



VNS Therapy frequently asked questions

One of the most popular ways to learn more about VNS Therapy for treatment-resistant depression (TRD) is by phone, during live telephone conferences. These are held at 7 PM Central Time on the first and third Tuesday of every month. Here are some of the questions asked most often during these educational sessions.

Does VNS Therapy cause weight gain?

Weight gain is a commonly reported side effect of other antidepressant treatments. The 12-month study of VNS Therapy had weight data for 172 patients. Of these, 12% gained more than 7% of their baseline body weight, and 13% lost more than 7% of baseline body weight.¹ Fewer than 2% of people in the clinical study reported weight gain.²

Can VNS Therapy be used with electroconvulsive therapy (ECT)?

VNS Therapy and ECT can be used together, and VNS Therapy has been shown to succeed in people who have had ECT. Of the patients in clinical studies of VNS Therapy, about a third had received ECT during their current depression.¹ People who had received ECT were just as likely to experience improvement over time as the overall study population.²

VNS Therapy patients can receive ECT if they need it. The VNS Therapy pulse generator must be turned off during the ECT session.

What are the most common side effects?

Side effects with VNS Therapy are mild to moderate, occur only during stimulation, and typically become less noticeable over time. The most common side effects with VNS Therapy include temporary hoarseness or a slight change in voice tone, increased coughing, shortness of breath upon physical exertion, and a tickling in the throat. Your psychiatrist can adjust the VNS Therapy dose to avoid or reduce many of these side effects (see page 3 of this newsletter for more information).

VNS Therapy has not been associated with many of the common side effects of other antidepressant treatments. Very few patients have reported sleep disturbance or weight gain, and VNS Therapy has not been associated with sexual dysfunction.²

Will VNS Therapy help my anxiety?

Researchers are conducting studies to better understand the impact of VNS Therapy on anxiety, but so far, VNS Therapy is not approved for the treatment of anxiety.

VNS Therapy rarely increases anxiety. Less than 5% of people in the yearlong study of VNS Therapy reported anxiety as a side effect.³

Will my insurance company cover the procedure?

In many cases, after what may seem like a long wait, the answer is yes. Since VNS Therapy was approved for TRD fairly recently, most insurance companies have not yet established their coverage policies. Even though Medicare recently announced a noncoverage position on VNS Therapy in TRD, case-by-case approvals have been obtained from more than 300 different payers.

You may have to go through several appeals to gain coverage for VNS Therapy in TRD, and the process and the number of steps vary from state to state and plan to plan. In addition, if you have a self-funded employee benefit plan and your health plan denies coverage, your employer can help you gain access. A Cyberonics nurse case manager can help you and your psychiatrist determine if your insurance covers VNS Therapy by verifying your benefits and determining the best way to pursue approval.

References: **1.** Rush AJ, Sackeim HA, Marangell LB, et al. Effects of 12 months of vagus nerve stimulation in treatment-resistant depression: a naturalistic study. *Biol Psychiatry*. 2005;58:355-363. **2.** Data on file. Cyberonics, Inc. **3.** Physician's Manual. VNS Therapy™ Pulse Model 102 Generator and VNS Therapy™ Pulse Duo Model 102R Generator. Houston, TX: Cyberonics, Inc.

INSIDE

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Meet John, a VNS Therapy patient

"Eleven years ago, my life was great," said 45-year-old John, with a caring, supportive wife and a rewarding career in finance. However, in 1996 everything changed for the worse. John began sleeping 14 to 18 hours a day and often called in to work sick for 3 or 4 days at a time.



Diagnosed with depression, John began taking antidepressant medications. But for the next 4 years, he continued to struggle. He tried many classes of antidepressant medications and psychotherapy, without long-term relief.

In 2000, John changed jobs. Despite his struggles, his depression continued to deepen in a stressful work environment. Even after a 3-month medical leave, his depression made it difficult to concentrate or handle his responsibilities. He had to leave his job. John admitted himself to a psychiatric hospital for evaluation. The psychiatrist there recommended ECT. John had 12 ECT sessions over 3 months in 2003. While they had a good short-term effect, John's depression soon worsened again. He stopped ECT after an additional 28 maintenance sessions in 2004 because of side effects, including short- and long-term memory loss.

Soon afterwards, John learned about VNS Therapy. He researched it and worked with his psychiatrist to get insurance coverage. Within months of the procedure in February 2006, John's depression improved. His energy levels increased and his mood lifted. He began waking up in the morning without an alarm clock and walking with his wife before she left for work. "We were both amazed with the improvement," he said.

