2024

VNS Therapy™ Codes

Click to navigate

Hospital | Neurology | Surgery

VNS Therapy™ Commonly Billed Codes | Hospital

Epilepsy | 2024

SENTIVA™

Effective January 1, 2024

DIAGNOSIS CODES[1] | EPILEPSY

ICD-10-CM Codes	Description
G40.211	Localization-related *(focal) (partial)* symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, with status epilepticus
G40.219	Localization-related *(focal) (partial)* symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, without status epilepticus
G40.011	Localization-related *(focal) (partial)* idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, with status epilepticus
G40.019	Localization-related *(focal) (partial)* idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, without status epilepticus
G40.111	Localization-related *(focal) (partial)* symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, with status epilepticus
G40.119	Localization-related *(focal) (partial)* symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, without status epilepticus
G40.813*	Lennox-Gastaut syndrome, intractable, with status epilepticus
G40.814*	Lennox-Gastaut syndrome, intractable, without status epilepticus
G40.833*	Dravet syndrome, intractable, with status epilepticus
G40.834*	Dravet syndrome, intractable, without status epilepticus
Z45.42	Encounter for adjustment and management of neurostimulator

**LivaNova's approved indication of use for the VNS Therapy System is 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. CMS has approved certain reimbursement related to the syndromes of Lennox-Gastaut and Dravet. Those syndromes may have various or mixed seizure types that may include focal onset seizures. Providers are responsible for making appropriate decisions related to coding and reimbursement submissions. This information is not intended to encourage or promote off-label use of LivaNova products or of any medical device.*

GENERATOR & ELECTRODE

CPT® Codes[2]	Description	Ambulatory Payment Classification (APC)	Status Indicator[3]	Medicare National Payment[4]
	FULL SYSTEM PLACEMENT OR REPLACEMENT			
64568	Open Implantation of cranial nerve *(eg, vagus nerve)* neurostimulator electrode array and pulse generator	5465	J1	$29,617.07
	GENERATOR/BATTERY REPLACEMENT			
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array	5464	J1	$20,864.52
64569	Revision or replacement of cranial nerve *(eg, vagus nerve)* neurostimulator electrode array, including connection to existing pulse generator	5463	J1	$12,992.46
64570	Removal of cranial nerve *(eg, vagus nerve)* neurostimulator electrode array and pulse generator	5432	Q2	$6,353.57
	REMOVAL OF GENERATOR			
61888	Revision or removal of cranial neurostimulator pulse generator or receiver	5463	J1	$12,992.46

HCPCS II DEVICE CODES[5,6] | NON-MEDICARE

These codes are used by the entity that purchased and supplied the medical device, DME, drug, or supply to the patient. For implantable devices, that is generally the facility. HCPCS Level II device codes are only reported on outpatient bills. For specific Medicare hospital outpatient billing instructions for medical devices, see the Device C-Codes (Medicare) below.

HCPCS II Codes	Description
L8680	Implantable neurostimulator electrode, each
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension

DEVICE C-CODES[6] | MEDICARE

Medicare provides C-codes, a type of HCPCS Level II code, for hospital use in billing Medicare for medical devices in the outpatient setting. Although other payers may also accept C-codes, regular HCPCS Level II device codes are generally used for billing non-Medicare payers. Unlike regular HCPCS Level II device codes, the extension is coded using a separate C-code.

HCPCS C Codes	Description
C1767	Generator, neurostimulator *(implantable)*, non-rechargeable
C1778	Lead, neurostimulator *(implantable)*

GENERATOR & ELECTRODE ANALYSIS | PROGRAMMING CODES

CPT® Codes[2]	Description	Ambulatory Payment Classification (APC)	Status Indicator[3]	Medicare National Payment[4]
95970	Electronic analysis of implanted neurostimulator pulse generator/ transmitter *(eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient electable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters)* by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming	5734	Q1	$121.84
95976	Electronic analysis with simple cranial nerve neurostimulator pulse generator/ transmitter programming by physician or other qualified health care professional	5741	S	$35.98
95977	Electronic analysis with complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional	5742	S	$92.33

Revenue Codes	Description
278	Medical devices and implants
360	General classification OR services

