# **Vagus Nerve Stimulation (VNS) Fact Sheet**

## **Bottom Line:**

The efficacy of VNS remains too controversial to recommend its use in all but the most desperate clinical situations. Noninvasive VNS devices may become available for depression treatment in the future.

#### **FDA Indications:**

Treatment-resistant depression (adults); refractory seizure disorder (ages 12 and up).

## **Off-Label Uses:**

Autoimmune and chronic inflammatory disorders such as rheumatoid arthritis, Crohn's disease, irritable bowel syndrome, and fibromyalgia.

#### **Procedure:**

In a surgical procedure, a small stimulator device is implanted under the skin in the chest, and wires from the device are wound around one of the vagus nerves in the neck. After full recovery from the surgery (about two weeks), the device is programmed using a handheld transmitter. Pulses are delivered to stimulate the vagus nerve at regular intervals—usually for a 30-second period every five minutes.

**Pre-VNS Evaluation:** No specific labs are required. Patients will typically have a full medical workup in preparation for surgery.

**Cost:** \$\$\$\$\$; insurance company coverage is unlikely in most cases.

#### Side Effects:

- Most common: Voice hoarseness or alteration (over 50%), headache, cough, neck pain, shortness of breath that may be managed by altering the stimulus parameters.
- Serious but rare: Infection, nerve damage.
- Pregnancy/breastfeeding: Not enough data to recommend.

#### Mechanism, Treatment Course, and Drug Interactions:

- VNS's mechanism is unknown. The vagus nerve (cranial nerve X) sends fibers to the median raphe nucleus and locus coeruleus, key areas of serotonergic and noradrenergic innervation relevant to depression. Stimulation of the nerve may modulate levels of both serotonin and norepinephrine.
- The device is left implanted for years, and periodic visits with neurologists and psychiatrists are necessary to monitor the device and the response.
- Medications and VNS: All psychiatric medications may be continued after implantation of VNS.

#### **Clinical Pearls:**

- The efficacy of VNS for depression is controversial. The only randomized controlled trial that randomized patients to VNS vs sham VNS found no significant difference in response rates after 10 weeks (15% for VNS vs 10% for sham). Long-term follow-up studies imply that benefits may accrue over time, with a five-year cumulative response rate of 67.6%; however, there was no comparable control group, so this could represent a nonspecific response.
- LivaNova's VNS Therapy System is a small battery-powered stimulator that requires battery removal and replacement approximately every six years.
- Noninvasive devices that stimulate the vagus nerve have been approved in Europe for depression, epilepsy, and pain. Recently, a similar device was FDA cleared in the US for cluster headache treatment (www.tinyurl.com/ y6c6frv4).

#### **Fun Fact:**

Patients with seizure disorders can sometimes tell if a seizure is about to happen, and seizure patients who have VNS implanted can swipe a magnet over the stimulator area to send an extra burst of stimulation to the brain—which may prevent the seizure.