He started working outside, mowing his lawn for the first time in 4 years. His memory and concentration have improved, and he can now run errands and drive. His positive, upbeat personality is returning.

As John continues to feel better, he looks forward to the future. "It has been years since I've been this active and enjoyed life," he said. "In July 2006 I did the unthinkable—I went camping with my wife and friends. I thought I would never enjoy spending time with my loved ones again. VNS Therapy is the best gift I was ever given," he continued. "It improved not only my quality of life but my friends' and family's as well."

Report from patient advocacy groups

Three mental health consumer groups held national meetings this summer. Here are some highlights from those meetings.

Mental Health America

During its 2007 annual meeting on June 6–9 in Washington, DC, Mental Health America (formerly the National Mental Health Association—NMHA) honored Representatives Patrick Kennedy (D-RI) and Jim Ramstad (R-MN), and the rock band The Fray, among others, with its second annual forWARDS awards. These awards pay tribute to the people, actions, and events that move the cause of mental health forward each year. The meeting's theme was "Bringing Wellness Home." For more information about the organization, visit www.NMHA.org.

National Alliance on Mental Illness (NAMI)

Highlights of the meeting "Building our Movement, Building our Future," held June 20–21 in San Diego, CA, included:

- The national kick-off of the new NAMI Connection recovery support group program
- A focus on mental illness within the gay, lesbian, bisexual, and transgender community
- A special session on neuroscience perspectives on recovery
- A Spanish-language forum
- A screening of the film *Canvas*, with the film's star Joe Pantoliano in attendance

Read more about NAMI at www.nami.org.

Depression and Bipolar Support Alliance (DBSA)

The national conference entitled "Making the Recovery Connection" took place August 10–12, in Orlando, FL. Keynote speakers included Olympic champion diver Greg Louganis; Kathy Cronkite, popular writer, journalist, and public speaker; and Joseph Rogers, founder and executive director of the National Mental Health Consumers' Self-Help Clearinghouse.

In addition, nationally recognized mental health experts led informational general sessions on topics such as "Getting the most from the time you have with your clinician" and the popular "Ask the Doctor" Q&A panel discussion.

Looking for the latest news from the DBSA? Go to www.dbsalliance.org.

Ask the doctor

Steven Buser, MD
Family Life Learning Center
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How will my doctor find the best VNS Therapy dose for me while minimizing the hoarseness during simulation?

No one dose setting of VNS Therapy works for everybody, just as no one medication dose works for everybody. Some people notice improvements at lower doses while others require higher doses, and different people are comfortable at different settings, too. A higher dose does not necessarily mean a better, or quicker, response.

The overall dose is determined by 5 different parameters, so there are many possible combinations to find the right dose. In clinical trials of VNS Therapy for TRD, the median output current at 1 year was 1.0 mA (milliamperes).¹ The median stimulation period lasted 30 seconds. The median time between pulses was 5 minutes.

Typically, when the VNS Therapy pulse generator is turned on, the first current setting is 0.25 mA. Most people go home from the initial visit at this setting. A few people have no discomfort at 0.25 mA, so occasionally the doctor may increase the dose during this initial visit.

Once the dose setting from the initial visit becomes comfortable, the doctor increases the dose by another 0.25 mA every 2–3 weeks over the next 6–8 weeks or so to a target dose of about 1.0 mA. Often at that point we'll slow the adjustments down to obtain higher output dosages more gradually. This allows the body to adapt better to higher settings. Some people have an even more robust response at levels between 1.0–2.0 mA.

The 1.0 mA target dose is based on the dose settings used in the clinical trials of VNS Therapy. Increasing the current by 0.25 mA at a time allows the psychiatrist to achieve the most appropriate dose for each person while minimizing possible side effects. The duration of the pulses and the time between them can also be adjusted. Some physicians find that lowering the time during which stimulation occurs often helps reduce side effects, including hoarseness.²

The doctor then monitors the person's progress with VNS Therapy over the next several months and continues to adjust the dosage as needed. Once the depression symptoms resolve, few additional adjustments are necessary.

VNS Therapy works over time, so it may take several months before symptoms improve. The most important thing to remember is that people have different responses to different dose settings, so doctors and patients should work together to find the correct dose setting for each individual. Time and patience may be key.