IMPORTANT POINTS TO REMEMBER

- Correct coding: CMS reimburses hospitals at the APC payment rate assigned to a specific CPT code. Use of correct codes helps to ensure appropriate payment.
- Hospitals will need to review the charge master for supplies used during VNS Therapy implant surgery to ensure the HCPCS codes for these supplies are present. Charges for the procedure and device will need to be assigned to the appropriate CPT or HCPCS code.
- CMS believes coding of devices is vital to enhancing the device-dependent APC claims data and is critical for setting future APC payment rates. Hospitals will be required to include device category codes on claims when such devices are used in conjunction with procedures billed and paid for under OPPS.
- Complete and accurate coding is necessary for appropriate reimbursement and critical for setting future APC payment rates. Paying particular attention to this detail now may be extremely beneficial to future payments. Please feel free to share this document with others at the hospital that may find this information beneficial.
- Some state Medicaid contractors may require HCPCS codes:

  L8686 Generator

  L8680 Lead
- Some payers may choose to adopt CMS-mandated codes at a later date.
- The information contained in this document is for informational purposes only and is current as of January 5, 2024. It is always the responsibility of the provider to determine if the services actually provided are accurately described by any specific code(s) and to report services consistent with specific payer requirements. This information is subject to change at any time, and LivaNova strongly recommends you consult your payers regarding their reimbursement policies. In all cases, services billed must be medically necessary, actually performed as reported and appropriately documented.

FDA INDICATION FOR USE IN EPILEPSY

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.

LivaNova has compiled this coding information for your convenience. It is the provider's responsibility to file claims with appropriate ICD-10, CPT-4, HCPCS and revenue along with charges for the services provided. Please contact your local payer if you have questions regarding appropriate coding guidelines.

Additional information can also be accessed through CMS. CMS has posted APC materials, including all addendums in its Medicare Manuals on the internet. You should also contact your Medicare Administrative Contractor to clarify questions and/or concerns regarding billing and coding.

Disclaimer:

Reimbursement information provided by LivaNova is gathered from third party sources and is presented for illustrative purposes only. This information does not constitute legal or reimbursement advice. LivaNova makes no representation or warranty regarding this information or its completeness, accuracy, timeliness or applicability with any particular patient. LivaNova specifically disclaims liability or responsibility for the results or consequences of any actions taken in reliance on information in this document. LivaNova encourages providers to submit accurate and appropriate claims for services. Laws, regulations and payer policies concerning reimbursement are complex and change frequently. Providers are responsible for making appropriate decisions related to coding and reimbursement submissions. Accordingly, LivaNova recommends that customers consult with their payers, reimbursement specialists and/or legal counsel regarding coding, coverage and reimbursement matters. Please note: This document is intended to provide comprehensive coding information and as such may include codes for which LivaNova has no cleared or approved products. This information is not intended to encourage or promote off-label use of LivaNova products or of any medical device.

References:

1. Centers for Disease Control and Prevention, National Center for Health Statistics. International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM). https://www.cdc.gov/nchs/icd/icd10cm.htm. Updated October 2023.
2. CPT copyright 2024 American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association. Applicable FARS/DFARS Restrictions Apply to Government Use. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.
3. Status Indicator (SI) shows how a code is handled for payment purposes:
   - Status indicator for APC with a (J1) "Hospital Part B services paid through comprehensive APC"
   - Status indicator for APC with an (S) "Significant procedure, no multiple surgical procedure reduction"
   - C codes remain required for reimbursement and data collection purposes. (CPT code 64568 will require both C1767 and C1778 for appropriate claim adjudication and payment)
   - Status Indicator for APC with a Q1 "STV Packaged Codes, not paid separately when billed with an S, T or V status procedure"
   - Status Indicator for APC with a Q2 "T-Packaged Codes, not paid separately with a T status procedure"
4. OPPS and ASC Final Rule, Federal Register (88 FR 81540), November 22, 2023. CMS-1786-FC.
5. HCPCS codes L8680 and L8688 are not recognized by Medicare. For non-Medicare payers, codes L8680 and L8688 remain available. However, all providers should check with the payer for specific coding and billing instructions.
6. Healthcare Common Procedure Coding System (HCPCS) Level II codes, including device C-codes, are maintained by the Centers for Medicare and Medicaid Services. http://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS.html. Accessed January 3, 2024.

