved indication: For use as an adjunctive therapy in reducing the frequency of seizures that are refractory to antiepileptic medications.

FDA Premarket Approval Database for VNS Therapy™ System:

- FDA-approved indication: For the adjunctive long-term treatment of chronic or recurrent depression for patients 18 years of age or older who are experiencing a major depressive episode and have not had an adequate response to four or more adequate antidepressant treatments.