

When is VNS Therapy recommended?

A psychiatrist's viewpoint



An article in the January 2006 issue of *Clinical Psychiatry News*, "Selecting Patients for VNS," addressed this question. Since the approval of VNS Therapy for people with treatment-resistant depression (TRD), many psychiatrists have recommended it. Author A. John Rush, MD, holds the Betty Jo Hay Distinguished Chair in Mental Health and the Rosewood Corporation Chair in Biomedical Science at the University of Texas Southwestern Medical Center in Dallas.

As Dr. Rush's article stated, the U.S. Food and Drug Administration (FDA) has approved VNS Therapy. VNS Therapy is approved for patients 18 years or older with chronic or recurrent depression that has not responded adequately to 4 adequate treatment trials. This wording is very important.

"Chronic" and "recurrent" point to the need for a long-term solution to depression. *Chronic* refers here to depression lasting 2 years or more. *Recurrent* depression comes back over time.

Adequate response means that with treatment, depression does not meaningfully interfere with your life. An *adequate treatment trial* means that you've tried a treatment at high enough doses for long enough to see if it worked for you.

- How long is long enough? At least 8 weeks to see if your depression responds
- How high a dose? Preferably the high end of the approved dosage range

The Food and Drug Administration's approval of vagus nerve stimulation for the long-term treatment of severe depression is an important development for psychiatry.

A. John Rush, MD, "Selecting Patients for VNS"
Clinical Psychiatry News, January 2006

Your psychiatrist can tell you how many adequate treatment trials you've had.

An *adequate treatment trial* refers to all kinds of approved treatments, including medications, structured talk therapies (cognitive-behavioral therapy, for example), and ECT. Keeping a list will help both you and your psychiatrist in planning future treatments.

INSIDE!

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Meet Laura, a VNS Therapy patient



Laura, now 35, has battled depression her entire life. By her mid-20s, she could no longer control or hide the symptoms. She was angry, cried for hours on end, and struggled with simple daily tasks and events. She was officially diagnosed with depression in 1994. She saw numerous doctors and was prescribed more than 30 treatments.

By 2000, Laura had reached rock bottom. She couldn't work or even get out of bed most days. Each breath was a chore, and the only thing she could feel was pain and exhaustion.

"I felt so hopeless because the treatments weren't working and I couldn't see an end to the pain. Everything was a struggle and each day a marathon."

Psychiatrists told her she had tried everything else they could think of, but she refused ECT. She researched treatments extensively. "My mother heard about VNS Therapy on TV in 1999, and we knew it was for me. While the University of Minnesota was being considered as a possible test site, I learned the name of the psychiatrist in charge." She laughs, "Dr. Rittberg was pretty surprised when I walked into his office one day begging to participate." Laura was the first patient to enroll in that clinical trial.

Today, Laura is doing well. "I'm confident that with VNS Therapy and medication, the depression will continue to improve. My quality of life is so much

better. I'm not just alive—I'm living again. When the depression flares up now, I can trust that it will only last a few hours or a day."

Laura still has to talk herself into doing some things, even fun things like parties and hobbies. Today, she works full-time and has started 2 small businesses. She also makes jewelry, plays the piano, entertains friends at her home, opens her mail, returns phone calls, and enjoys life.

I'm not just alive—I'm living again.

"I have great friends and family, a successful career, and a beautiful home. Thanks to VNS Therapy, I'm able to support and care for myself and I look forward to the future. VNS Therapy was the key difference between life and death."

Ask a VNS Therapy patient

How did you know you were responding to VNS Therapy?

Sue: I knew something was happening about a month after the implant was inserted. I laughed out loud for the first time in at least 6 years. I scared my family because they weren't used to hearing me laugh.

Donna: After I began VNS Therapy, I saw many tiny improvements that just kept adding up over a long time. It was as if the blinds were open and more and more light came in. I started asking for help when I needed it. I could make decisions. The periods of time when I couldn't answer the phone became fewer and shorter. I could actually look in my closet and pick out something to wear. I could read again and even laugh occasionally. It was like a jigsaw puzzle—pieces of "Donna" came back here and there, very gradually. I totally cherished every improvement, no matter how small, as it came about.



Ask the doctor

Scott Aaronson, MD

Director of Clinical Research Programs, Sheppard Pratt Health System, Baltimore, MD



How can I tell if VNS Therapy is working?

Each person's experience is different. Some people experience meaningful changes within the first few weeks of treatment, while other patients may not experience significant benefit for 6 or even 12 months, and it may be very gradual. It is very important to keep your scheduled appointments with your psychiatrist and follow his or her instructions.

In the clinical study of VNS Therapy in depression, many people experienced meaningful benefits in their everyday life. When measured after 9 months of VNS Therapy, improvements were seen in¹:

- Vitality—increased energy
- Social functioning—increased social interaction with family and/or friends
- Emotional well-being—better function at work and in daily activities
- Mental health—more positive feelings

Often, family and friends may notice improvements even before you do. The VNS Therapy Web site (www.VNSTherapy.com) includes journal pages that can help you and your psychiatrist keep a record of your experience over time. Start by filling one out for a baseline, and then complete another page every few months.

Reference: 1. Data on file. Cyberonics, Inc.

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

Please see the full indication and safety information enclosed.



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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, May 2 and 16, June 6 and 20, July 4 and 18
 - 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

**Antidepressant tip of the month
Had your thyroid checked recently?**



Low levels of thyroid hormones have been linked to depression. If your psychiatrist doesn't check your hormone levels regularly, ask your primary care physician to order the test and have the results sent to your psychiatrist.

Mark your calendar

Two major patient advocacy organizations have announced their annual meetings. Both meetings are in Washington, DC.

- **June 8–10:** The annual meeting of the National Mental Health Association (NMHA). The theme: "Building the Movement." For more information: www.nmha.org.
- **June 28–July 2:** The annual convention of the National Alliance on Mental Illness (NAMI). The theme: "Changing Minds. Changing Lives. Keeping the Promise!" For more information: www.nami.org.



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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.)