VNS Therapy™ Commonly Billed Codes | Neurology/Programming

Epilepsy | 2024

SENTIVA™

Effective January 1, 2024

DIAGNOSIS CODES[1] | EPILEPSY

ICD-10-CM Codes	Description
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G40.833*	Dravet syndrome, intractable, with status epilepticus
G40.834*	Dravet syndrome, intractable, without status epilepticus
Z45.42	Encounter for adjustment and management of neurostimulator

**LivaNova's approved indication of use for the VNS Therapy System is 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. CMS has approved certain reimbursement related to the syndromes of Lennox-Gastaut and Dravet. Those syndromes may have various or mixed seizure types that may include focal onset seizures. Providers are responsible for making appropriate decisions related to coding and reimbursement submissions. This information is not intended to encourage or promote off-label use of LivaNova products or of any medical device.*

GENERATOR & ELECTRODE ANALYSIS | PROGRAMMING CODES

CPT® Codes[2]	Description	Medicare National Payment			
		Facility[3]		Non-Facility[3]	
		RVUs	Payment	RVUs	Payment
95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter *(eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters)* by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming	0.54	$17.68	0.56	$18.34
95976	Electronic analysis with simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional	1.15	$37.66	1.17	$38.31
95977	Electronic analysis with complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional	1.53	$50.10	1.56	$51.08

Click to navigate ▸ Hospital Neurology Surgery

IMPORTANT POINTS TO REMEMBER

Parameters available for programming can vary between systems and may need to be adjusted multiple times during a single programming session. The iterative adjustments to parameters provide information that is required for the physician or other qualified health care professional to assess and select the most appropriate final programming parameters to provide for consistent delivery of appropriate therapy. The values of the final program parameters may differ from the starting values after the programming session.

Cranial nerve neurostimulator analysis with programming (95976, 95977) are reported based on the number of parameters adjusted during a programming session. Simple programming of a neurostimulator pulse generator/transmitter includes adjustment of one to three parameter(s). Complex programming includes adjustment of more than three parameters. For purposes of counting the number of parameters being programmed, a single parameter that is adjusted two or more times during a programming session counts as one parameter.

Programming may be performed in the operating room, postoperative care unit, inpatient, and/or outpatient setting. Programming a neurostimulator in the operating room is not inherent in the service represented by the implantation code and may be reported by either the implanting surgeon or other qualified health care professional when performed.

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Additional information can also be accessed through CMS. CMS has posted APC materials, including all addendums in its Medicare Manuals on the internet. You should also contact your Medicare Administrative Contractor to clarify questions and/or concerns regarding billing and coding.

References:

1. ICD-10-CM 2023. American Medical Association, Chicago, IL
2. CPT copyright 2024 American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association. Applicable FARS/DFARS Restrictions Apply to Government Use. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.
3. Medicare Physician Fee Schedule Final Rule, Federal Register (88 FR 78818), November 16, 2023. CMS-1784-F, Addendum B.

VNS Therapy™ Commonly Billed Codes | Surgery

Epilepsy | 2024

SENTIVA™

Effective January 1, 2024

DIAGNOSIS CODES[1] | EPILEPSY

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COMMON CODING OPTIONS & SCENARIOS

CPT® Codes[2]	Description	Global Period	Total Facility RVU	Medicare National Payment[3]
	FULL SYSTEM PLACEMENT OR REPLACEMENT			
64568	Open Implantation of cranial nerve *(eg, vagus nerve)* neurostimulator electrode array and pulse generator pulse generator/transmitter, without programming	90	18.23	$596.93
	GENERATOR/BATTERY REPLACEMENT			
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array	90	16.20	$530.46
64569	Revision or replacement of cranial nerve *(eg, vagus nerve)* neurostimulator electrode array, including connection to existing pulse generator	90	23.48	$768.83
64570	Removal of cranial nerve *(eg, vagus nerve)* neurostimulator electrode array and pulse generator	90	22.60	$740.02
	REMOVAL OF GENERATOR			
61888	Revision or removal of cranial neurostimulator pulse generator or receiver	10	12.17	$398.50
64585	Revision or removal of peripheral neurostimulator electrode array	10	4.33	$141.78

Click to navigate ▸ Hospital Neurology Surgery

CPT® Codes[2]	Description	Global Period	Total Facility RVU	Medicare National Payment[3]
	PROGRAMMING			
95976	Electronic analysis with simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional	NA	1.15	$37.66
95977	Electronic analysis with complex cranial nerve neurostimulator pulsegenerator/transmitter programming by physician or other qualified health care professional	NA	1.53	50.10

If LivaNova is providing requested technical assistance related to the programming of the device (e.g., LivaNova is operating programming tablet at provider's direction), provider may be prohibited from and should evaluate its ability to request reimbursement for that activity.

