BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Vagus Nerve Stimulation

Policy # 00134
Original Effective Date: 06/05/2002
Current Effective Date: 11/20/2013

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services Are Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider vagus nerve stimulation as a treatment of medically refractory seizures to be **eligible for coverage**.

Note: Medically refractory seizures are defined as seizures that occur in spite of therapeutic levels of antiepileptic drugs or seizures that cannot be treated with therapeutic levels of antiepileptic drugs because of intolerable adverse effects of these drugs.

When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of vagus nerve stimulation as a treatment in patients with seizures other than medically refractory seizures to be **investigational.***

Based on review of available data, the Company considers vagus nerve stimulation as a treatment for any other condition, including but not limited to heart failure, fibromyalgia, depression, essential tremor, obesity, and headaches to be **investigational.***

Background/Overview

Stimulation of the vagus nerve can be performed by means of an implantable stimulator within the carotid artery sheath. This technique has been proposed as a treatment for refractory seizures, depression, and other disorders.

Significant advances have occurred in surgical treatment for epilepsy and in medical treatment of epilepsy with newly developed and approved medications. Despite these advances, however, 25%–50% of patients with epilepsy experience breakthrough seizures or suffer from debilitating adverse effects of antiepileptic drugs. Vagus nerve stimulation (VNS) has been investigated as a treatment alternative in patients with medically refractory partial-onset seizures for whom surgery is not recommended or for whom surgery has failed.

While the mechanisms for the therapeutic effects of VNS are not fully understood, the basic premise of VNS in the treatment of various conditions is that vagal visceral afferents have a diffuse central nervous system projection, and activation of these pathways has a widespread effect on neuronal excitability. Surgery for

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implantation of a vagal nerve stimulator involves wrapping two spiral electrodes around the left vagus nerve within the carotid sheath. The electrodes are connected to an infraclavicular generator pack. The programmable stimulator may be programmed in advance to stimulate at regular times or on demand by patients or family by placing a magnet against the subclavicular implant site.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
In 1997, the FDA approved a VNS device called the NeuroCybernetic Prosthesis (NCP®)‡† system through the Premarket Approval (PMA) process. The device was approved for use in conjunction with drugs or surgery "as an adjunctive treatment of adults and adolescents over 12 years of age with medically refractory partial onset seizures."

Since 1997, it has been reported that recipients of a vagus nerve stimulator have experienced improvements in mood. Therefore, there has been research interest in VNS as a treatment for refractory depression. On July 15, 2005, Cyberonics received PMA supplement approval by the FDA for the VNS Therapy™† System "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."

Vagus nerve stimulation therapy has also been investigated for use in other conditions such as headaches, obesity, and essential tremors.

Centers for Medicare and Medicaid Services (CMS)
Medicare coverage policy notes that "Clinical evidence has shown that VNS is safe and effective treatment for patients with medically refractory partial onset seizures, for whom surgery is not recommended or for whom surgery has failed. VNS is not covered for patients with other types of seizure disorders that are medically refractory and for whom surgery is not recommended or for whom surgery has failed." Effective for services performed on or after May 4, 2007, VNS is not reasonable and necessary for resistant depression.

Rationale/Source

The most recent update covered the period from January 2012 through January 2013.

Treatment of Seizures
The policy regarding treatment of seizures has expanded the indications over time but was originally based, in part, on a 1998 TEC Assessment that offered the following conclusions.

- Published evidence from 2 large, well-designed multicenter trials involving over 300 patients demonstrates that the use of VNS as an adjunct to optimal use of antiepileptic drugs in the treatment of medically refractory patients with at least 6 partial-onset seizures/month reduces seizure frequency by approximately 25% after 3 months of treatment. In patients who achieve an initial reduction in seizure frequency, the beneficial treatment effect appears to be maintained and may increase with time.

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- Adverse effects are mild and consist primarily of hoarseness or voice change during “on” periods of stimulation.
- There is limited information about the use of vagus nerve stimulation in patients with other types of seizure disorders.

Based on this TEC Assessment, earlier versions of this policy supported the use of VNS for partial-onset seizures for patients older than 12 years of age.

Since that time, there has been interest in expanding the use of VNS to younger patients. Several studies have now reported results that support the safety of the device in children with refractory seizures. For example, 60 pediatric patients were treated as part of the double-blind clinical trials conducted to support the FDA application. At 18 months, the median reduction in seizure frequency was 50%, similar to the results achieved in adults. Adverse events were also similar to those recently reported in adults, and none resulted in termination of stimulation. Hornig and colleagues reported on a case series of 19 pediatric patients, with observation periods ranging up to 30 months. Overall, 50% of patients had a 50% reduction in seizure frequency. Patwardhan and colleagues reported that among 38 patients aged 11 months to 16 years, 29% had a greater than 90% reduction in seizure frequency, while 39% had 50% to 90% reduction. The major limitations of VNS are the following issues: that stimulation generally does not completely eliminate seizures, and it is not possible to predict which patients will optimally respond. Therefore, some authors suggest that VNS may be most appropriately used in patients with refractory seizures who are not candidates for surgery (i.e., bilateral or unresectable foci or no identified structural abnormality).

