

FDA approves VNS Therapy System for chronic or recurrent depression

First FDA-approved treatment specifically for chronic or recurrent depression

HOUSTON, Texas—On July 15, 2005, Cyberonics, Inc., announced that the US Food and Drug Administration (FDA) had approved VNS Therapy (vagus nerve stimulation) “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.”

VNS Therapy, used in combination with antidepressant medications, is the only FDA treatment approved specifically for patients with chronic or recurrent depression.

VNS Therapy was first approved as a treatment for drug-resistant epilepsy in the

US in 1997. Over 32,000 patients worldwide have used VNS Therapy. VNS Therapy is also available in the European Union and Canada. For more information on VNS Therapy for treatment-resistant depression, visit www.VNSTherapy.com or call **1-877-NOW-4VNS**.

Major depressive disorder, a common serious illness, affects nearly 19 million Americans every year.¹ According to the National Institute of Mental Health, depression is the leading cause of disability in the United States and worldwide. Approximately 20% of Americans with depression, or approximately 4 million people, experience chronic or recurrent depression that has failed to respond to multiple antidepressant treatments, according to articles in the medical journals *Archives of General Psychiatry* and *Psychiatric Clinics of North America*.^{1,2} The treatments included antidepressant medications, talk therapy, and in some patients, ECT (electroconvulsive therapy).

References: 1. Kessler RC, Chiu WT, Demler O, Walters EE. Prevalence, severity, and comorbidity of 12-month DSM-IV disorders in the National Comorbidity Survey Replication. *Arch Gen Psychiatry*. 2005;62:617-627. 2. Fava M, Rush AJ, Trivedi MH, et al. Background and rationale for the Sequenced Treatment Alternatives to Relieve Depression (STAR*D) study. *Psychiatr Clin North Am*. 2003;26:457-494.

About chronic or recurrent depression

- **Chronic depression:** depression that lasts 2 years or more without relief
- **Recurrent depression:** 2 or more episodes of depression over time

INSIDE!

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Meet Karmen, a VNS Therapy patient

Karmen is a 35-year-old wife and mother. Having spent nearly half of her life battling depression, Karmen was one of the first people to receive VNS Therapy. Her story is remarkable.

First hospitalized for depression at age 19, Karmen spent her 20s in and out of depressive episodes—and hospitals. “I honestly do not remember how many drugs I have taken through the years; double digits definitely,” she said. “I felt like a guinea pig. I would either sleep continuously, all the time, or I would be awake for days on end.” In late 1998, still depressed despite 5 medications, she heard about VNS Therapy in a group therapy session and applied for a research trial.

Within 2 or 3 weeks after Karmen started VNS Therapy in February 1999, her family noticed a difference—a twinkle in her eye that seemed to stay and get brighter. “Within 6 weeks, I noticed my attention span was lengthening,” she recalled. Within 6 months, “I no longer slept away every day. I stayed longer at social gatherings. I was singing along with the radio.” She became optimistic about what the day would bring. Relationships with her husband, family, and friends improved.

In addition, Karmen was able to decrease her medications. When she became pregnant in 2002, she was down to 2, which then decreased to 1. Daughter Claire was born in 2003, “the best thing that could have

happened. There is no way on earth that I could have dealt with the stresses of a new baby before VNS Therapy, whereas I could afterwards,” she commented. “VNS Therapy didn’t just change my life, it made my life.”

VNS Therapy helped Karmen in bad times, too. When her job was downsized after 14 years, VNS Therapy gave Karmen the courage to change her career and stick with her job search. She’s now an executive assistant in the Human Resources department of a major healthcare firm.



Would she recommend VNS Therapy to others? “To patients considering VNS Therapy, I would encourage them to do their research; but really, the benefits that I reaped from VNS Therapy have been a pleasant surprise. The difference in my life has really been night and day.”



Ask the doctor

Robert H. Howland, MD, is an associate professor of psychiatry at the University of Pittsburgh School of Medicine.

Will VNS Therapy work for me?

At this point there is no known way to predict accurately who may benefit from any antidepressant treatment, including VNS Therapy. In a study of 235 people with chronic or recurrent treatment-resistant depression, 1 in 3 people who received VNS Therapy for a year experienced significant mood improvement, compared with 1 in 8 of those who received only other antidepressant treatments.

If I have VNS Therapy, will I still need to take medications?

VNS Therapy is added to your current medications. It is not a replacement for them. Some people in the clinical trials were able to reduce their medications over time. You and your psychiatrist will determine your ongoing treatment regimen. It is important to always follow your psychiatrist's recommendations about your medications.

Connections: a VNS Therapy resource program for you

- Brochures
- Live phone conferences
- Nurse case managers who can answer your questions about VNS Therapy and help with insurance coverage
- For more information, call **1-877-NOW-4VNS** (1-877-669-4867) or visit **www.VNSTherapy.com**

Antidepressant tip of the month Changes

As the seasons change and the days become shorter, be sure to stay on your schedule for medications as directed by your psychiatrist

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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.)