Vagus Nerve Stimulation

MEDICAL POLICY NUMBER: 181

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INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PLAN PRODUCT AND BENEFIT APPLICATION

☒ **Commercial** ☒ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

COVERAGE CRITERIA

I. Implantable vagus nerve stimulation may be considered **medically necessary** as a treatment of seizures when **all** of the following criteria (A.-C.) are met:

A. Seizures are refractory to ≥ 2 antiepileptic drugs (AEDs) or AEDs are contraindicated; **and**
B. Surgery has failed or patient is not a surgical candidate; **and**
C. Left or bilateral vagotomy has not been performed.

II. Revision of a vagus nerve stimulation device may be considered **medically necessary** when any of the following (A.-C.) criteria are met:

A. Documented complications related to the device placement; **or**
B. Replacement is for the end of the useful life of the device; **or**
C. Replacement is due to a device malfunction.

III. Removal of a vagus nerve stimulation device may be considered **medically necessary** if it has been thoroughly evaluated and found to be no longer functional and was appropriately placed for medical necessity

IV. Vagus nerve stimulation is considered **investigational and not covered** when criteria I. or II. above are not met, including, but not limited to any of the following:

A. Non-invasive/non-implantable vagus nerve stimulation devices
B. Percutaneous and transcutaneous vagus nerve stimulation devices
C. Vagus nerve stimulation devices such as the AspireSR generator that add additional automatic stimulation utilizing an individualized cardiac-based algorithm

D. Indications other than seizures, including but not limited to the following (1.-5.):
   1. Treatment-resistant depression
   2. Alzheimer's disease
   3. Obesity
   4. Migraine headaches
   5. Essential tremor

Link to Evidence Summary

POLICY CROSS REFERENCES

None

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

BACKGROUND

Epilepsy

Epilepsy is a neurological disorder that causes recurrent and unprovoked seizures. Although epilepsy can develop in people of all ages, it is most common in children in the elderly. The cause of epilepsy varies and may be due to structural abnormalities, abnormal brain development, traumatic brain injury, or brain tumors. Use of a single antiepileptic drugs (AEDs) is the first-line therapy for epilepsy, however, up to 20-30% of these patients may develop drug-resistant (i.e., drug-refractory) epilepsy. The International League Against Epilepsy defines drug-refractory epilepsy as "a failure of adequate trials of 2 tolerated and appropriately chosen and used AED schedules." Some drug-refractory epilepsy patients may be surgical candidates. However, "not all patients with drug-resistant epilepsy can undergo surgery and some patients continue to experience seizures following surgery." Vagus nerve stimulation is an option for these AED-refractory patients who are not surgical candidates.

Vagus Nerve Stimulation (VNS)

Implantable

A VNS device consists of a programmable generator, wire leads, and electrodes. The generator is implanted subcutaneously into the patient's chest. The generator then delivers periodic pulses of electrical current through the leads to the electrodes, which are attached to the vagus nerve in the left side of the neck. The frequency and intensity of the electrical pulses is adjusted for each patient's needs.

Percutaneous, Transcutaneous, and Non-invasive/Non-implantable

Percutaneous vagus nerve stimulation (pVNS) and transcutaneous vagus nerve stimulation (tVNS) are proposed as minimally invasive and methods to modulate vagal nerve activity via electrical signal. In a

similar manner, non-invasive or non-implantable (nVNS) devices deliver electrical pulses by attachment to the skin (e.g., by earlobe clip or through the side of the neck).

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

Implantable VNS

Numerous implantable stimulator systems marketed by Cyberonics, Inc have gained premarket approval from the FDA, though the approval orders link back to the original 1997 issuance. FDA Product Codes: MUZ and LYZ.

