



# VNS Therapy™ connections™

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## Lauri: My first year of VNS Therapy

Although she first experienced depression at the age of 5, Lauri, now 36, made straight A's and was a star athlete in school. But by her teens, the San Antonio resident was suicidal and abusing drugs and alcohol.

By her late 20s, she was sober again, but still depressed. Psychiatrists prescribed many medications, and she was hospitalized more times than she can count. She even had a year of electroconvulsive therapy (ECT). It helped at first, but after memory loss and severe headaches, "I decided that I couldn't continue long term."

Lauri researched depression treatments online and learned about VNS Therapy. Her doctor agreed that this long-term treatment for treatment-resistant depression (TRD) should be her next step. Medicare covered her procedure (coverage varies by insurance providers).

She had the VNS Therapy procedure in January 2006. "After about 2 months, my moods became more level. Then I noticed that I could fall asleep without my mind racing, and without sleeping pills." After 3 months, she began to want to go back to work. In August, she began working part-time as a church secretary. "I used to worry that VNS Therapy would eventually stop working for me, like other treatments." But by September, "I relaxed when I realized I could now work through emotions that used to paralyze me." With the help of her psychiatrist, she has discontinued all her antidepressant medications over the past year.

Lauri is less anxious and impulsive. "I think before I act." And she can manage her emotions. "Life is not easy. Everyone has rough days. But I no longer panic at the first sign of feeling down."

Lauri doesn't notice the mild stimulation any more, but her voice gets low and hoarse when the VNS Therapy device goes off—30 seconds every 5 minutes. If she wants to talk for a while, a magnet held over the device turns it off temporarily.

She credits the support and understanding of her husband and son, now 15, in her recovery. "VNS Therapy saved my life and my marriage. I'm feeling happy for the first time in my life. Now I'm the mom and wife I've always wanted to be."

Her free time is filled with family, home, friends, church activities and her great joy—cooking. "I love to cook, mostly Mexican and Tex-Mex."

Lauri ended her first year on VNS Therapy by celebrating New Year's Eve with 250,000 other people in downtown San Antonio. "It meant so much to me. All the people, all the noises, all the lights and sounds—I loved it! I never would have been able to do that before."

She remembers the high school high achiever who never finished college because of depression. Now she is considering returning to school. VNS Therapy has opened a whole new life. "I wish I had found it sooner."

*Now, with VNS Therapy, I am the one in control of my life.*



### INSIDE!

- Ask the Doctor
- A timely tip for March



NOTE: The testimonials in this document are only examples of VNS Therapy results. Individual treatment results will vary.

**Ask the doctor**

**John P. O'Reardon, MD**

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**I have bipolar depression. Can VNS Therapy work for me?**

VNS Therapy has been shown to work in patients with bipolar depression. Of the 205 people evaluated in the major clinical study of VNS Therapy in depression, approximately 10% had been diagnosed with bipolar disorder.<sup>1</sup>

The clinical study reported 1-year data for 181 patients. Remission was defined as almost no depression symptoms. Response was an improvement of at least 50% in depression symptoms. Of the 17 people with bipolar depression, 4 experienced remission after a year of VNS Therapy.<sup>2</sup>

The rates of response and remission for people with bipolar depression were similar to those for unipolar depression and for the group as a whole.<sup>2</sup>

Although research is ongoing, the safety and efficacy of VNS Therapy have not been established in patients with the subtype of bipolar illness called rapid cycling. You and your psychiatrist together can best determine if VNS Therapy may be a long-term treatment option for you.

**References:** 1. Physician's Manual. VNS Therapy™ Pulse Model 102 Generator and VNS Therapy™ Pulse Duo Model 102R Generator. Houston, Tex: Cyberonics, Inc.; 2006. 2. Data on file. Cyberonics, Inc.; Houston, Tex.

**What can my doctor do to help me obtain insurance coverage?**

"Will my insurance pay for VNS Therapy?" Many people ask this question. And in a number of cases, after a wait that may seem long, the answer is yes.