Tecoma and Iragui observed in a 2006 review that, since approval of VNS for partial seizures, a number of case series including patients with generalized seizures have been published. These series report seizure reduction rates similar to or greater than those reported in partial epilepsy and note that “this body of evidence suggests that VNS has broad antiepileptic efficacy.” The authors suggest that these results may be particularly important since resective epilepsy surgery is generally not feasible in these patients. More recent reports are consistent with their observations. In a French study of 50 consecutive refractory adolescents and adults who were not eligible for surgery and 11 of whom had generalized epilepsy, 58% were classified as responders at 3 years’ follow-up. Generalized epilepsy was predictive of a better outcome than partial epilepsy seizures. The authors concluded that VNS was a useful palliative procedure in severe generalized epilepsies with atonic or tonic-clonic seizures resulting in frequent falls and entails less risk than callosotomy. In a multicenter study of 28 children with refractory seizures, You et al. reported that 15 children (53.6%) showed a greater than 50% reduction in seizure frequency and 9 (32%) had a greater than 75% reduction, and there were no significant differences when groups were compared by seizure type or etiology. Tecoma and Iragui cite a multicenter retrospective analysis of 50 children with Lennox Gastaut syndrome (LGS) treated with VNS. Median seizure reduction at 6 months was 88% for tonic seizures and 81% for atypical absence. You et al. compared VNS and total corpus callosotomy for LGS. Of the 14 patients who underwent a corpus callosotomy, 9 (64%) had a greater than 50% reduction in seizure frequency and 5 (36%) had a greater than 75% reduction. Of the 10 patients who underwent VNS implantation, 7 (70%) had a greater than 50% reduction in seizure frequency and 2 (20%) had a greater than 75% reduction. Seizure reduction of 61% was also reported in a case series of 12 patients with drug-

resistant idiopathic generalized epilepsy. Based on these data, one can conclude that VNS is an effective treatment for refractory seizures other than partial epilepsy.

Treatment of Refractory Depression
Interest in the application of VNS for treatment of refractory depression is related to reports of improvement in depressed mood among epileptic patients undergoing VNS. However, studies examining VNS for the treatment of depression are limited, and all published and unpublished data concerning clinical outcomes of VNS therapy for the indication of treatment-resistant depression come from company-sponsored clinical studies.

TEC Assessments written in 2005 and updated in 2006 concluded that evidence was insufficient to permit conclusions of the effect of VNS therapy on health outcomes. The available evidence for these TEC Assessments included study groups assembled by the manufacturer of the device (Cyberonics) and have since been reported on in various publications. Analyses from these study groups were presented for U.S. FDA review and consisted of a case series of 60 patients receiving VNS (Study D-01), a short-term (i.e., 3-month) randomized sham-controlled clinical trial of 221 patients (Study D-02), and an observational study comparing 205 patients on VNS therapy to 124 patients receiving ongoing treatment for depression (Study D-04). Patients who responded to sham treatment in the short-term randomized, controlled trial (RCT) (approximately 10%) were excluded from the long-term observational study.

The primary outcome evaluated was the relief of depression symptoms that can usually be assessed by any one of many different depression symptom rating scales. A 50% reduction from baseline score is considered to be a reasonable measure of treatment response. An improvement in depression symptoms may allow reduction of pharmacologic therapy for depression, with a reduction in side effects related to that form of treatment. In the studies evaluating VNS therapy, the 4 most common instruments used were the Hamilton Rating Scale for Depression, Clinical Global Impression, Montgomery and Asberg Depression Rating Scale, and the Inventory of Depressive Symptomatology (IDS).

Several case series studies published before the randomized trial showed rates of improvement, as measured by a 50% improvement in depression score of 31% at 10 weeks to greater than 40% at 1 to 2 years, but there are some losses to follow-up. Natural history, placebo effects, and patient and provider expectations make it difficult to infer efficacy from case series data.

The randomized study (D-02) that compared VNS therapy to a sham control (implanted but inactivated VNS) showed a non-statistically significant result for the principal outcome. Fifteen percent of VNS subjects responded versus 10% of control subjects (p=0.31). The Inventory for Depressive Symptomatology Systems Review (IDS-SR) score was considered a secondary outcome and showed a difference in outcome that was statistically significant in favor of VNS (17.4% vs. 7.5%, respectively, p=0.04).