Product and Manufacturer	Indications for Use	Contraindications for Use
The VNS Therapy™ System by Cyberonics Inc.[1]	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.	Vagotomy—The VNS Therapy System cannot be used in patients after a bilateral or left cervical vagotomy. Diathermy—Do not use shortwave diathermy, microwave diathermy, or therapeutic ultrasound diathermy (hereafter referred to as diathermy) on patients implanted with a VNS Therapy System. Diagnostic ultrasound is not included in this contraindication.

Prior to June of 2017, the FDA indications for the VNS Therapy System™ were for patients 12 years of age and older.

Non-implantable VNS

electroCore, LLC markets a non-invasive VNS (gammaCore™), indicated for treatment of cluster headache. The intent is to reduce the frequency of cluster headache attacks. The device received approval in 2017 and is intended for non-invasive vagus nerve stimulation on the side of the neck. Product code: PKR

Percutaneous and Transcutaneous Vagus Nerve Stimulation

The Parasym Device has been given an Investigational Device Exception for several indications currently under investigation for research use only.[2] The device is not approved for purchase in the United States.

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of vagus nerve stimulation as a treatment for seizures and other purported indications. Below is a summary of the available evidence identified through November 2021.

Implantable Vagus Nerve Stimulation

Medically Refractory Seizures

- In 2020, the Washington State Health Care Authority updated a 2009 health technology assessment (WA HTA) of vagal nerve stimulation for epilepsy and depression prepared by the Center for Evidence-Based Policy at Oregon Health & Science University.[3,4] The evidence regarding implantable vagal nerve stimulation for epilepsy was evaluated comparing VNS to treatment as usual, surgery, and responsive neurostimulation. Based on the available evidence which was found to be very-low to low-quality to moderate across 20 studies, VNS was found to be associated with similar reductions in seizure frequency compared to ongoing medication or surgery. Adverse events included changes in voice or hoarseness and some breathlessness. Rates of AEs were not different between high- and low-stimulation.

- Panebianco and colleagues published an updated Cochrane review in 2015, regarding the efficacy and tolerability of vagus nerve stimulation as an adjunctive therapy for treating people with medically refractory partial epilepsy.[5] Five trials were included in the analyses, totalling 439 participants, of which four were included in meta-analyses: Handforth et al. (1998), Michael (1993), The Vagus Nerve Stimulation Study Group (1995), and Klinkenberg et al (2012).[6-9] Amongst the five studies, two were rated as low risk of bias, and three as unclear. Effective blinding for VNS is difficult given the associated effects during use (e.g., voice alteration). The authors noted this may alter the validity of effects observed. Overall, the review concluded that VNS for partial seizures appeared to be effective and well tolerated in the 439 patients studied.

Depression

- In 2021, Hayes published an updated Health Technology Assessment evaluating vagus nerve stimulation for treatment-resistant depression.[10] Authors evaluated a total of 16 studies (23 publications) (3 randomized controlled trials [RCTs], 8 comparative studies, and 5 uncontrolled studies). The longest follow-up times ranged from 1 to 2 years. Studies followed patients up to 2 and 3 years with response rates in the low fifty percent range and remission rates reported as 53% and 25%, respectively. The outcomes of interest included changes in depression severity, quality of life (QOL), changes in medication and therapies for depression, suicide rates and rates for suicide ideation, and complications.

  Overall, VNS was associated with ≥ 50% reduction in depression severity scores (Hamilton Depression Rating Scale [HDRS]) in 15% to 50% of patients within the first year, 27% to 55% at 1 year, and 42% to 53% at 2 years. “However, while a ≥ 50% improvement of HDRS baseline scores is generally considered clinically significant, patients with high scores at baseline could still have moderate to severe depression, even after ≥ 50% improvement in scores. Therefore, it is

possible that, despite a 50% improvement, the patient still suffers from severe depression. Furthermore, in the only randomized controlled trial (RCT), active VNS with an implantable device (n=112) was no more effective than sham VNS (n=110) in alleviating symptoms of depression."[10] Based on the evidence from 2 studies there was insufficient evidence to determine if VNS therapy reduces medication use and therapies for depression. The results of 2 studies indicated that VNS therapy does not decrease suicide rates in patients with severe depression. There was insufficient data to thoroughly evaluate complications related to VNS therapy for depression.