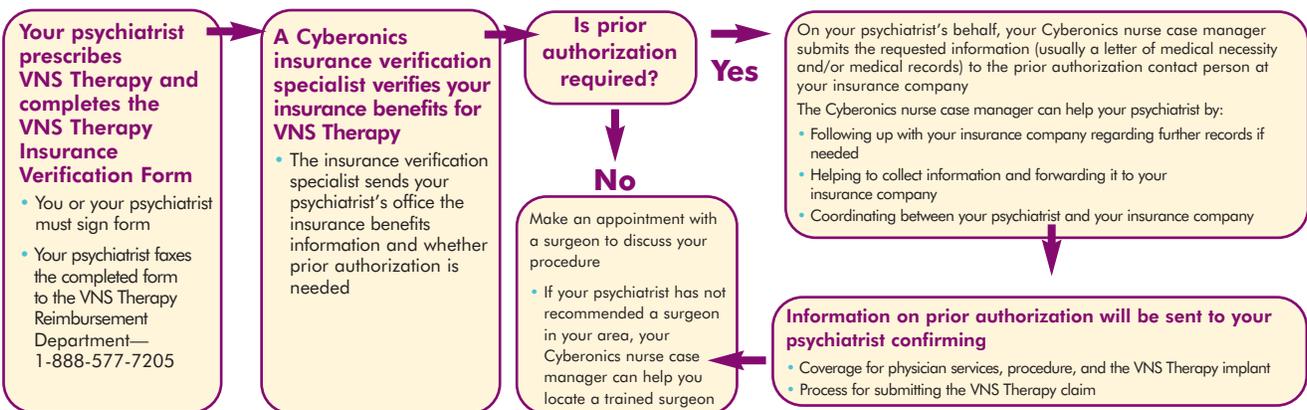
The insurance process usually begins when a psychiatrist prescribes VNS Therapy, fills out a VNS Therapy Insurance Verification Form, and faxes it to the VNS Therapy Reimbursement Department at Cyberonics at 1-888-577-7205.

In response, a Cyberonics insurance specialist will verify your benefits and send your doctor this information. Insurance companies usually require a letter of medical necessity—a letter from your psychiatrist describing your treatment history and explaining why you need VNS Therapy.

Since VNS Therapy was approved for treatment-resistant depression fairly recently, most insurance companies have not yet established coverage policies. However, if your insurance company denies coverage, Cyberonics can help.

- Your psychiatrist and the Cyberonics nurse case manager can help appeal the decision
- Together, they can provide the appeals department of your insurance company with additional information, such as more medical records documenting the severity of your depression
- You may participate in the appeal by writing a letter or making a phone call to your insurance company

**Obtaining insurance benefits for VNS Therapy**



### Ask a VNS Therapy patient

#### What advice would you give to a person waiting for insurance coverage?

**Adrienne:** When you are depressed, it's very hard to function. If you don't have the energy to struggle with your insurance company, see if your doctor or a family member or friend can help. While you are waiting for approval, try to surround yourself with positive people and keep busy. Whatever you do, don't give up.

**Lisa:** Hang on! Just hang on each hour of each day of each week that you have to wait. Know that once the procedure is approved you may have great things from VNS Therapy and that will be worth the struggle.

And follow up frequently with your claim so it doesn't get lost in the crowd.

#### What did you do to help get insurance approval for VNS Therapy?

**Adrienne:** I contacted my insurance company directly. I found a supportive rep at my insurance company and explained my situation. The rep who helped me had a son with depression and was very sympathetic. She pushed my paperwork along.

**Lisa:** To get insurance approval, I created a packet of information, including letters from my doctors and counselors, as well as articles about VNS Therapy, and information from the FDA and Cyberonics. I sent this to my employers' appeal board and followed up with the appeal each day so that I wouldn't get lost in the shuffle. In the end I was approved and the insurance paid for my procedure.

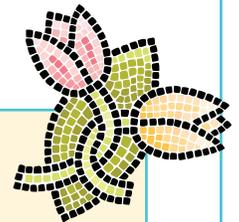
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### Connections: a VNS Therapy resource program for you

- Brochures
- Live phone conferences—VNS Therapy Phone Facts Sessions
  - Hear from a patient about his or her experience with VNS Therapy
  - Listen to a psychiatrist experienced with VNS Therapy
  - Tuesdays, March 6 and 20, April 3 and 17
  - 7:00 PM Central Time
  - Call TOLL-FREE 1-866-598-9336
- Nurse case managers who can answer your questions about VNS Therapy and help with insurance benefits verification
- For more information, call **1-877-NOW-4VNS** (1-877-669-4867) or visit [www.VNSTherapy.com](http://www.VNSTherapy.com)



#### Timely tip for March



The coming of spring can remind you that just as beautiful flowers grow from tiny seeds, big goals can be reached by starting small. So whatever you want to accomplish—whether it's getting more exercise, getting more organized, or eating healthier—start with a small step. Then continue taking small steps every day until you get the job done.

Please see the full indication and safety information enclosed.

## 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.

### 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.

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.

### 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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