References: 1. Rush AJ, Sackeim HA, Marangell LB, et al. Effects of 12 months of vagus nerve stimulation in treatment-resistant depression: a naturalistic study. *Biol Psychiatry*. 2005;58:355-363. 2. Heck C, Helmers SL, DeGiorgio CM. Vagus nerve stimulation therapy, epilepsy, and device parameters. Scientific basis and recommendations for use. *Neurology*. 2002;59(Suppl 4):S31-S37.

VNS Therapy Phone Facts Sessions

- Live phone conferences
 - Hear from a patient about his or her experience with VNS Therapy
 - Listen to a psychiatrist experienced with VNS Therapy
 - Tuesdays, September 18, October 2 and 16, November 6 and 20
 - 7:00 PM Central Time
 - Call TOLL-FREE 1-866-598-9336
- For more information, call **1-877-NOW-4VNS** (1-877-669-4867) or visit www.VNSTherapy.com

Timely tip

Mark your calendar: Thursday, October 11

National Depression Screening Day (NDSD) is the largest provider of mental health screening services in the country through its partnership with thousands of community-based, college and primary care screening sites. NDSD has expanded in recent years to offer both in-person and online screening for depression and bipolar disorder as well as other mental health problems.

Last year over 450,000 people were screened at 8,000 in-person and on-line sites. If you would like to volunteer to help screen, contact www.mentalhealthscreening.org/events/ndsd.



SAFETY INFORMATION FOR THE VNS THERAPY™ SYSTEM*

INTENDED USE/INDICATIONS – UNITED STATES

The VNS Therapy System is indicated 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.

CONTRAINDICATIONS

The VNS Therapy System cannot be used in patients after a bilateral or left cervical vagotomy. Do not use short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy on patients implanted with the VNS Therapy System. Diagnostic ultrasound is not included in this contraindication. Injury or damage can occur during diathermy treatment whether your VNS Therapy System is turned "ON" or "OFF".

WARNINGS

This device is a permanent implant. It is only to be used in patients with severe depression who are unresponsive to standard psychiatric management. It should only be prescribed and monitored by physicians who have specific training and expertise in the management of treatment-resistant depression and the use of this device. It should only be implanted by physicians who are trained in surgery of the carotid sheath and have received specific training in the implantation of this device.

Physicians should inform patients about all potential risks and adverse events discussed in the VNS Therapy System *Physician's Manual*, including information that VNS Therapy has not been determined to be a cure for depression. Patients being treated with adjunctive VNS Therapy should be observed closely for clinical worsening and suicidality, especially at the time of VNS Therapy stimulation parameter changes or drug or drug dose changes.

The safety and efficacy of the VNS Therapy System have not been established for uses outside the approved indications for use. Device malfunction could cause painful stimulation or direct current stimulation. Device removal requires an additional surgical procedure. Do not manipulate the Pulse Generator and Lead through the skin.

Patients who have pre-existing swallowing, cardiac, or respiratory difficulties (including, but not limited to, obstructive sleep apnea and chronic pulmonary disease) should discuss with their physicians whether VNS Therapy is appropriate for them since there is the possibility that stimulation might worsen their condition. Patients with the VNS Therapy System or any part of the VNS Therapy System implanted should not have full body MRI.

PRECAUTIONS

The safety and efficacy of the VNS Therapy System have not been established for use during pregnancy. Patients who smoke may have an increased risk of laryngeal irritation.

ADVERSE EVENTS

The most commonly reported ($\geq 10\%$) side effects from stimulation included hoarseness, increased cough, neck pain, dyspnea (shortness of breath), dysphagia (difficulty swallowing), paresthesia (prickling feeling in the skin), and laryngismus (sore throat). The most commonly reported ($\geq 10\%$) side effects from the implant procedure included incision pain, hoarseness, incision site reaction, device site pain, device site reaction, pharyngitis (sore throat), dysphagia, and hypesthesia (numbness).

*THE INFORMATION CONTAINED IN THIS SUMMARY REPRESENTS PARTIAL EXCERPTS OF IMPORTANT PRESCRIBING INFORMATION TAKEN FROM THE PRODUCT LABELING. THE INFORMATION IS NOT INTENDED TO SERVE AS A SUBSTITUTE FOR A COMPLETE AND THOROUGH UNDERSTANDING OF THE VNS THERAPY SYSTEM, NOR DOES THIS INFORMATION REPRESENT FULL DISCLOSURE OF ALL PERTINENT INFORMATION CONCERNING THE USE OF THIS PRODUCT. (CAUTION: U.S. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.)



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