The body of evidence was determined to be of low quality. Studies have reported inconsistent findings and have significant limitations by individual study. Additionally, most studies were funded by the device manufacturer and had significant design limitations. For bipolar disorder there is such a paucity of data, the evidence was found to be of very-low-quality. Ultimately, Hayes gave the following ratings for the use of VNS to treat refractory major depression disorder:

- C – For VNS as an adjunctive treatment for adults with severe major depression or bipolar disorder I and II when symptoms associated with a major depressive episode are refractory to multiple regimens of noninvasive treatments such as medication, psychotherapy, and electroconvulsive therapy. Patients should be free of comorbidities that could increase the risk of VNS-related complications. This Rating is based on the positive reports from nonrandomized and noncontrolled studies, the lack of evidence from randomized studies, the lack of thorough safety data regarding the device, and the substantial burden of treatment-resistant depression. Considering the safety concerns regarding VNS, noninvasive treatments should be exhausted before this option is considered, and patients should be specifically informed of the risks and properly followed up.

- D2 – For VNS for adults with severe, treatment-resistant rapid cycling bipolar disorder. This Rating reflects the limited evidence available for this patient population.

- In 2020, Bottomley and colleagues conducted a systematic review and meta-analysis assessing the safety and efficacy of VNS for treatment-resistant depression.[11] Investigators systematically searched the literature through June 2019, identified eligible studies, assessed study quality, extracted data and pooled results. Of 22 identified studies, there were two randomized controlled (RCT), sixteen single-arm and four nonrandomized comparative studies. Numerous depression-specific, safety and QOL measures were reported. Metaanalysis was possible for three efficacy scales, and three safety scales but no quality of life measures. Data beyond 2 years was not poolable. Analyses demonstrated that antidepressant benefits improved to 24 months and safety issues were minimal. Limitations included high, statistically significant heterogeneity, conflicts of interest with a VNS device manufacturer, lack of randomized controlled trials available for review, and lack of long-term follow-up. Investigators called for additional comparative studies describing safety and quality of life outcomes to better determine the safety and efficacy profile of VNS for treatment-resistant depression.

- In 2020, ECRI conducted an evidence review assessing the Symmetry Vagus Nerve Stimulation Therapy System (LivaNova) for treatment-resistant depression.[12] Searching the literature

through March 25, 2020, ECRI reviewed full text of 2 SRs reporting on 2,635 patients. Evidence from a systematic review (SR) of mostly single-arm studies suggests that Symmetry VNS plus treatment as usual (TAU) may achieve 2-year remission in 22% to 38% of patients with medically refractory depression of various etiologies; however, results need confirmation in randomized, sham-controlled trials to account for placebo effects. Another SR reported that VNS did not reduce or increase completed suicide incidence rates at 4-year follow-up. All except 2 studies in the SRs were at high risk of bias from retrospective design, single-center focus, high patient attrition, or lack of randomization, blinding, or controls. The SRs pooled outcomes from patients with different depression types (e.g., unipolar depression, bipolar depression, rapid cycling bipolar disorder), severity, and prior antidepressant treatment failures (2 to 6 failed treatments). Only 1 RCT (in the Bottomley et al. SR) compared VNS to sham and found no differences in response rates between the active VNS and sham control VNS groups. Authors called for additional studies are needed in patient populations with varying severities of different depression types and to compare VNS with other neurostimulation methods (e.g., deep brain stimulation, electroconvulsive therapy). Authors concluded that evidence supporting the VNS Therapy System was "inconclusive."