SAMPLE REPORT OF OPERATION

GENERAL HOSPITAL
123 Main Street
Anytown, USA 12345

Date of Surgery: 01/01/2024
Surgeon: Surgeon's Name
Assistant: If applicable
Preoperative Diagnosis: Intractable refractory epilepsy (partial onset seizures)
Postoperative Diagnosis: Same
Operative Procedure: Vagus nerve stimulator/implantation of neurostimulator electrode lead
Anesthesia: Local or general

Operative Findings: We had good placement of lead and good lead impedance as appropriate. The data are available on the chart.

OPERATIVE TECHNIQUE:

Following adequate levels of general anesthetic, the patient was prepped with DuraPrep and draped in a sterile fashion. A transverse neck incision was made midway between the clavicle and mastoid process to expose the vagus nerve on the left side of the neck. With sharp and blunt dissection, we incised the platysma with electrocautery. We identified the facial vein and ligated it proximally and distally. Careful dissection identified the vagus nerve in its proper position between the carotid artery and internal jugular vein. This was isolated several centimeters and vessel loops placed around for better exposure. We then made an infraclavicular pocket at the anterior fold of the left axilla with sharp dissection and produced a subcutaneous pocket for the vagus nerve stimulator generator. The lead was then passed subcutaneously with a tunneling device from the neck incision to the generator pocket. Once the lead was in proper position, we then carefully attached each coil to the vagus nerve in its proper position placing both the positive and negative coils around the vagus nerve and then the anchor coil around the vagus nerve. We had good positioning. Once everything was in proper position, the lead was affixed to fascia inside the carotid sheath using 2 tie downs provided in the lead packaging. The lead was also attached to the sternocleidomastoid muscle using 1 tie down. The tie downs were secured with 4-0 silk. Once this was in place, we then obtained the generator and attached the lead appropriately to the generator using a torque wrench. The computer interrogations and tests of the generator found it to be functioning perfectly. The generator was then placed in the pocket and the excess lead was placed behind the pocket. The generator was secured to the pocket using 4-0 silk. All sites were then irrigated with antibiotic solution. The deep spaces were then closed with interrupted 4-0 Dexon suture and the skin sites were closed with interrupted 5-0 Maxon suture and Dermabond glue. The generator and lead were again retested and functioned perfectly. The patient was then returned to the recovery room in good condition. A chest x-ray was taken to document the lead placement.

Estimated Blood Loss: 50 cc

All sponge and instrument counts were correct. No blood was given.

Surgeon Name, MD

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- Cranial nerve neurostimulator analysis with programming (95976, 95977) are reported based on the number of parameters adjusted during a programming session. Simple programming of a neurostimulator pulse generator/transmitter includes adjustment of one to three parameter(s). Complex programming includes adjustment of more than three parameters. For purposes of counting the number of parameters being programmed, a single parameter that is adjusted two or more times during a programming session counts as one parameter.
- Programming may be performed in the operating room, postoperative care unit, inpatient, and/or outpatient setting. Programming a neurostimulator in the operating room is not inherent in the service represented by the implantation code and may be reported by either the implanting surgeon or other qualified health care professional when performed.
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Typical Intra-Operative Steps

1. Interrogate generator
2. For AspireSR™ (M106), SenTiva™ (M1000), SenTiva Duo™ (M1000-D), select Verify Heartbeat Detection and adjust Heartbeat Sensitivity, if necessary
3. Interrogate generator
4. Perform System Diagnostics
   - For Pulse™ (M102/102R) series generators, perform System and Normal Mode Diagnostics only after patient can tole rate 1.0 mA
5. Always interrogate generator as last step in session to verify settings

FDA INDICATION FOR USE IN EPILEPSY

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3. Medicare Physician Fee Schedule Final Rule, Federal Register (88 FR 78818), November 16, 2023. CMS-1784-F, Addendum B.

