Could your patient be a candidate for adjunctive VNS Therapy™?

Indication Requirements

- Age 4 or older
- Partial-onset seizures
- They failed to achieve seizure freedom after adequate trials of 2 tolerated, appropriately chosen and used antiepileptic drug schedules[1]

Do any of these additional statements apply to your patients?

- ☐ They are a poor surgical candidate for resection/ disconnection/ LITT Therapy

- ☐ They have refused brain surgery

- ☐ They are adversely affected by polypharmacy

- ☐ They experienced a successful initial response to anti-seizure medications (ASMs) that diminished with time[2]

- ☐ They have an unsatisfactory quality of life

- ☐ They experience repeated ER visits or hospital admissions

- ☐ They experience intolerable adverse events and/or nonadherence to anti-seizure therapy

- ☐ They frequently use rescue medications (such as rectally and nasally administered benzodiazepines to stop the onset of a seizure)[3]

REFERENCES:

1. Kwan P, Arzimanoglou A, Berg AT, et al. Definition of drug resistant epilepsy: consensus proposal by the ad hoc Task Force of the ILAE Commission on Therapeutic Strategies. Epilepsia. 2010; 51(6):1069-1077.
2. Epilepsy Foundation. Tolerance and the honeymoon effect. Accessed July 9, 2025. https://www.epilepsy.com/stories/tolerance-and-honeymoon-effect.
3. Epilepsy Foundation. Seizure rescue therapies. Accessed July 9, 2025. https://www.epilepsy.com/treatment/ seizure-rescue-therapies.

SHORT-FORM SAFETY INFORMATION FOR PHYSICIANS – VNS THERAPY™ SYSTEM FOR EPILEPSY (US) (APRIL 2025)

INTENDED USE / INDICATION

Epilepsy (US)—The VNS Therapy System is indicated for use as an adjunctive therapy in reducing the frequency of seizures in patients 4 years of age and older with partial-onset seizures that are refractory to antiepileptic medications.

CONTRAINDICATIONS

Not for use in patients with a bilateral or left cervical vagotomy. Do not use shortwave diathermy, microwave diathermy, or therapeutic ultrasound diathermy on patients implanted with a VNS Therapy System.

WARNINGS & PRECAUTIONS

All potential risks and adverse events are discussed in the VNS Therapy System Physician's Manuals. The VNS Therapy System should only be prescribed and monitored by physicians who are experienced in the diagnosis and treatment of epilepsy and have specific training and expertise in the management of seizures and the programming and use of this device. Patients implanted with the VNS Therapy System should have MRI procedures performed only as described in the MRI Guidance instructions for use.

VNS Therapy is not a cure for epilepsy. The safety and efficacy of the VNS Therapy System have not been shown for people with these conditions: cardiac arrhythmias; history of dysautonomias, previous therapeutic brain surgery or CNS injury, respiratory conditions (including dyspnea and asthma), ulcers, vasovagal syncope; only one vagus nerve; other concurrent forms of brain stimulation; pre-existing hoarseness; progressive neurological diseases other than epilepsy; primary generalized seizures; under 4 years of age.

Postoperative bradycardia can occur in patients with certain underlying cardiac arrhythmias. Dyspnea (shortness of breath) and dysphagia (difficulty swallowing) may occur with active stimulation, and aspiration may result from the increased swallowing difficulties. Patients with underlying pulmonary conditions such as COPD or asthma and patients with pre-existing swallowing difficulties or a history of drooling or hypersalivation may be at increased risk. Patients with obstructive sleep apnea (OSA) may have an increase in apneic events during stimulation. Vagus nerve stimulation may cause new onset sleep apnea in patients not previously diagnosed with this disorder. Device malfunction could cause painful stimulation or direct current stimulation which could cause nerve damage.

ADVERSE EVENTS

The most commonly reported side effects from stimulation include voice alteration or hoarseness, increased coughing, pharyngitis, paresthesia and dyspnea. The most commonly reported complication from the implant procedure is infection, which may require that the device be explanted. Pediatric patients 4-11 years of age may have a greater risk for wound infection. Other adverse events reported during clinical studies as statistically significant (in alphabetical order): ataxia; dyspepsia; hypoesthesia; insomnia; laryngismus; nausea; pain; vomiting.

Please see additional Important Safety Information available at **www.livanova.com/epilepsy-vnstherapy/en-us/hcp/safety-information**

VNS Therapy System Physician's Manuals and Patient Guides are available at **www.livanova.com.**

*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 or the material presented in the Physician's Manuals, nor does this information represent full disclosure of all pertinent information concerning the use of the product, potential safety complications, or efficacy outcomes.