The observational study that compared patients participating in the RCT and a separately recruited control group (D-04 vs. D-02, respectively) evaluated VNS therapy out to 1 year and showed a statistically significant difference in the rate of change of depression score. However, issues such as unmeasured differences between patients, nonconcurrent controls, differences in sites of care between VNS therapy

patients and controls, and differences on concomitant therapy changes raise concern about this observational study. Analyses performed on subsets of patients cared for in the same sites, and censoring observations after treatment changes, generally showed diminished differences in apparent treatment effectiveness of VNS and almost no statistically significant differences. Given these concerns about the quality of the observational data, these results did not provide strong evidence for the effectiveness of VNS therapy.

Adverse effects of VNS therapy included voice alteration, headache, neck pain, and cough, which are known from prior experience with VNS therapy for seizures. Regarding specific concerns for depressed patients such as mania, hypomania, suicide, and worsening depression, there does not appear to be a greater risk of these events during VNS therapy.

Patient selection for the randomized trial and the observational comparison trial may be of concern. VNS is intended for treatment-refractory depression, but the entry criteria of failure of 2 drugs and a 6-week trial of therapy may not be a strict enough definition of treatment resistance. Treatment-refractory depression should be defined by thorough psychiatric evaluation and comprehensive management. It is important to note that patients with clinically significant suicide risk were excluded from all VNS studies.

Data from the case series and clinical trials have been reanalyzed in subsequent publications to show what proportions of patients who respond at one time are still responders at a subsequent time point. Among those who achieved a response at 3 or 12 months, 60–75% of such patients were judged to remain a responder after 1 year. However, this information by itself does not provide evidence of the efficacy of VNS beyond that provided by the original comparative trials. Overall, the available scientific evidence does not demonstrate efficacy of VNS for treatment-resistant depression.

A systematic review of the literature for VNS of treatment-resistant depression identified the randomized trial described above among the 18 studies that met the study's inclusion criteria. VNS was found to be associated with a reduction in depressive symptoms in the open studies. For example, a preliminary report from an ongoing European multicenter open-label efficacy and safety study of VNS for treatment-resistant depression described 1 responder (of 11) at 3 months, 2 responders at 6 months, and 6 responders (55%) at 1 year; 3 patients (27%) were considered to be in remission. However, results from the only double-blind trial were considered to be inconclusive. Daban et al. concluded that further clinical trials are needed to confirm efficacy of VNS in treatment-resistant depression. Ongoing studies of VNS in depression documented at online site clinicaltrials.gov include a registry for patients with treatment-resistant depression.

A review by Fitzgerald and Daskalakis states that "given the invasive nature of vagal nerve stimulation and potential side effects, further research is urgently required." A guideline statement from the Canadian Network for Mood and Anxiety Treatments included a review of the literature on VNS for depression in 2009 and concluded that there is a lack of substantial evidence for short-term and long-term efficacy in acute severe depression and that the appropriate place of VNS remains to be determined.

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Other case review reports identified do not substantially strengthen the evidence supporting VNS. A case series study by Bajbouj et al. that followed patients for 2 years showed that 53.1% (26/49) patients met criteria for a treatment response and 38.9% (19/49) met criteria for remission. A small study of 9 patients with rapid-cycling bipolar disorder showed improvements in several depression rating scales over 40 weeks of observation. Another case series by Cristancho et al. that followed patients for one year showed that 4/15 responded and 1/15 remitted according to the principal response criteria.

Given the limitations of prior literature as described in the 2006 TEC Assessment, combined with the lack of substantial new clinical trials, the scientific evidence is considered to be insufficient to permit conclusions concerning the effect of this technology on major depression.

Other Conditions
Treatment of Essential Tremor
Handforth and colleagues studied VNS in 9 patients with essential tremor. Four weeks after implantation of the VNS device, tremor assessment using a masked videotape of patients was performed. Raters found no improvement in upper extremity tremors. Therefore, the authors of the study concluded that VNS is not likely to have any clinically meaningful effect in essential tremor treatment.

Treatment of Headaches
Drawing on the analgesic effects noted with VNS in the treatment of depression, Mauskop evaluated VNS in 5 patients with severe, refractory chronic cluster and migraine headaches. Mauskop reported excellent results in 1 patient who was able to return to work and significant improvement in 2 patients. Other than nausea developed by 1 patient, VNS was well-tolerated. Cecchini et al. evaluated VNS in 4 patients suffering from daily headache and chronic migraine. However, these studies are too small to draw conclusions on the effects of VNS for the treatment of headache, and further study is needed.