Brief Summary[1] of Safety Information for the VNS Therapy™System [Epilepsy Indication] (August 2022)

1. INTENDED USE / INDICATIONS

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.

2. CONTRAINDICATIONS

Vagotomy—The VNS Therapy System cannot be used in patients after a bilateral or left cervical vagotomy.

Diathermy—Do not use short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy on patients implanted with a VNS Therapy System. Diagnostic ultrasound is not included in this contraindication.

3. WARNINGS — GENERAL

Physicians should inform patients about all potential risks and adverse events discussed in the physician's manuals. This document is not intended to serve as a substitute for the complete physician's manuals. The safety and efficacy of the VNS Therapy System have not been established for uses outside the "Intended Use/Indications" section of the physician's manuals. The safety and effectiveness of the VNS Therapy System in patients with predisposed dysfunction of cardiac conduction systems (re-entry pathway) have not been established. Post-implant electrocardiograms and Holter monitoring are recommended if clinically indicated. Postoperative bradycardia can occur among patients with certain underlying cardiac arrhythmias. It is important to follow recommended implantation procedures and intraoperative product testing described in the Implantation Procedure chapter of the physician's manuals. During the intraoperative System Diagnostics (Lead Test), infrequent incidents of bradycardia and/or asystole have occurred. If asystole, severe bradycardia (heart rate < 40 bpm), or a clinically significant change in heart rate is encountered during a System Diagnostics (Lead Test) or during initiation of stimulation, physicians should be prepared to follow guidelines consistent with Advanced Cardiac Life Support (ACLS). Difficulty swallowing (dysphagia) may occur with active stimulation, and aspiration may result from the increased swallowing difficulties. Patients with pre-existing swallowing difficulties and those with a history of drooling or hypersalivation are at greater risk for aspiration. Use of the magnet to temporarily stop stimulation while eating may mitigate the risk of aspiration. Dyspnea (shortness of breath) may occur with active VNS Therapy. Any patient with underlying pulmonary disease or insufficiency such as chronic obstructive pulmonary disease or asthma may be at increased risk for dyspnea. Patients with obstructive sleep apnea (OSA) may have an increase in apneic events during stimulation. Lowering stimulus frequency or prolonging "OFF" time may prevent exacerbation of OSA. Vagus nerve stimulation may also cause new onset sleep apnea in patients who have not previously been diagnosed with this disorder. Device malfunction could cause painful stimulation or direct current stimulation. Either event could cause nerve damage. Patients should be instructed to use the magnet to stop stimulation if they suspect a malfunction, and then to contact their physician immediately for further evaluation. Patients with the VNS Therapy System, or any part of the VNS Therapy System, implanted should have MRI procedures performed only as described in the MRI with the VNS Therapy System instructions for use. In some cases, surgery will be required to remove the VNS Therapy System if a scan using a transmit RF body coil is needed. Excessive stimulation at an excess duty cycle (that is, one that occurs when "ON" time is greater than "OFF" time) and high frequency stimulation (i.e., stimulation at ≥ 50 Hz) has resulted in degenerative nerve damage in laboratory animals. Patients who manipulate the generator and lead through the skin (Twiddler's Syndrome) may damage or disconnect the lead from the generator and/or possibly cause damage to the vagus nerve. The Wand, Programmer, and patient magnet are MR unsafe devices. These devices are projectile hazards and must not be brought into the MR scanner room.

Generators with AutoStim only—The AutoStim Mode feature should not be used in patients with clinically meaningful arrhythmias currently being managed by devices or treatments that interfere with normal intrinsic heart rate responses (e.g., pacemaker dependency, implantable defibrillator, beta adrenergic blocker medications). Patients also should not have a history of chronotropic incompetence [commonly seen in patients with sustained bradycardia (heart rate < 50 bpm)].