- In the WA HTA report referenced above, authors identified 5 studies reported in 9 publications that evaluated VNS as a treatment for depression.[3,4] Between high-stimulation and low-stimulation Montgomery-Åsberg Depression Rating Scale (MADRS) scores were improved though all other outcomes were not different between groups. When VNS was compared to sham and treatment as usual, differences in outcomes were not significantly different or were inconsistent; thus, the report authors stated that robust conclusions about effectiveness were difficult to discern. Adverse effects were similar as those experienced by individuals treated for epilepsy.

Other Indications

The evidence review identified studies evaluating other purported indications for VNS therapy, including but not limited to:

- Alzheimer's disease[13,14]
- Migraine headaches[15-18]
- Essential tremor[19]

Non-invasive/Non-implantable Vagus Nerve Stimulation

The only non-implantable VNS (nVNS) device with U.S. Food and Drug Administration (FDA) clearance is gammaCore™ (electroCore, Inc.), which is indicated for adjunctive use for the preventive treatment of cluster headache and for the acute treatment of pain associated with episodic cluster headache and migraine headache in adult patients.[20] As such, this evidence summary will focuses solely on the gammaCore™ device and approved indications.

Cluster Headache

In 2021, Hayes published a Health Technology Assessment evaluating noninvasive vagus nerve stimulation with gammaCore for prevention or treatment of cluster headache.[21] Four clinical studies were identified that used gammaCore for acute treatment (2 studies) or prevention (2 studies) of episodic and chronic cluster headaches (eCH and cCH) in adult patients. All of the studies compared nVNS in addition to standard treatments. Follow up ranged from 15 minutes to 1 year and the evidence base was found overall to be of very-low-quality. Adverse events related to gammaCore were reported in up to 27% of patients receiving active nVNS stimulation with gammaCore in 3 studies. Device-related adverse events included depressed mood, malaise, oropharyngeal pain, cluster headache, paresthesia, muscle twitching, muscle spasms, feeling hot, acne, pain, throat tightness, dizziness, hyperhidrosis, toothache, decreased appetite, skin irritation, erythema, facial edema, chest pain, fatigue, pruritus, musculoskeletal stiffness, parosmia, application-site pain, application-site irritation, lip or facial drooping or twitching, or dysgeusia. No serious device-related adverse events were reported. Due to the inability to draw conclusions from the existing body of literature, Hayes applied a D2 rating to the use of nVNS with gammaCore for the acute treatment of eCH or cCH as well as the use of nVNS as a prophylactic in the prevention of eCH or cCH.

The ACT1 and ACT2 trials were reported out by Silberstein et al. and Goadsby et al. in 2016 and 2018, respectively.[22,23] Both of the manufacturer-sponsored randomized trials were double-blind and sham-controlled evaluations of the gammaCore nVNS device.

ACT1 (N=150) included 1 month of treatment comparison, followed by a 3-month open-label phase. Participants used the device following their first cluster headache attack, and use of rescue medication within 60 minutes was considered treatment failure. All endpoints were assessed by patient-recorded diaries, the primary end-point being the proportion of all subjects who achieved a pain intensity score of 0 or 1 on a 5-point scale (0, no pain; 4, very severe pain) at 15 minutes after treatment initiation. During the first month, 22 participants dropped out (nVNS, N=14; sham, N=8); a large proportion of participants guessed their treatment allocation beyond chance. In the second phase, 28 participants dropped out (nVNS, N=17; sham, N=11). For the analysis, 133 subjects met the criteria for intention-to-treat (nVNS, N=60; sham, N=73). The participants had originally been split into two distinct cohorts – one for episodic cluster headaches (eCH), and one for chronic cluster headaches (cCH). Response rates were significantly higher with nVNS than with sham for the eCH cohort (nVNS, 34.2%; sham,10.6%; p =0.008) but not the cCH cohort (nVNS, 13.6%; sham, 23.1%; p = 0.48). In the total population, a significant difference in response rates between the nVNS and sham groups was not observed.