Treatment of Obesity
Unintended weight loss has been observed in participants in studies of VNS, prompting interest in use of the technology to prevent or treat obesity. Bodenlos et al. investigated whether VNS might affect food cravings in patients with chronic, treatment-resistant depression. They recruited 33 participants and divided them into 3 groups; 11 subjects receiving VNS for depression, 11 patients with depression but not receiving VNS, and 11 healthy controls. Most participants (42%) had a body mass index (BMI) in the normal range. Participants viewed food images on a computer in random order and then a second time in the same order and were asked after each viewing how much they would like to eat each food if it were available and how well they would be able to resist tasting each one. VNS devices were turned on for one viewing and off for the other. The depression VNS group had greater differences in food cravings between viewings in the sweet food category than the other 2 groups. No significant differences between groups were found for foods in proteins and vegetables/fruits categories. A significant proportion of the variability in VNS-related changes in cravings for sweet foods was attributed to clinical VNS device settings, depression scores, and BMI. A number of limitations in the study prevent drawing conclusions about the impact of VNS on eating behavior including small study size, selection and lack of randomization, heterogeneity of groups with respect to depression, BMI, and age. Comorbidities including anxiety and medical conditions and drugs that

might influence food intake and cravings were not considered. Large, well-designed and executed controlled studies are needed to evaluate the impact of VNS on eating behavior and obesity.

Treatment of Chronic Heart Failure
A case series Phase II trial of VNS therapy for chronic heart failure was found. In this study, De Ferrari et al. showed improvements in New York Heart Association (NYHA) class quality of life, 6-minute walk test, and left ventricular ejection fraction. These case series findings require confirmation in controlled clinical trials. A randomized study of VNS for heart failure is currently recruiting patients, according to clinicaltrials.gov.

Treatment of Fibromyalgia
Lange et al. conducted a Phase I/II trial of VNS of 14 patients with fibromyalgia. At 3 months, 5 patients had attained efficacy criteria based on a composite measure of improvement of fibromyalgia symptoms. At 11 months, 8 patients met efficacy criteria. This single arm trial does not provide sufficient evidence for efficacy of VNS for this indication.

Summary
For patients with refractory seizures, RCT evidence supports a reduction in seizure frequency following vagus nerve stimulation. A TEC Assessment concluded that the evidence is sufficient to permit conclusions on the efficacy of this technique for treatment of refractory seizures. Therefore, vagus nerve stimulation may be considered medically necessary for patients with refractory seizures.

For patients with depression, there is some evidence supporting improvements in depressive symptoms following vagus nerve stimulation. However, there are a number of limitations of these data, including uncertain clinical significance, lack of evidence on durability, and lack of comparison to alternative treatments. As a result, it is not clear if vagus nerve stimulation is as effective as alternatives for specific populations of patients with depression, and vagus nerve stimulation is considered investigational for this indication.

For other conditions, including headaches, obesity, essential tremor, heart failure, and fibromyalgia, the evidence is limited and not sufficient to permit conclusions on efficacy. Vagus nerve stimulation is considered investigational for these indications.

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Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0312T, 0313T, 0314T, 0315T, 0316T, 0317T, 61885, 61886, 61888, 64553, 64568, 64569, 64570, 95974, 95975
HCPCS	C1767, C1778, C1787, C1816, C1820, C1883, L8680, L8681, L8682, L8683, L8685, L8686, L8687, L8688, L8689, L8695
ICD-9 Diagnosis	332.0, 333.0, 340, 345.00 thru 345.91, 346.00, 362.57, 648.44, 781.3, 788.20, 788.32, 788.41, 788.5, 788.63, 788.69
ICD-9 Procedure	01.22, 86.94, 86.98

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05/07/2004	Medical Director review
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06/28/2004	Managed Care Advisory Council approval
06/07/2005	Medical Director review
06/21/2005	Medical Policy Committee review. Clinical criteria revised to add investigational statement for VNS treatment for essential tremor
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06/07/2006	Medical Director review

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06/21/2006	Medical Policy Committee approval. Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged
08/04/2006	Medical Director Review
08/09/2006	Medical Policy Committee approval
11/07/2007	Medical Director Review
11/15/2007	Medical Policy Committee approval. Added headaches to the investigational policy statement.
11/05/2008	Medical Director Review
11/18/2008	Medical Policy Committee approval. No change to coverage eligibility.
11/12/2009	Medical Policy Committee approval
11/18/2009	Medical Policy Implementation Committee approval. Deleted “partial-onset” verbiage from “medically refractory seizures” in the coverage section. Added the treatment of obesity as an investigational indication.
11/04/2011	Medical Policy Committee review
11/16/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/31/2010	Coding updated.
11/03/2011	Medical Policy Committee review
11/16/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/01/2012	Medical Policy Committee review
11/28/2012	Medical Policy Implementation Committee approval. Added heart failure and fibromyalgia to the list of investigational indications.
01/23/2013	Coding updated
11/07/2013	Medical Policy Committee review
11/20/2013	Medical Policy Implementation Committee approval. No change to coverage.

Next Scheduled Review Date: 11/2014

*****Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. in accordance with nationally accepted standards of medical practice;
B. clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

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For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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