Generators with AutoStim only—For anticipated use of the AutoStim feature, it is important to follow the recommended pre-surgical surface assessment described in the Implantation Procedure to determine a location for the generator to reside in which it can accurately detect heart beats

4. WARNINGS — EPILEPSY

The VNS Therapy System should only be prescribed and monitored by physicians who have specific training and expertise in the management of seizures 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. The VNS Therapy System is not curative. Physicians should warn patients that the VNS Therapy System is not a cure for epilepsy and that since seizures may occur unexpectedly, patients should consult with a physician before engaging in unsupervised activities, such as driving, swimming, and bathing, and in strenuous sports that could harm them or others. Sudden unexpected death in epilepsy (SUDEP): Through August 1996, 10 sudden and unexpected deaths (definite, probable, and possible) were recorded among the 1,000 patients implanted and treated with the VNS Therapy device. During this period, these patients had accumulated 2,017 patient-years of exposure. Some of these deaths could represent seizure-related deaths in which the seizure was not observed, at night, for example. This number represents an incidence of 5.0 definite, probable, and possible SUDEP deaths per 1,000 patient-years. Although this rate exceeds that expected in a healthy (nonepileptic) population matched for age and sex, it is within the range of estimates for epilepsy patients not receiving vagus nerve stimulation, ranging from 1.3 SUDEP deaths for the general population of patients with epilepsy, to 3.5 (for definite and probable) for a recently studied antiepileptic drug (AED) clinical trial population similar to the VNS Therapy System clinical cohort, to 9.3 for patients with medically intractable epilepsy who were epilepsy surgery candidates.

5. PRECAUTIONS — GENERAL

Physicians should inform patients about all potential risks and adverse events discussed in the VNS Therapy physician's manuals. Prescribing physicians should be experienced in the diagnosis and treatment of epilepsy and should be familiar with the programming and use of the VNS Therapy System. Physicians who implant the VNS Therapy System should be experienced performing surgery in the carotid sheath and should be trained in the surgical technique relating to implantation of the VNS Therapy System. The safety and effectiveness of the VNS Therapy System have not been established for use during pregnancy. VNS should be used during pregnancy only if clearly needed. The VNS Therapy System is indicated for use only in stimulating the left vagus nerve in the neck area inside the carotid sheath. The VNS Therapy System is indicated for use only in stimulating the **left vagus nerve below where the superior and inferior cervical cardiac branches separate from the vagus nerve.** It is important to follow infection control procedures. Infections related to any implanted device are difficult to treat and may require that the device be explanted. The patient should be given antibiotics preoperatively. The surgeon should ensure that all instruments are sterile prior to the procedure. Children 4-11 years of age may have a greater risk for infection when compared to adolescent and adult patients (≥ 12 years). Careful monitoring for site infection as well as the avoidance of manipulation of the surgical site post implant in children should be stressed. The VNS Therapy System may affect the operation of other implanted devices, such as cardiac pacemakers and implanted defibrillators. Possible effects include sensing problems and inappropriate device responses. If the patient requires concurrent implantable pacemaker, defibrillatory therapy or other types of stimulators, careful programming of each system may be necessary to optimize the patient's benefit from each device. Reversal of lead polarity has been associated with an increased chance of bradycardia in animal studies. It is important that the electrodes are attached to the left vagus nerve in the correct orientation. It is also important to make sure that leads with dual connector pins are correctly inserted (white marker band to + connection) into the generator's lead receptacles. The patient can use a neck brace for the first week to help ensure proper lead stabilization. Do not program the VNS Therapy System to an "ON" or periodic stimulation treatment for at least 14 days after the initial or replacement implantation. For Models 100, 101, 102 and 102R do not use frequencies of 5 Hz or below for long-term stimulation. Resetting the generator disables or turns the device OFF (output current = 0 mA). For Model 100, 101, 102 and 102R, resetting the generator will result in device history loss. Patients who smoke may have an increased risk of laryngeal irritation.

Generators with AutoStim only—Because the device senses changes in heart rate, false positive detection may cause unintended stimulation. Examples of instances where the heart rate may increase include exercise, physical activity, and normal autonomic changes in heart rate, both awake and asleep, etc. Adjustments to the AutoStim feature's detection threshold should be considered; which may include turning the feature OFF.

Generators with AutoStim only—The physical location of the device critically affects the feature's ability to properly sense heart beats. Care must be taken to follow the implant location selection process outlined in the Implantation Procedure.

Generators with AutoStim only—Talk to your patient about use of the AutoStim feature since use of the feature will result in faster battery drain and the potential for more frequent device replacements. The physician's manual describes the impacts to the battery life. The patient should return to their physician at appropriate intervals to further evaluate whether they are receiving benefit from the current AutoStim settings.