ACT2 enrolled 102 subjects (nVNS, N=50; sham, N=52) for a 2-week, randomized, double-blind period; and a 2-week, open-label period wherein all subjects received nVNS therapy. Overall, the authors concluded that nVNS was superior to sham therapy for acute treatment of attacks in patients with eCH but not those with cCH or in the total population. This finding was in alignment with the ACT1 study.

These studies represent short-term early conclusions that nVNS may be beneficial to patients with eCH, though not cCH, but more research is needed to know for sure.

Migraine

In 2018, three publications reported on the double-blind, sham-controlled nVNS trial, PRESTO.[24-26] The primary results, and both post-hoc analyses were funded by the manufacturer, electroCore, Inc. Authors

of all three papers disclosed receiving electroCore consultancy fees, being electroCore employees, and receiving electroCore stock ownership. PRESTO aimed to evaluate the efficacy, safety, and tolerability of gammaCore (nVNS) for the acute treatment of migraine. Two hundred and forty-eight participants with episodic migraine with/without aura were randomized to receive nVNS (N=122) or sham (N=126) within 20 minutes from pain onset. Participants were to repeat treatment if pain had not improved in 15 minutes. The double-blind study period lasted 4 weeks or until patients had treated 5 attacks. An open-label period subsequently followed, lasting 4 weeks or 5 attacks. There was no statistically significant difference in the primary endpoint: the proportion of participants who were pain-free without using rescue medication at 120 minutes following therapy (30.4% [nVNS] vs 19.7% [sham], p=.067), though nVNS was superior to sham for freedom from pain at 30 (12.7% vs 4.2%; p = 0.012) and 60 minutes (21.0% vs 10.0%; p = 0.023). Adverse events in PRESTO (nVNS = 22, sham = 23) were most commonly application site discomfort and nasopharyngitis. Given these reports all demonstrate marginally or non-statistically significant superior nVNS outcomes as a results of a single trial, additional well-designed RCT's are needed to determine overall health outcomes.

VNS with Cardiac-Based Algorithm (i.e., AspireSR Vagus Nerve Stimulator)

The evidence review identified 4 studies evaluating VNS that adds additional automatic stimulation utilizing an individualized cardiac-based algorithm (i.e., AspireSR VNS).[27-30] Due to methodological limitations (lack of randomized controlled design, small sample sizes, lack of blinding, lack of statistical analyses, and short follow-up periods), these studies provide insufficient evidence to support the safety and clinical utility of this device compared to the standard VNS device. Additional good-quality studies are needed to demonstrate that VNS with automatic stimulation based on an individual's cardiac rhythm improves health outcomes in patients with refractory epilepsy.

CLINICAL PRACTICE GUIDELINES

Seizures

American Academy of Neurology (AAN)

The 2013 AAN evidence-based clinical practice guideline for vagus nerve stimulation as adjunctive therapy for partial-onset seizures in patients >12 years gave the following recommendations:[31]

- VNS may be considered as adjunctive treatment for children with partial or generalized epilepsy (Level C).
- VNS may be considered in patients with Lennox-Gastaut Syndrome (LGS) (Level C).
- In adult patients receiving VNS for epilepsy, improvement in mood may be an additional benefit (Level C).
- VNS may be considered progressively effective in patients over multiple years of exposure (Level C).
- Optimal VNS settings are still unknown, and the evidence is insufficient to support a recommendation for the use of standard stimulation vs. rapid stimulation to reduce seizure occurrence (Level U).
- Patients may be counseled that VNS magnet activation may be associated with seizure abortion when used at the time of seizure auras (Level C) and that seizure abortion with magnet use may be associated with overall response to VNS treatment (Level C).