M1000/1000-D only — Since the Scheduled Programming feature allows the generator to apply therapy increases at scheduled intervals, it may not be appropriate for use in patients who are nonverbal or are unable to use the patient magnet to stop undesired stimulation. Similarly, exercise caution for use of this feature in patients with a history of obstructive sleep apnea, shortness of breath, coughing, swallowing difficulties, or aspiration.

6. ENVIRONMENTAL AND MEDICAL THERAPY HAZARDS

Patients should exercise reasonable caution in avoiding devices that generate a strong electric or magnetic field. If a generator ceases operation while in the presence of electromagnetic interference (EMI), moving away from the source may allow it to return to its normal mode of operation. VNS Therapy System operation **should always be checked** by performing device diagnostics after any of the procedures mentioned in the physician's manuals. For clear imaging, patients may need to be specially positioned for mammography procedures, because of the location of the generator in the chest. Therapeutic radiation may damage the generator's circuitry, although no testing has been done to date and no definite information on radiation effects is available. Sources of such radiation include therapeutic radiation, cobalt machines, and linear accelerators. The radiation effect is cumulative, with the total dosage determining the extent of damage. The effects of exposure to such radiation can range from a temporary disturbance to permanent damage, and may not be detectable immediately. External defibrillation may damage the generator. Use of electrosurgery [electrocautery or radio frequency (RF) ablation devices] may damage the generator. Magnetic resonance imaging (MRI) should not be performed using a transmit RF body coil for certain VNS therapy device configurations or under certain specific conditions. In some cases, heating of the lead caused by the transmit RF body coil during MRI may result in serious injury. Static, gradient, and radio frequency (RF) electromagnetic fields associated with MRI may change the generator settings (i.e., reset parameters) or activat e the VNS device if the Magnet Mode output remains "ON". Note that certain magnetic resonance (MR) system head coils operate in receive-only mode and require use of the transmit RF body coil. Other MR systems use a transmit/receive RF head coil. Local or surface coils may also be receive-only RF coils that require the transmit RF body coil for MRI. **The use of a receive RF coil does not alter hazards of the transmit RF body coil.** Exposure of the VNS Therapy System to any transmit RF coil must be avoided. Do not perform MRI scans using any transmit RF coil in the defined exclusion zones. See MRI with the VNS Therapy System instructions for use for details or further instructions for special cases such as lead breaks or partially explanted VNS Therapy systems. Extracorporeal shockwave lithotripsy may damage the generator. If therapeutic ultrasound therapy is required, avoid positioning the area of the body where the generator is implanted in the water bath or in any other position that would expose it to ultrasound therapy. If that positioning cannot be avoided, program the generator output to 0 mA for the treatment, and then after therapy, reprogram the generator to the original parameters. If the patient receives medical treatment for which electric current is passed through the body (such as from a TENS unit), either the generator should be set to 0 mA or function of the generator should be monitored during initial stages of treatment. Routine therapeutic ultrasound could damage the generator and may be inadvertently concentrated by the device, causing harm to the patient. For complete information related to home occupational environments, cellular phones, other environmental hazards, other devices, and ECG monitors, refer to the physician's manuals.

7. ADVERSE EVENTS — EPILEPSY

Adverse events reported during clinical studies as statistically significant are listed below in alphabeticl order: ataxia (loss of the ability to coordinate muscular movement); dyspepsia (indigestion); dyspnea (difficulty breathing, shortness of breath); hypoesthesia (impaired sense of touch); increased coughing; infection; insomnia (inability to sleep); laryngismus (throat, larynx spasms); nausea; pain; paresthesia (prickling of the skin); pharyngitis (inflammation of the pharynx, throat); voice alteration (hoarseness); vomiting.

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1 The information contained in this Brief Summary for Physicians represents partial excerpts of important prescribing information taken from the physician's manuals. (Copies of VNS Therapy physician's and patient's manuals are posted at www.livanova.com.) The information is not intended to serve as a substitute for a complete and thorough understanding of the material presented in all of the physician's manuals for the VNS Therapy System and its component parts nor does this information represent full disclosure of all pertinent information concerning the use of this product, potential safety complications, or efficacy outcomes

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