National Institute for Health and Care Excellence (NICE)

For epilepsy diagnosis and management, a 2021-updated NICE guideline states, "Vagus nerve stimulation is indicated for use as an adjunctive therapy in reducing the frequency of seizures in adults who are refractory to antiepileptic medication but who are not suitable for resective surgery. This includes adults whose epileptic disorder is dominated by focal seizures (with or without secondary generalisation) or generalised seizures."[32] The same statement is made for children.[33]

Depression

Department of Veterans Affairs/Department of Defense (VA/DoD)

The 2016 evidence-based VA/DoD clinical practice guideline for the management of major depressive disorder (MDD) recommended "against offering vagus nerve stimulation (VNS) for patients with MDD, including patients with severe treatment-resistant depression outside of a research setting."[34]

National Institute for Health and Care Excellence (NICE)

The 2020 evidence-based NICE guideline for vagus nerve stimulation for treatment-resistant depression stated, "evidence on the safety of implanted vagus nerve stimulation for treatment resistant depression raises no major safety concerns, but there are frequent, well-recognized side effects. Evidence on its efficacy is limited in quality. Therefore this procedure should be used only with special arrangements for clinical governance, consent and audit or research."[35] Authors also recommended additional randomized controlled trials evaluating VNS, reporting details of patient selection and relevant outcome measures.

Cluster Headache

Department of Veterans Affairs and the Department of Defense (VA/DoD)

In 2020, the Department of Veterans Affairs and the Department of Defense (VA/DoD) published a clinical practice guideline addressing the primary care management of headache.[36] The guideline included a recommendation with a weak strength of evidence which stated, "We suggest noninvasive vagus nerve stimulation for the acute treatment of episodic cluster headache."

EVIDENCE SUMMARY

There is sufficient evidence to establish the efficacy and safety of implantable vagus nerve stimulation (VNS) for medically-refractory epilepsy. Additionally, the American Academy of Neurology and National Institute for Health and Care Excellence recommend VNS in medically-refractory epilepsy patients.

There is insufficient evidence to establish the efficacy and safety of implantable VNS for any other indication, including, but not limited to Alzheimer's disease, migraine headaches, or essential tremor. There is a paucity of compelling evidence for non-implantable, percutaneous, and transcutaneous VNS devices as well. All identified studies had significant methodological limitations, including, lack of randomized controlled design, small sample sizes, lack of comparator group, and short follow-up

periods. For implantable VNS therapy, FDA-approval does not exist for these additional indications. For non-implantable, percutaneous, and transcutaneous VNS therapy, additional research is still needed to draw conclusions about the overall health outcomes. Additional good-quality studies and expanded FDA-approval are required to support the medical necessity of VNS therapy for these indications and device types.

BILLING GUIDELINES AND CODING

CODES*		
CPT	61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array
	61886	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays
	61888	Revision or removal of cranial neurostimulator pulse generator or receiver
	64553	Percutaneous implantation of neurostimulator electrode array; cranial nerve
	64568	Open implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator
	64569	Revision or replacement of cranial nerve (eg, vagus nerve) neurostimulator electrode array, including connection to existing pulse generator
	64570	Removal of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator
	95970	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (ie, cranial nerve, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming
	95974	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, with or without nerve interface testing, first hour
	95975	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour (List separately in addition to code for primary procedure)
HCPCS	C1767	Generator, neurostimulator (implantable), non-rechargeable
	C1778	Lead, neurostimulator (implantable)
	C1816	Receiver and/or transmitter, neurostimulator (implantable)

	C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
	C1823	Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads
	C1827	Generator, neurostimulator (implantable), non-rechargeable, with implantable stimulation lead and external paired stimulation controller
	C1883	Adapter/extension, pacing lead or neurostimulator lead (implantable)
	E0735	Non-invasive vagus nerve stimulator
	~~K1020~~	**TERMED 12/31/2023** ~~Non-invasive vagus nerve stimulator~~
	L8679	Implantable neurostimulator, pulse generator, any type
	L8680	Implantable neurostimulator electrode, each
	L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
	L8682	Implantable neurostimulator radiofrequency receiver
	L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
	L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
	L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
	L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
	L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension
	L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

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POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.
4/2023	Interim review. Criteria added for device removal.
1/2024	Q1 2024 code set.